Capacity planning NTLM 180925

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UKTLC Chairs

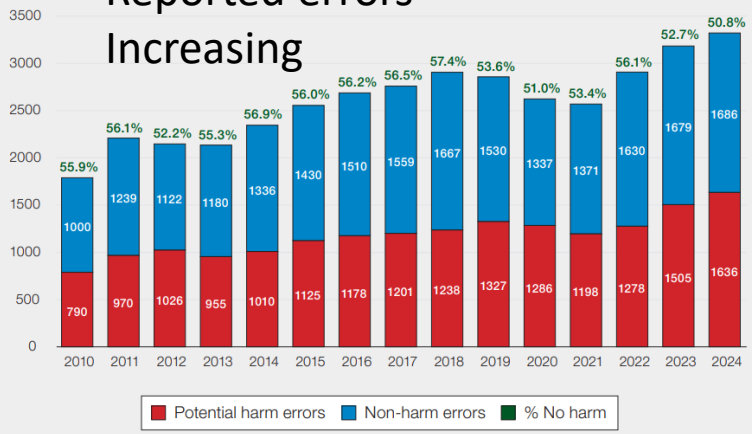
IBI recommendation

Recommendation 7c

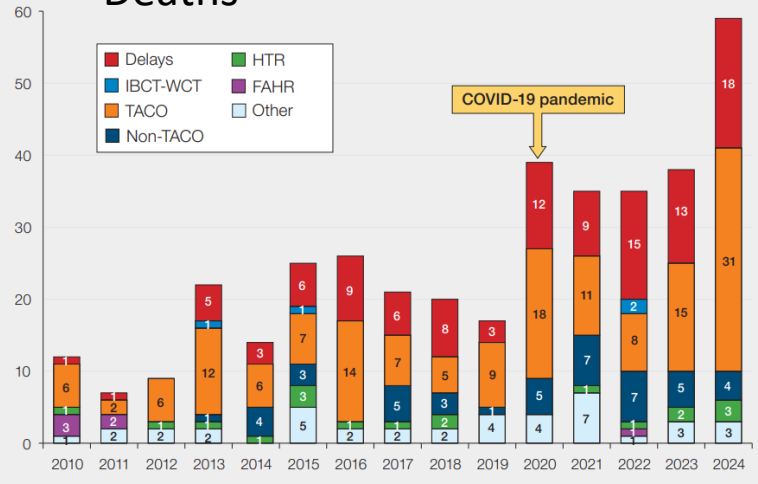
Transfusion laboratories should be staffed (and resourced) adequately to meet the requirements of their functions.

SHOT Serious Hazards of Transfusion

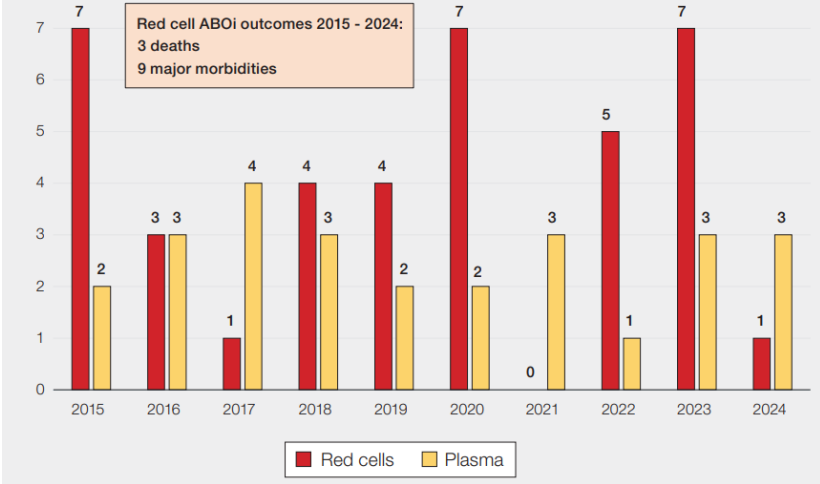
Reported errors Increasing

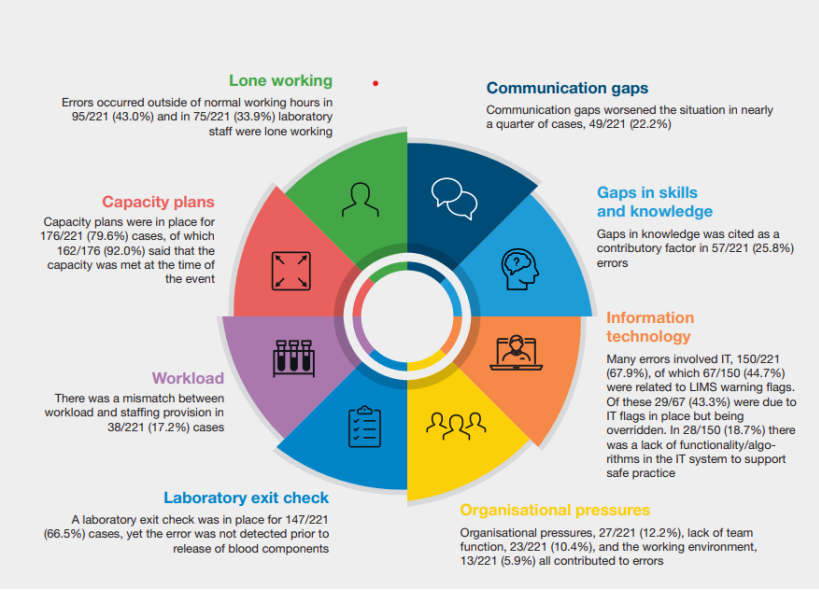


Deaths



ABO incompatible transfusions *





Lab errors increasing

*Annual SHOT report 2024

The Good Practice Guide

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.

This underpins the fact that personnel are a 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 task to ensure business continuity through an adequate capacity plan.

To ensure adequate resource, relevant evidence needs to be provided so sufficient capacity is available to suit all situations so business continuity can be preserved..

Importance of a capacity plan

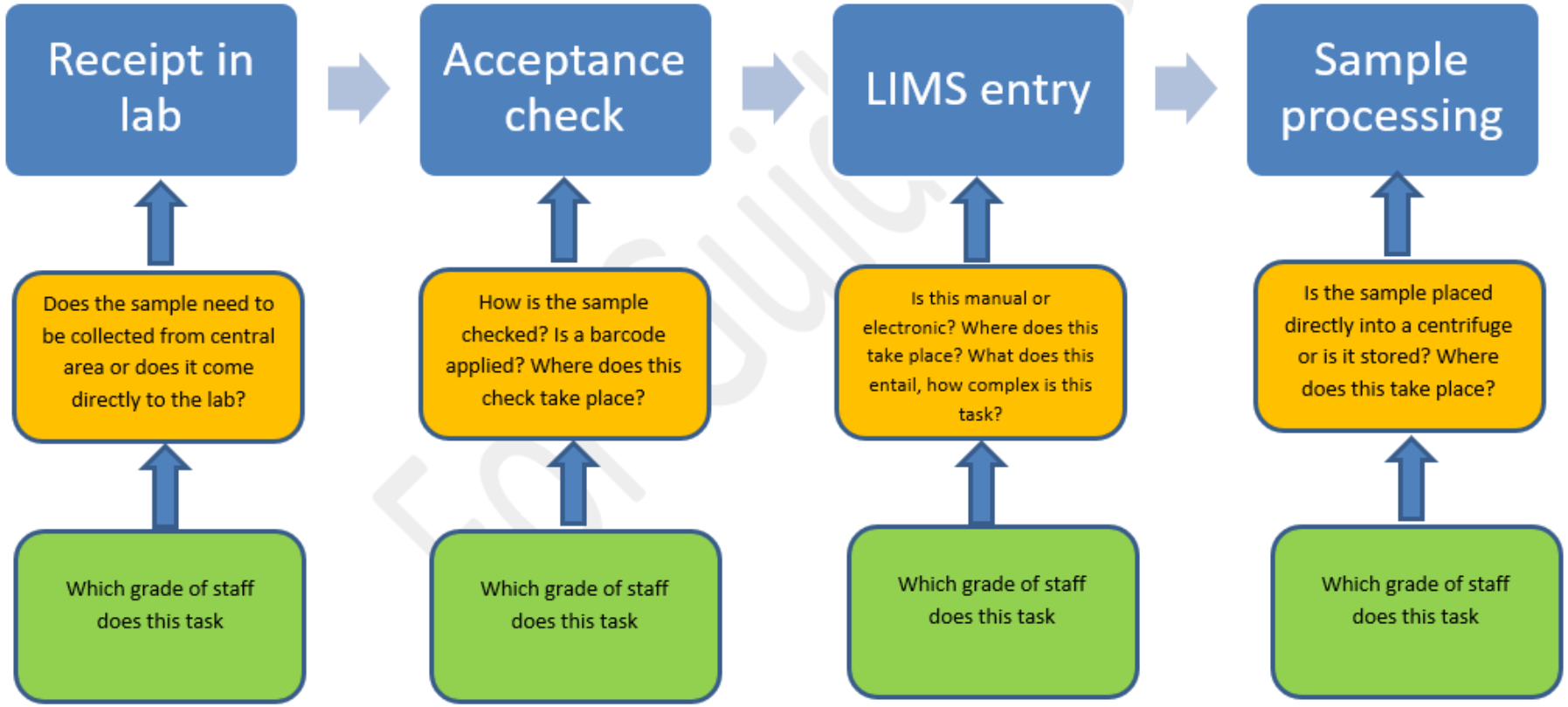
- Capacity plan covering all service elements including QMS & education functions
- Adequate number of staff to provide a safe service
- Adequate specialist staff for supervision and advice
- Incorporate risk assessment and review through governance structure
- Highlight risks to senior managers prompting staffing review and potential investment or mitigation strategy
- Regulatory requirement

Capacity Planning Guidance and Methodology for Transfusion Laboratories

Capacity Planning

- Identify work areas
- Identify tasks and skill levels (remember to include training and education time)
- Calculate time needed for completion (use tools such as workload figures, time and motion studies, analyser information)
- Map actual resource
- Identify gaps and summarise
- Identify risks - escalate if needed
- Detail actions
- Map to Good Practice Guide where possible

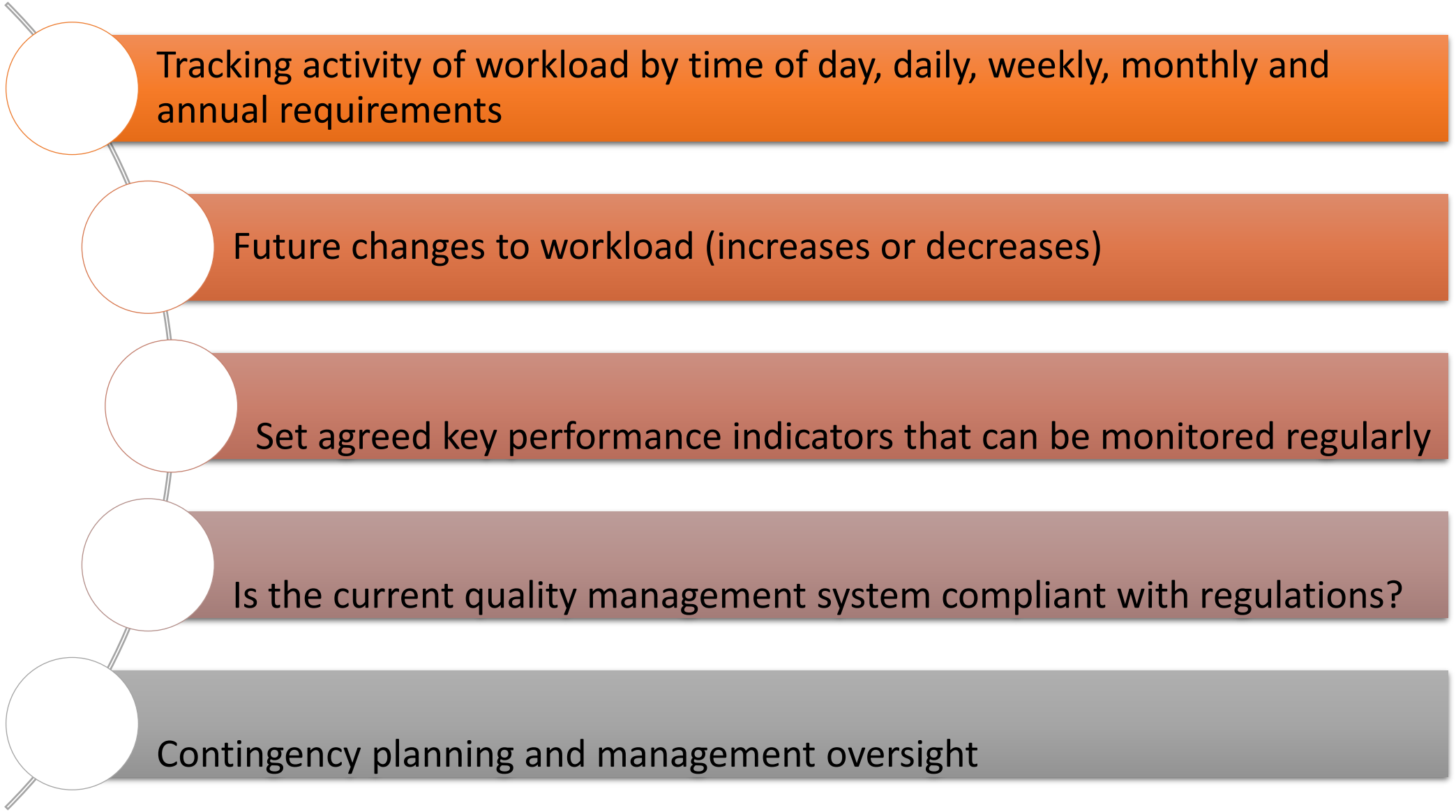
Process map


Receipt in lab
Acceptance check
LIMS entry
Sample processing
Does the sample need to be collected from central area or does it come directly to the lab?
How is the sample checked? Is a barcode applied? Where does this check take place?
Is this manual or electronic? Where does this take place? What does this entail, how complex is this task?
Is the sample placed directly into a centrifuge or is it stored? Where does this take place?
Which grade of staff does this task
Which grade of staff does this task
Which grade of staff does this task
Which grade of staff does this task

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)

Workload


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 that can be monitored regularly
Is the current quality management system compliant with regulations?
Contingency planning and management oversight

Calculating task time

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)					

Estimating number of staff required

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**

Monitoring compliance

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%)							

Escalation

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

Escalation

Expectation of a TLM is to effectively and articulately escalate clear risks if capacity plan not met

Ensure you know your route to do this

• Major findings at MHRA inspections

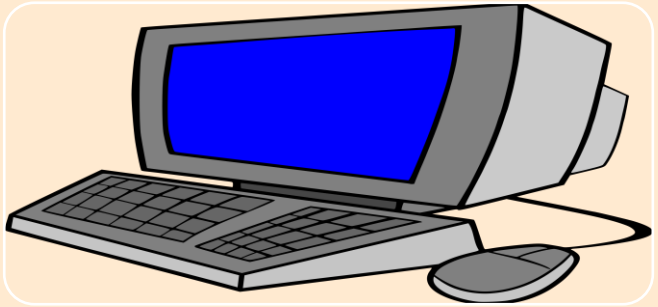
- Common deficiency groups, associate with insufficient capacity were identified and included:

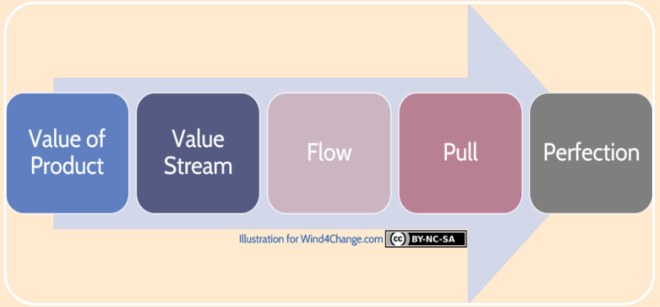
  - Senior management not fulfilling their responsibilities – Insufficient buy in
  - Non-conformances/incidents/events and CAPA implementation – Identified but not acted upon
  - Change control management – Not completed before the introduction of the change
  - Self-inspection – Audits not carried out but scheduled
  - Resourcing and training – Only 60%, or less, staff trained
  - Failure to complete previous commitments – Not clearing previous regulatory non conformances
  - No resource plan to define the required resource levels to support operational delivery and the quality system

- **A capacity and resource plan should be put in place to demonstrate that the staffing and resource levels are sufficient to cover the workload including out-of-hours working and effective implementation of the quality management system. Where a shortfall is identified, senior management should take action to ensure sufficient resource will be made available.**

Provided by MHRA Mike Dawe

Working smarter





Technology

- LIMS
- EBMS
- Telephone
- EDN

People

- Non-HCPC
- QMS
- Locums

Environment

- Lean principles
- Removing non-value adding tasks

Other considerations

- 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

Summary

- Know your processes – process mapping to find the component parts
- Objectives and aims – What is your business and the processes to deliver function (regular audit)
- Consider everything – Interactions both internal and external
- Evidence based capacity planning – Make it realistic, don’t be afraid to challenge but it’s not a battle between management and staff – Both sides must be understood
- Start Assessing the Impact on Business Continuity – Risk Assess and suggest mitigation – Log it and keep what you have done and said.
- Best use of available resource – resource is NOT just staff
- Communication is key – at all levels of the management chain and throughout the whole business processes
- The Regulations – They are a reference to help make your case

The Future

- Working group for recommendation 7
- Capacity plan is likely to be the tool for setting safe staffing levels – expanded to TP and clinical roles

Questions & discussion