Capacity Planning Guidance and Methodology for Transfusion Laboratories

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1.0 Introduction

The Serious Hazards of Transfusion (SHOT) reports have consistently demonstrated high levels of errors within the laboratory setting, in the SHOT report 2019[1] laboratory errors accounted for 23.4% of all accepted reports. Review of SHOT data on laboratory errors has resulted in recommendations including clear and robust procedures, staff knowledge and understanding and implementation of appropriate information technology to support safe practice. SHOT data indicate that laboratory errors occur most frequently in component labelling, availability, selection and storage of components. Whilst information technology can be employed to reduce the risk of human error, they cannot take the place of laboratory staff. The human workforce within the laboratory is key to effective service delivery and safe practice. The United Kingdom Transfusion Laboratory Collaborative (UKTLC) was convened in 2006 with the aim to review the level of expertise and knowledge available in transfusion laboratories. The UKTLC have published minimum standards for transfusion laboratories[2], and surveys[3] monitoring compliance with the standards. The results of the survey have revealed a consistent problem with recruitment and training of staff, staffing levels, education and morale. The problems faced by laboratories to retain a knowledgeable, competent and adequate workforce need to be addressed urgently to reduce the risk of error in this critical service.

One of the key features to provision of a safe service is an understanding of the staffing levels required to deliver that service. Resourcing and training deficiencies are a common finding at inspections undertaken by the Medicines and Healthcare Products Regulatory Agency (MHRA), as shared via the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee[4], these include insufficient resources to maintain effective quality management system at the same time as ensuring service delivery. ISO15189:2012[5] standard also requires that that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the user. Personnel are the central cog in the management of every quality management system and, as such, the management has the ultimate responsibility for providing this resource that is fit for the task to ensure business continuity through an adequate capacity plan.

A capacity plan provides the staffing level that is sufficient to cover the laboratory workload, including out of hours working, and effective implementation of the quality management system. An effective capacity plan needs engagement and agreement from all levels of staff, including senior management. Once the plan is in place it can then be used to monitor compliance and identify risk that can be escalated to senior management. This guidance document, produced by a collaboration between the UKTLC and SHOT, aims to set out the methodology for creating and monitoring a laboratory capacity plan. It must be noted that this document is for guidance only, not as a complete operational model, the examples provided are theoretical and should be tailored to local requirements. The guidance does not cover staff capabilities, knowledge, skills and competency assessments, which are covered by the UKTLC standards[2].

2.0 Blood Safety & Quality Regulations

The Good Practice Guidelines[6] (GPG) that relate to staffing levels and capacity planning are detailed below:

1.2.2. The Quality System encompasses quality management, quality assurance, continuous quality improvement, **personnel,** premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection (Directive 2005/62/EC/Annex 1.1.2).

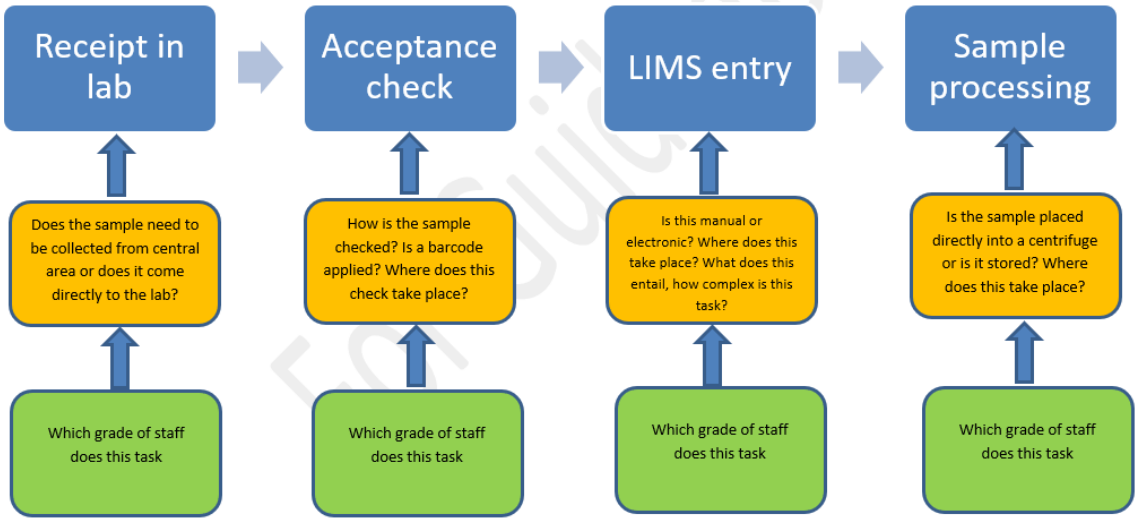
1.2.5. **Executive management has the ultimate responsibility** to ensure that an effective Quality System is in place and resourced adequately, and that roles and responsibilities, are defined, communicated and implemented throughout the organisation. Executive management's leadership and active participation in the Quality System is essential. This leadership should ensure the support and commitment of staff at all levels and sites within the organisation to the Quality System.

2.2. The organisation should have an **adequate number of personnel with the necessary qualifications and experience**. Management has the ultimate responsibility to determine and provide adequate and appropriate resources (human, financial, materials, facilities and equipment) to implement and maintain the Quality Management System and continually improve its suitability and effectiveness through participation in management review. The responsibilities placed on any one individual should not be so extensive as to present any risk to quality. Adequate resource must be ensured so sufficient capacity is available to suit all situations, including out of hours, so business continuity can be preserved.

3.0 Creating a capacity plan

Effective capacity planning is underpinned by robust process mapping, an understanding of the individual tasks required for service delivery and the time taken by staff involved in delivering the service. A process map will identify the component parts of the service, the resources required to ensure business continuity, this in turn underpins capacity planning and compliance with regulations. Senior management may see a strategic view of laboratory service delivery but in order to calculate the resources required to achieve this effectively it is necessary to break this down into its component parts such as workload, staff, automation and technology. In order for the capacity plan to be effective it needs to be understood and agreed by staff and management, and it needs to be evidenced based. An example of a process map is shown in figure 1.

Figure 1: Example of a process map for sample receipt



A spaghetti diagram, as described by NHS Improvement[7], can be used to establish the optimum layout of the department. This is based on observations of the distances travelled by staff or products whilst undertaking a task. By reviewing the current spaghetti map, you can see where there is potential to make processes more efficient and improve layouts to reduce distances travelled.

Staffing level calculations

When calculating staffing levels for safe and functional service provision consideration should be given to time lost as a result of sickness, annual leave, maternity leave, mandatory training, and course attendance. The following minimum estimates can be used for these calculations:

- Staff annual leave (approximate 30 days/ year)
- Statutory & mandatory training (approximately 3 days/ year/staff member)
- Attendance at courses (internal/ external) (approximately 5 days/ year/staff member)
- Approximate sickness (approximately 3 days/ year/staff member)
- Supervised annual training for assessed staff (UKTLC) (approximately 10 days/ year/staff member minimum)
- To calculate how many staff can be given leave per day - total staff x 30 days= (X / 220) (total number of working days (Monday-Friday) in a year)

When reviewing the component parts of the service, the following should also be considered (the lists are not exhaustive and will vary in different departments):

Workload

General

- Tracking activity of workload by time of day, daily, weekly, monthly and annual requirements
- Future changes to workload (increases or decreases)
- Set agreed key performance indicators (e.g. turnaround times outside of scope, incidents raised, CAPA open post target dates, overdue audits, overdue SOPs, overdue training and competency assessments) that can be monitored regularly
- Is the current quality management system compliant with regulations? Ensure that the audit calendar is realistic, inclusive and part of the routine workload, not something that is done just before an inspection
- Contingency planning – ensure that the contingency plan includes details of normal, major deficiency and critical deficiency staffing levels and the service level that can, and cannot, be delivered when staffing levels reach trigger points. Ensure that senior management have oversight and understanding of the contingency plan and limitations of the service should staffing levels be adversely affected

Administrative (example band 2/3)

- Sample booking in
- Blood component/product management (would you say this involves recording traceability or is this a different point?)
- Telephone answering
- Email monitoring
- Cleaning
- Dereservation
- Responding to equipment alerts
- Reagent management

Testing (example band 5/6)

- Equipment management
- Validation of analyser results
- Manual testing, reflex testing (including second check)
- Crossmatching
- Blood component/product issue
- Referral tests
- Re-validation of analysers/equipment/reagents
- Trouble shooting
- Completing QMS activities (e.g. checklists, handover sheets, IQC/EQA)

- Responding to technical telephone queries/phoning results

QMS (example band 7/8)

- Training, teaching, competency assessment
- Audits
- Supplies and supplier management
- Incident investigations and CAPA implementation (including reporting to SABRE/SHOT)
- SOP/policy review and writing
- Key performance indicator monitoring
- Change controls
- Meeting attendance
- HR processes
- Responding to emails, requests for support and information

Staff:

- Skill mix
- Number of staff in training that need to be supported
- Shift times, breaks, handovers, leave absence
- Sickness absence, turnover, succession planning

Automation and technology

- LIMs – up to date, fit for purpose, acceptable level of downtime, number of updates that need validation, rules, flags and algorithms fit for purpose
- Analyser – fit for purpose, acceptable levels of downtime, maintenance requirements, validation requirements, interfacing, workarounds
- Electronic patient blood management systems

4.0 Time required for tasks by job role

- The time taken to perform tasks can be estimated by producing a simple time and motion for each task and asking staff to record start and stop times This can be completed by a few members of staff for a set number of times the task is undertaken, an average time can then be used as the estimate. A simple time and motion record for a serological crossmatch is shown in figure 2

Figure 2: An example of a simple manual time and motion record that can be used to ascertain the staff time required to complete a serological crossmatch.

Serological Cross-Match, Not by Electronic Issue **SCM**

Please complete this form when you conduct a **serological cross-match** of a red blood cells for a patient.

Date _____

Please record the following information for all tasks on one sheet, if several staff members perform different tasks then please record this on one sheet. If a task was not completed please state this and a reason why e.g. list checked by someone else previously. If there is anything unusual about the time taken, please record details in the comments column.

Task	Start - Time of day (to the nearest minute)	Finish- Time of day (to the nearest minute)	Staff performing task (initials)	Number of units issued	Comments
E.g.	12:15	12:25	JD	2	Units to be dispatched tomorrow
1. Check request validity and any antigen negative/specific requirements					
2. Select units and set up SCM on appropriate RBC units (select units>crossmatch incubating)					
3. Complete serological crossmatch (Read results)					
4. Enter results in LIMs and authorise					
5. Check units and store ready for dispatch (affix label, place in lab crossmatch fridge)					

- Alternatively, an observed time and motion study can be performed, where an observer, from the same staff group, follows one staff member during their shift, noting the start and stop times of each activity. The manual record shown in figure 2 can be used for an observed time and motion study
- Time and motion studies do not need to be paper based, simple records can be set up in electronic format using excel
- Electronic tools designed to collect and analyse time and motion data are available such as WOMBAT. WOMBAT (work observation method by activity timing) tool has been developed by the Australian Institute of Health Innovation[8] to enable capture of the multi-dimensional aspects of activities in real time, taking into account interruptions and multitasking. This provides an app and a web app to collect and analyse data collected during an observed time and motion study
- When performing any kind of time and motion study care must be taken to ensure that this does not adversely affect the performance of the staff delivering the service, or place the general service delivery at risk
- Not all tasks are performed every day, for these you can estimate the daily, weekly, monthly or annual time required to support the staffing requirement by looking at how often the task is performed and how long it takes
- Estimation of the staff required for regular and expected tasks will enable creation of a base line staffing requirement. Remember that workload is often unpredictable, large projects that happen very occasionally cannot be covered well in capacity planning but should be considered within the change control, and staffing issues such as sickness absence can cause short term capacity issues. Base estimates on average times to ensure that you do not under- or over-estimate your staffing requirements

- The process map and task times can be used to create a simple spreadsheet for estimate of staff requirements. Examples are shown below in figure 3 demonstrating use of the time and motion studies to calculate the staffing requirement (full time equivalent (FTE) for each staff group:

Figure 3 (a, b and c): the following figures show examples of how the time taken to perform tasks in the laboratory can be used to ascertain the number of staff required for service delivery

Figure 3a: Estimation of full time equivalent (FTE) required for provisioning administrative tasks

Administrative (band 2/3)	Details	Time required (hours per day)
· Sample booking in	Based on 100 samples per 12 hour core period, manual booking in process by unregistered staff, including sample acceptance check, barcode application, LIMs entry and in/out centrifuge (t= 7 mins)	11.7
· Blood component/product management	Based on 20 components delivered, 50 products, electronic ordering, EDN entry (t=2 mins/unit)	2.3
· Telephone answering	Based on 1 call every 15 minutes, each call takes 5 mins	4
· Email monitoring	Based on average time estimate t=20 mins/12 hours	0.3
· Cleaning	Based on daily bench/equipment clean(10 minute) , 5 fridges cleaned weekly (each fridge takes 20 minutes)	0.5
· Dereservation	Based on 6 units per day (collecting from fridge, IT, placing in stock fridge) taking average 5 mins per unit)	0.5
· Responding to equipment alerts	Based on average time estimate t=20 mins/12 hour	0.3
· Reagent management	Based on reviewing stock, ordering, rotation, replacement t=20/12 hour	0.3
Total time required in core day shift		**19.9**
FTE		**2.7**

Figure 3b: Estimation of full time equivalent (FTE) required for provisioning laboratory testing tasks

Testing (band 5/6)	Details	Time required (hours per day)
· Equipment management	Based on 100 sample per core 12 hour period (sample management, reagent, qc, maintenance) t= 2 mins/sample	3.3
· Validation of analyers results	Based on 100 sample per core 12 hour period (review results, add on tests, sample storage) t= 1 mins/sample	1.7
· Manual testing, reflex testing (including second check)	Based on 5 ABID, 3 KLE, 2 DAT per 12 hour period (setting up, reading, reporting results) t=15 mins/12 hour (average)	2.5
· Crossmatching	Based on 10 EI (2 mins), 10 manual (10 mins) per 12 hour period	2
· Blood component/product issue	Based on 20 red cells (t=120), 10 plasma (t=5 mins/unit), 15 products (t=2 mins/unit)	3.3
· Referral tests	Based on 2 per 12 hour period (packing, result entry) t= 10 per referral	0.3
· Re-validation of analysers/equipment/reagents	Estimate 30 mins/12 hour shift	0.5
· Trouble shooting	Estimate 30 mins/12 hour shift	0.5
QMS (checklists, handover sheets, EQA IQC)	Estimate 30 mins/12 hour shift	0.5
Total time required in core day shift		**14.6**
FTE		**1.9**

Figure 3c: Estimation of full time equivalent (FTE) required for providing supervisory, management and quality tasks

QMS (band 7 or above)	Details	Time required (hours per day)
· Training/teaching	Based on 1 trainee per 12 hour shift	8
· Audits	Based on review and action of 1 audit per day	0.5
· Incident investigations (including reporting to SABRE/SHOT)	Estimated on 4 rejected samples/12 hour t=12 mins, 1 clinical t=30 mins, 1 SHOT/SABRE/month t= 6 hours	1.3
· SOP/policy review and writing	Estimated t=60 mins/ 12 hours	1
· Change controls	Estimated t= 60/ 12 hours	1
· Meeting attendance	Estimated t = 60 mins/12 hours	0.3
· HR processes	Estimated t= 30 mins/12 hours	0.2
Responding to emails, request	Estimated t= 30 mins/12 hours	0.2
Total time required in core day shift		**12.5**
FTE		**1.7**

- Review the workload in the out of hours setting and subject to the same principles above

5.0 Review the capacity plan

Once you have established your capacity requirements to provide a safe service you should test it, preferably over a core working week. This may require planning and collaboration with other departments to provide multidisciplinary staff. This will enable you to determine if the staffing estimate is correct or if it needs adjusting. Gaining feedback from the staff at this point is valuable to see if they felt that they were able to provide a safe service, or if they felt there were too little or too many staff in the department.

If your capacity plan and testing reveals that staffing levels are deficient this should be escalated to management for urgent review. The following aspects can be considered following review of the capacity plan and when discussing actions to address deficits with management:

- Work smart with technology– can IT solutions be used to free up staff time (e.g. implement Electronic Issue, Remote Issue, Electronic Delivery Note, Electronic Patient Record systems, automated rules in laboratory information management systems, automated assays (e.g. crossmatching, phenotyping, DAT) on analysers, electronic patient blood management systems, automated telephone triage system. Ensure that these solutions are designed in accordance with your processes by creating a user requirement specification designed to meet operational need. Implementation of IT solutions is not a quick fix for capacity deficits

- Work smart with people – can tasks that are only performed at defined intervals be undertaken by staff in the wider laboratory pool (e.g. cleaning and stock delivery by unregistered staff in Blood Sciences specimen reception)? Can tasks be moved from one group to another to free up resources, or can BMS tasks be performed by unregistered staff? Can some QMS tasks be performed by trained staff in the wider laboratory (e.g. quality management team, haematology or chemistry quality leads)

- Work smart with the system and environment– use lean working principles, as described by the Lean Enterprise Institute[9], process mapping and spaghetti mapping to see if tasks can be removed or amended to improve efficiency. Review the process map to see if some complex tasks can be simplified, use questioning to understand why tasks are done in a particular way and if they can be amended

- Staff recruitment – if funding is made available for additional staff ensure that the best use is made of the funding. Locum staff may be a quick fix but are the training and supervision requirements adversely impacting on resources? Can staff at lower banding be recruited, can part time staff cover some roles, are evening/night staff only required? Can staff be seconded for a fixed term period to cover large projects?

- Non-conformances – has the review identified issues with automated equipment, storage devices, supplies, reagents or other material that are taking staff time to resolve? Are devices or equipment unfit for purpose and should be replaced?

- Ensure that shift rotas include consideration of skill mix and level of experience/autonomy of the staff
- Restrict staff leave for large planned projects (which should be planned well in advance)
- Plan attendance at external professional meetings and other CPD activities in advance to prevent cancelling – include this in the forward planning leave/shift rota
- Change control – include staffing requirements when planning for change, locally or externally induced, change may increase or reduce staff resource

6.0 Monitoring and compliance

- Review the weekly shift rota daily, noting if the full complement of staff was achieved each day. This can be collated into a monthly staff capacity indicator which can be reviewed regularly at management meetings. A risk matrix with agreed staffing target levels as shown in figure 4 below provides a simple visual chart for daily staffing levels

Figure 4: An example of monitoring compliance with agreed staffing levels on a daily basis

Transfusion laboratory staffing levels							
Task	Staff group	FTE (from capacity plan)	Actual FTE (core shift)				
			Day 1	Day 2	Day 3	Day 4	Day 5
Administrative	Band 2/3	2.7	1	2	1	1.5	2
Testing	Band 5/6	1.9	2	1.5	2	1	1
QMS	Band 7 and above	1.7	1	1	1.5	1	2
Key:							
Adequate staff							
Reduced (60-80%)							
Inadequate (<60%)							

- If a senior is performing tasks of another staff group- this is counted as not available for senior task
- Review key performance indicators (e.g. turnaround times outside of scope, incidents raised, CAPA open post target dates, overdue audits, overdue SOPs, overdue training and competency assessments) on a regular basis and report slippage to senior management
- Trending of incidents- how often is staff shortage implicated in incidents as a contributory factor?
- Review the number of vacancies, are appropriate actions being taken to resolve these?
- Visualise deficiencies in staffing, as demonstrated in the example below and identify the risks associated with inadequate staffing levels
- The Plan, Do, Check, Act model can be used as an approach to identifying and resolving problems, this provides a cycle for continuous improvement

- Review the capacity plan on a regular basis, at least once a year, has anything changed that has increased or decreased the staff requirement?

7.0 Communication, Transparency & Oversight

- Escalate staffing issues via the formal quality/risk meetings and management meetings. This can be achieved using a risk status and impact record as shown in figure 5 below. The record should include the risk of non-compliance with the KPI along with any mitigations in place and the impact on the service and compliance with regulatory requirements

Figure 5: Example of a risk status and impact record highlighting deficiencies in compliance with the KPI training and competency assessment

Severity and risk status against KPI						
Reporting quarter:		Year:				
KPI	Required capacity FTE	Current capacity FTE	Associated risks	Mitigation plan	Risk rating	Impact
Training and competency	0.3	0.1	Currently only achieving 70% compliance as no capacity to release staff for training and competency assessment. Senior staff unable to attend conferences and meetings	No mitigation, staffing levels below requirement, long term absence needs addressing		Unable to meet regulation 2.2 of GPG. Inability to train staff impacting on SABRE reportable events which have seen an increase in 2% from last quarter attributable to inadequate

- Ensure that senior management/governance have oversight of compliance with key performance indicators, including staffing levels
- Ensure that staffing level risks are included in risk assessments relating to provision of a safe transfusion practice and regulatory compliance (*The Chief Executive Officer for a hospital Blood bank is the Person Responsible (PR) for management of the hospital blood bank).* Ensure that risk assessments are reviewed and updated if monitoring of staffing levels and KPI indicate slippage and appropriate escalation is undertaken

8.0 References

1. SHOT report 2019: Laboratory Errors https://www.edqm.eu/en/good-practice-guidelines-blood-establishments
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9. Lean Principles (https://www.lean.org/WhatsLean/)