NHS Improvement

Template structure for essential services laboratory – Blood sciences provision

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

Contents

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About 130 NHS trusts and foundation trusts provide their own pathology services, often using outdated operating models that need investment in premises, IT and equipment.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.

Definition of essential services laboratory

As mentioned above, in the 'hub and spoke' model of pathology optimisation through consolidation, each spoke is an ESL. These are also commonly referred to as 'hot labs', 'spoke labs', 'STAT labs' and 'hospital labs'.

An ESL provides a fit-for-purpose scope of pathology testing focused on time critical, near-patient tests. Where there is no impact on safety or the quality of patient care, non-urgent testing should be centralised to the hub laboratory.

ESLs' work largely concerns the provision of urgent, near-patient blood sciences through a mixture of point of care testing (POCT) and laboratory testing.

[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)

Purpose

This document informs laboratories that are consolidating their pathology services about possible structures and service offerings for ESL blood sciences provision. It outlines the scope of blood sciences testing that these laboratories should consider offering – including haematology, clinical biochemistry, coagulation science and blood transfusion – while factoring in the dynamic demand from urgent and acute clinical specialities.

We recognise that an ESL also needs to provide services related to urgent microbiology, histopathology and POCT – such as urgent cerebrospinal fluid (CSF) testing, frozen section analysis and blood gas analysis. Guidance on these services will be issued in subsequent documents.

We recommend that POCT is operated and controlled by the pathology laboratory under the clinical governance of a consolidated pathology network.

We also provide an overview of the equipment required to perform this scope of testing, and guidance on potential staffing structures for ESL blood science laboratories, again factoring in different demand structures.

Methodology

We have compiled this guidance by drawing on a combination of laboratory management experience and expertise, reviewing ISO:15189 laboratory accreditation standards and input from the Royal College of Pathologists (RCPath), The Institute of Biomedical Sciences and the Association of Independent Pathology Providers.

Disclaimer

We provide general guidance only and each individual ESL and network should assess the model for delivering essential laboratory services to ensure testing scope, turnaround times, logistics, IT and quality systems are in accordance with ISO:15189 and other industry guidelines such as those from the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE). The configurations, location and capacity of hub services will also define the essential services delivered at a spoke site. This template structure may need to be adapted for local use.

Useful links

Please also refer to the following:

- The Royal College of Pathologists www.rcpath.org/
- Institute of Biomedical Sciences www.ibms.org/
- United Kingdom Accreditation Service www.ukas.com/
- National Institute for Health and Care Excellence www.nice.org.uk/
- British Society for Haematology www.b-s-h.org.uk/
- Medicines and Healthcare products Regulatory Agency www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Operational functionality

Clinical governance

ESLs should fall under the clinical governance structure of the network, with the network's clinical governance policy making it clear who holds overall clinical and operational responsibility for its ESLs.

Laboratory information management system

An ESL must use the same information management system as the hub laboratory or be connected to it via a seamless integration engine with bidirectional messaging. This makes it easier to separate those tests within a request to be centralised from those to be performed locally. Operating on the same laboratory information system allows seamless delivery of results to referrers, batch and receipt of specimens, tracking of specimens, additional and follow-on testing, as well as either an ESL or hub to request and perform recollect testing.

Logistics

Due to the nature of centralising pathology specimens, a robust logistics system should be designed between ESLs and a hub laboratory. Transport between ESL and hub is required and this operation can be managed by either an in-house or contracted-out courier service. Each ESL needs to decide where it locates specimen reception and data entry; there are several operational models for this, two of which are described below.

Example specimen reception model 1

Direct access specimens (cold work) are sent directly from the community setting to the hub laboratory where a central specimen reception (CSR) department receipts and books them in. All specimens collected on a site with an ESL (acute work) are receipted and booked in onsite. Testing that falls outside the scope of the ESL is batched and sent directly to the hub laboratory.

This model maximises the economies of scale efficiency of a centralised specimen reception area, but compromises the tracking transparency of specimens.

Example specimen reception model 2

Direct access tests within a defined geographical radius are sent to an ESL where they are receipted, booked, batched and transported to the hub laboratory. All specimens collected at the ESL (acute work) are receipted and booked in onsite. Testing that falls outside the scope of the ESL is batched and sent directly to the hub laboratory.

This model requires more investment in resources at the ESL, but increases the ability to track specimens and gives the hub laboratory more time to prepare for the demand. For example, specialised testing can be prepared and batch testing planned before the specimens arrive at the laboratory.

Quality

An ESL should conform to ISO:15189 standards through a centrally run quality management system and to industry guidelines such as those from NICE and MHRA. The quality management system should involve an internal audit schedule at the discipline and operational function level. The internal audit system should be controlled centrally with quality leads at each ESL site. These leads can have scientific duties as well as their quality roles, provided they give sufficient time to ensure ESL quality standards.

Health and safety

An ESL should conform to the same health and safety standards as the hub laboratory.

Training

Where possible, all training management should be centralised to minimise the training burden on a single laboratory. An ESL should only be responsible for site-specific training, resource this function appropriately and follow accepted professional training programmes to ensure all aspects of training are delivered for the right grade of individual. The regular rotation of staff from hub to spoke provides training and experience of different working environments and can help develop staff.

Business continuity

With a hub-and-spoke model, consideration needs to be given to how an ESL can continue to provide the desired level of service if the hub is compromised – such as in the event of fire, IT and power failures or natural disasters. An element of spare capacity and scope may need to be built into an ESL to handle central specimens if required.

Scope of testing

The scope of testing performed at ESLs will depend on local geography, patient base, logistics and CSR model. The testing covered should also consider guidance from professional bodies such as RCPath, IBMS, MHRA and NICE guidelines.

Table 1 identifies a suggested scope of blood sciences testing. Aside from specific local requirements, we suggest that testing that falls outside the agreed scope of the ESL and direct access (cold work) is centralised to a hub laboratory. This scope does assume that a level of POCT is available throughout the operations of the hospital/laboratory.

The scope of blood sciences testing should consider the full patient pathway, such as keeping certain testing capability onsite if this allows for more efficient patient discharge. What an ESL can cover should also consider agreed turnaround time targets, whether or not retesting and additional testing will be possible within an appropriate timeline, and the robustness of the network's logistics system.

Table 1: Suggested scope of blood sciences testing for an ESL

	Test	Specimen	Method
Biochemistry	Biochemical profile*	Serum CSF, urine	Chemistry analyser
	CRP	Serum	Chemistry analyser
	Magnesium	Serum	Chemistry analyser
	Lactate	Serum	Chemistry analyser
	Therapeutic drug monitoring	Serum	Chemistry analyser
	Troponin	Serum	Chemistry analyser
	CK	Serum	Chemistry analyser
	TSH	Serum	Chemistry analyser
	Ammonia	Serum	Chemistry analyser
	βHCG	Serum	Chemistry analyser
	Ethanol**	Serum	Chemistry analyser
	Paracetamol**	Serum	Chemistry analyser
Coagulation	PT(INR)	Plasma	Coagulation analyser
	APTT	Plasma	Coagulation analyser
	TT	Plasma	Coagulation analyser
	Anti-Xa antibody	Plasma	Coagulation analyser
	D-dimer	Plasma	Coagulation analyser

	Test	Specimen	Method
Haematology	FBC (inc morphology examination) Malaria Reticulocyte count	Whole blood Whole blood Whole blood	Haematology analyser and microscope Microscope examination (special stain) Haematology analyser
Immuno-haematology	Group Antibodies Crossmatch Antibody investigations Cord blood Red cell phenotyping Investigation of transfusion reaction DAT (Coombes)	Plasma/Red cells Plasma/Red cells Plasma/Red cells Plasma/Red cells Plasma/Red cells Red cells Plasma/red cells Red cells	Analyser, cards or tubes Analyser, cards or tubes Analyser, cards or tubes Analyser, cards or tubes Analyser, cards or tubes Manual card Analyser, cards or tubes Manual card
	Provision to supply:		**Method**
Blood banking	Trauma packs Red cells Platelets Plasma Red cells (irradiated, CMV–) Platelets (irradiated, CMV–) Blood products (IViG, albumin, etc)		Blood fridge Blood fridge Platelet rocker Freezer, thawing bath, blood fridge Blood fridge Platelet rocker Blood fridge

***** Biochemical profile: sodium, potassium, chloride, bicarbonate, urea, creatinine, urate, glucose, calcium (corrected), phosphate, bilirubin, total protein, albumin, AST, ALT, lipase, ALP, GGT, cholesterol, triglyceride, eGFR.
**Toxicity screen: ethanol, paracetamol (extensive POCT toxicity screens can provide qualitative toxicity information).

Laboratory clinicians and managers may evaluate local clinical requirements and, depending on these, add testing to their scope such as serum and urine osmolality, Kleihauer screen for fetomaternal haemorrhage or intraoperative parathyroid hormone (PTH) for hyperparathyroid removal.

Transfusion

Transfusion testing should follow existing guidelines from the British Society for Haematology (www.b-s-h.org.uk/) and MHRA (www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency).

Electronic issue and remote release should be used in a network with a robust laboratory IT infrastructure.

Required equipment

Table 2 lists the equipment required to perform the scope of testing outlined above. We have intentionally not specified particular analysers as the most appropriate one will depend on volume and site-specific requirements such as throughput, available space and agreed turnaround times.

This list covers department-specific scientific equipment and not general items such as reagent fridges, storage cupboards, etc. Due to the nature of urgent turnaround results in an ESL, the requirement for backup equipment should be assessed to mitigate the risk of analyser or equipment downtime or failure. This assessment should be made with consideration of the services provided by the hospital the ESL is serving and the business continuity plans across the network.

Table 2: Outline of equipment for an ESL

Biochemistry	Coagulation	Haematology	Immunohaematology
Centrifuge	Centrifuge	Haematology analyser	Blood fridge
Chemistry analyser	Coagulation analyser	Stainer	Freezer
Immunoassay analyser		Microscope	Platelet rocker
			Thawing bath
			Centrifuge
			Waterbath
			Incubator
			Immunohaematology analyser
			Card reader

Equipment platforms should be standardised so that testing results are standardised across the network, and the individual analysers should be fit for the required volume to minimise overcapacity. As a laboratory moves from a full service

laboratory to an ESL, existing equipment is likely to provide more capacity than required. Depending on the volume through the ESL, pre and post-analysis robotics may be considered for specimen sorting, decapping and storage.

Required resources

Like any laboratory, an ESL requires a skill mix of pathologists, biomedical scientists and medical laboratory assistants. Volume is the primary driver of required staffing resources; other factors include complexity of work, level of automation and technology integration, arrival patterns, shift patterns, organisational structure, resource weighting and workforce split.

Organisation structure

Management activities other than ESL site-specific management duties should be centralised. All policy and procedure development, quality systems, IT support, logistics management and scientific management should be centralised. Local operational functions such as roster development, HR functions, interaction with local hospital, local logistics and local quality management should be performed by an onsite laboratory manager at the ESL. Depending on the size and volume of the laboratory, this manager or supervisor should also perform scientific duties.

Scientific management and supervision

All scientific policies and procedures should be uniform across a network. Department or discipline managers should be located centrally and perform regular visits to and internal audits at each ESL. However we highly recommend that senior scientist representation is present in each discipline at an ESL.

Overall clinical and operational management of an ESL can be supported remotely by the hub, with supervision through regular site visits, management review meetings and interaction with referring clinicians in the associated hospitals.

Shift duties

Medical laboratory assistants should be trained to perform duties across all disciplines of an ESL. Multidisciplinary biomedical scientists are particularly useful for an ESL as they can multitask, allowing greater flexibility to achieve greater efficiency. Multidisciplinary scientists also allow scientific duties to be concentrated, which reduces the overall laboratory resource requirement.

Roster patterns

The following shift pattern and resource weighting is an example for an ESL processing approximately 1,500 daily samples (Tables 3 and 4). Roster patterns need to be considered alongside test request arrival patterns at the ESL.

The suggested shift patterns assume that once a laboratory no longer does direct access work, most specimens are received during a morning peak, with work tailing off into the evening and only emergency work received throughout the night. Efforts should be made to match capacity and demand, and any resource scheduling should be the result of a laboratory process review.

A robust shift roster should take into account annual leave and sickness rates and recognise flexible working conditions.

The roster patterns provided in this guide assume no multidisciplinary biomedical scientists are present. Efficiency gains could be made by introducing multidisciplinary scientists into an ESL. For example, many biomedical scientists in ESLs are cross-trained in both haematology and blood transfusion. The use of multidisciplinary scientists represents an opportunity for further efficiencies to this model.

Table 3: Shift patterns for an example ESL Monday to Saturday

Haematology BMS				
	Band 5-6	Band 7	Band 5-6	Band 5-6
0:00				1
1:00				1
2:00				1
3:00				1
4:00				1
5:00				1
6:00	1			
7:00	1	1		
8:00	1	1		
9:00	1	1		
10:00	1	1		
11:00	1	1		
12:00	1	1		
13:00	1	1		
14:00		1	1	
15:00			1	
16:00			1	
17:00			1	
18:00			1	
19:00			1	
20:00			1	
21:00			1	
22:00				1
23:00				1

Biochemistry BMS				
	Band 5-6	Band 5-6	Band 7	Band 5-6
0:00				1
1:00				1
2:00				1
3:00				1
4:00				1
5:00				1
6:00	1			
7:00	1	1		
8:00	1	1		
9:00	1	1		
10:00	1	1		
11:00	1	1		
12:00	1	1		
13:00	1	1		
14:00		1	1	
15:00			1	
16:00			1	
17:00			1	
18:00			1	
19:00			1	
20:00			1	
21:00			1	
22:00				1
23:00				1

Transfusion BMS				
	Band 5-6	Band 7	Band 5-6	Band 5-6
0:00				1
1:00				1
2:00				1
3:00				1
4:00				1
5:00				1
6:00	1			
7:00	1	1		
8:00	1	1		
9:00	1	1		
10:00	1	1		
11:00	1	1		
12:00	1	1		
13:00	1	1		
14:00		1	1	
15:00			1	
16:00			1	
17:00			1	
18:00			1	
19:00			1	
20:00			1	
21:00			1	
22:00				1
23:00				1

Medical Laboratory Assistants (incl Specimen Reception)						
	Band 2-4	Band 2-4	Band 2-4	Band 2-4	Band 2-4	Band 2-4
0:00						
1:00						
2:00						
3:00						
4:00						
5:00	1	0.5				
6:00	1	1				
7:00	1	1	1	1		
8:00	1	1	1	1		
9:00	1	1	1	1		
10:00	1	1	1	1		
11:00	1	1	1	1		
12:00	1	1	1	1		
13:00		0.5	1	1		
14:00			1	1	1	1
15:00					1	1
16:00					1	1
17:00					1	1
18:00					1	1
19:00					1	1
20:00					1	1
21:00					1	1
22:00						
23:00						

ESL Shift Pattern All Departments																		
	Band 2-4	Band 2-	Band 5-6	Band 5-6	Band 5-6	Band 2-4	Band 2-4	Band 7	Band 5-6	Band 7	Band 2-4	Band 2-4	Band 5-6	Band 7	Band 5-6	Band 5-6	Band 5-6	Band 5-6
0:00																1	1	1
1:00																1	1	1
2:00																1	1	1
3:00																1	1	1
4:00																1	1	1
5:00	1	0.5														1	1	1
6:00	1	1	1	1	1													
7:00	1	1	1	1	1	1	1	1	1	1								
8:00	1	1	1	1	1	1	1	1	1	1								
9:00	1	1	1	1	1	1	1	1	1	1								
10:00	1	1	1	1	1	1	1	1	1	1								
11:00	1	1	1	1	1	1	1	1	1	1								
12:00	1	1	1	1	1	1	1	1	1	1								
13:00		0.5	1	1	1	1	1	1	1	1								
14:00						1	1	1	1	1	1	1	1	1	1			
15:00											1	1	1	1	1			
16:00											1	1	1	1	1			
17:00											1	1	1	1	1			
18:00											1	1	1	1	1			
19:00											1	1	1	1	1			
20:00											1	1	1	1	1			
21:00											1	1	1	1	1			
22:00																1	1	1
23:00																1	1	1

Table 4: Shift patterns for an example ESL Sundays and bank holidays

Haematology BMS			
	Band 5-6	Band 5-6	Band 5-6
0:00			1
1:00			1
2:00			1
3:00			1
4:00			1
5:00			1
6:00	1		
7:00	1		
8:00	1		
9:00	1		
10:00	1		
11:00	1		
12:00	1		
13:00	1		
14:00		1	
15:00		1	
16:00		1	
17:00		1	
18:00		1	
19:00		1	
20:00		1	
21:00		1	
22:00			1
23:00			1

Biochemistry BMS			
	Band 5-6	Band 5-6	Band 5-6
0:00			1
1:00			1
2:00			1
3:00			1
4:00			1
5:00			1
6:00	1		
7:00	1		
8:00	1		
9:00	1		
10:00	1		
11:00	1		
12:00	1		
13:00	1		
14:00		1	
15:00		1	
16:00		1	
17:00		1	
18:00		1	
19:00		1	
20:00		1	
21:00		1	
22:00			1
23:00			1

Transfusion BMS			
	Band 5-6	Band 5-6	Band 5-6
0:00			1
1:00			1
2:00			1
3:00			1
4:00			1
5:00			1
6:00	1		
7:00	1		
8:00	1		
9:00	1		
10:00	1		
11:00	1		
12:00	1		
13:00	1		
14:00		1	
15:00		1	
16:00		1	
17:00		1	
18:00		1	
19:00		1	
20:00		1	
21:00		1	
22:00			1
23:00			1

Medical Laboratory Assistants			
	Band 2-4	Band 2-4	Band 2-4
0:00			
1:00			
2:00			
3:00			
4:00			
5:00	1		
6:00	1		
7:00	1	1	
8:00	1	1	
9:00	1	1	
10:00	1	1	
11:00	1	1	
12:00	1	1	
13:00		1	
14:00		1	1
15:00			1
16:00			1
17:00			1
18:00			1
19:00			1
20:00			1
21:00			1
22:00			
23:00			

ESL Shift Pattern All Departments												
	Band 2-4	Band 5-6	Band 5-6	Band 5-6	Band 2-4	Band 5-6	Band 5-6	Band 5-6	Band 2-4	Band 5-6	Band 5-6	Band 5-6
0:00										1	1	1
1:00										1	1	1
2:00										1	1	1
3:00										1	1	1
4:00										1	1	1
5:00	1									1	1	1
6:00	1	1	1	1								
7:00	1	1	1	1	1							
8:00	1	1	1	1	1							
9:00	1	1	1	1	1							
10:00	1	1	1	1	1							
11:00	1	1	1	1	1							
12:00	1	1	1	1	1							
13:00		1	1	1	1							
14:00					1	1	1	1	1			
15:00						1	1	1	1			
16:00						1	1	1	1			
17:00						1	1	1	1			
18:00						1	1	1	1			
19:00						1	1	1	1			
20:00						1	1	1	1			
21:00						1	1	1	1			
22:00										1	1	1
23:00										1	1	1

As shown in Table 5, the shift rosters are used to calculate the required number of shifts per annum and then the required number of full time equivalents (FTEs) to fulfil these shifts, factoring in five weeks of annual leave and five days of sick leave. The use of cross-trained or multidisciplinary biomedical scientists would lower this number of required FTEs.

Table 5: Shifts per annum and required number of FTEs

Staff	Shifts per annum	Required FTEs
Bands 2 to 4	1,854	8.1
Bands 5 and 6	3,285	14.3
Band 7	759	3.3
Lab supervisor	253	1
Total		26.7

Implementation

You should take care to implement an ESL structure at a speed that does not impact quality. We recommend a step change implementation involving quality impact assessments, with robust and appropriate logistics, IT and quality systems in place before testing of any specimens is centralised.

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