ISO 15189: 2022 what's new – laboratory manager perspective

BTLP & BBTS annual meeting

November 2024

University Hospital Southampton NHS
NHS Foundation Trust

Disclaimer

- UHS transition visit incomplete
- Perspective with NTLM hat on
- Controversial
- Opinions are my own and not of any organisation I work for

Aims

- Background – Why are we talking about this
- Process and gap analysis for a lab manager
- What's new?
- Example findings – themes, may not be entirely new
- Potential solutions
- Things to think about, wrap up and discussion

- What am I not going to cover – reading through lots of clauses!

Background

- “revised to enhance the quality and competence of medical laboratory services. Plays a crucial role in ensuring the reliability and accuracy of laboratory testing, which is vital for effective patient diagnosis and treatment”
- “The new standard places a heightened focus on risk management, which reflects a broader trend towards prioritizing patient welfare in healthcare protocols”
- “The inclusion of POCT in ISO 15189:2022 is expected to encourage more laboratories to seek accreditation for these services”

- A pragmatic approach which heightens focus on risk would be welcomed?

https://www.ukas.com/resources/resources/15189-transition-update/

The transition process

- Accredited labs to transition by December 2025
- Expectation to review ISO15189:2022 & perform ‘gap analysis’
- Gap analysis = implement the changes
- Submit gap analysis with evidence
- Have a transition visit

The gap analysis

- Template provided by UKAS
- Debate on user friendly?
- Changes characterised by extent (structural, minor, major, new)
- Useful to focus prioritisation at start of review
- 7 new clauses
- 16 major

CLAUSE	ISO 15189:2012	CLAUSE	ISO 15189:2022	EXTENT OF CHANGE	DETAILS OF CHANGES WITHIN YOUR MANAGEMENT SYSTEM WHICH HAVE/WILL BE TAKEN TO ADDRESS CHANGES	UKAS COMMENTS REGARDING INFORMATION SUPPLIED INCLUDING REFERENCE TO ANY IARS RAISED
4.1.1.4	Laboratory director	5.2	Laboratory director	Minor	Compliant – as documented BTTR 16.1	
		5.6b	Risk management	New	Risks communicated to BT laboratory director via HTT (CMR slides are shared at the end of each HT).	
4.1.1.4o	Contingency planning	7.8	Continuity and emergency preparedness planning	Minor	BT: BTQD 74 good practice guide: gap analysis being worked on for all contingencies and preparedness in BT. Mass casualties covered, exercised in conjunction with Trust, Trust plans (mass casualty, EPRR)	
		7.6.4	Control of data and information management: Downtime plans	Minor	Planned processes exist	
4.1.2	Management Responsibility			N/A		
4.1.2.1	Management Commitment	8.2.3	Management system documentation: Evidence of commitment	Minor	Compliant- CMR and HTT process in place	
4.1.2.2	Needs of users	4.3	Requirements for patients:	New	Compliant- BT: covered by NHSBT leaflets, including risks, benefits – NHSBT website. Informed consent: BSQR	
4.1.2.3	Quality Policy	5.5	Objectives and policies	Minor	Compliant- All in place, annual reviews BT: HTC minutes	
4.1.2.4	Quality objectives	5.5	Objectives and policies	Minor	Compliant- Quality objectives in place KPIs, CMR, Excel spreadsheet (BT)	
		8.1.3	Management system awareness	New	Compliant- Quality induction, QPulse document distribution / acknowledgement Learning disseminated in huddles and learning presentations and email	

What's new?

- Risk – lab director role expectations
- Requirements regarding patients clause
- Management system awareness and documentation
- Specify & document range of activities (POCT, sample collection)

- How new are these things….
- Requirements for patients – lots of resource within BT ☺

Trends in findings – the usual suspects

Trends in findings

- GEN6
- Requirement to reference accredited tests
- LIMs/reported with result
- Handbook or equivalent
- Is this confusing to users – debate….

6.2.3	Although the personnel interviewed are clearly competent to perform their respective specialized roles, there is no specific assessment of competency in place such as for verifications and indication of authorisation to perform specialized roles.

It is not clear how the laboratory authorise personnel to select, develop and modify methods.

6.2.3	There is no evidence that staff are authorised to carry out selection, development,modification, validation or verification of methods.

6.2.3	The laboratory have not reviewed authorize personnel to perform specific laboratory activities

Trends in findings – Authorization 6.2.3

- Authorisation of personnel to perform specific tasks
- How do we authorise someone to do a task?
- Particularly in validation and verification of methods

Trends in findings – Authorization 6.2.3

- Document how this done (policy, procedure)
- Job description
- Training records
- Competency assessment

- We already do this, don't tie yourself in knots

Trends in findings – risk-based approach to audit

- Risk based audit planning
- Two masters – MHRA v UKAS
- Audit calendar focussed on areas of risk
- Prioritise areas needing urgent attention/patient safety risks
- Welcome pragmatic approach
- With current pressures enables risk based prioritisation, move away from audit as a tick box exercise
- How? NCs, service changes, Continual Management review

EQA – 7.3.7.3

UK NEQAS
Haematology and Transfusion

- The laboratory shall establish a procedure for EQA enrollment, participation and performance for examination methods used, where such programmes are available

- Findings re no procedure for set up/enrolment/selection
- Findings re EQA as a supplier and review that material meets the laboratories needs

  - Review distributions at the end of each financial year to ensure meet clinical needs and cover repertoire signed off by clinical lead)

Batch QC of consumables 6.6.3

- “Consumables that can affect the quality of examinations shall be verified for performance before placing into use”
- Not a new requirement, but pattern in findings
- Risk assess?
- Build into current processes e.g. IQc

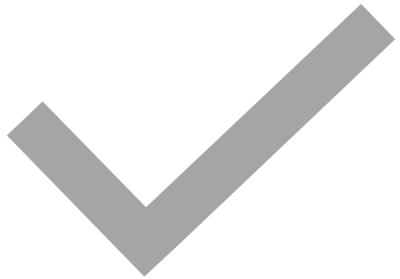
Other trends

- Immediate spin XM
- BSH guideline
- ?value
- Findings picked up for those still using this
- Risk assess or move away from use

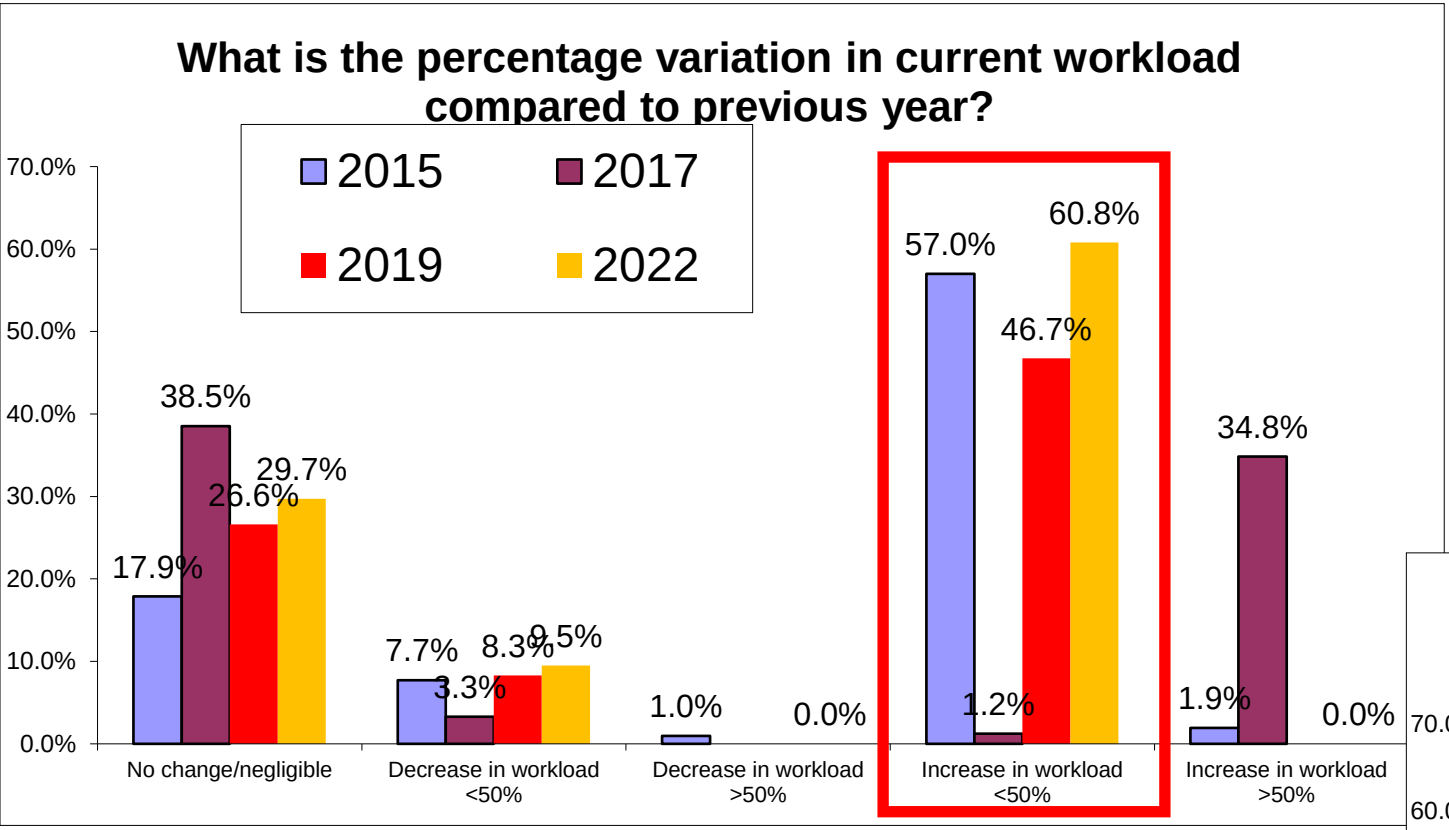
- 2nd check of manual entry
- Mostly serological XM
- Implement 2nd check ?effective, interface where possible

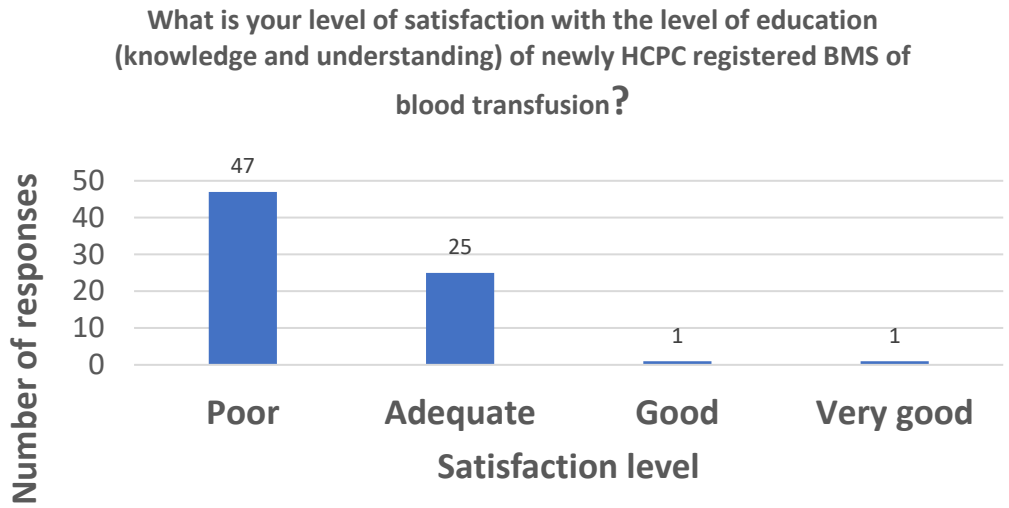
Trends in findings - ?standardised

Theme of lack of standardisation amongst assessors

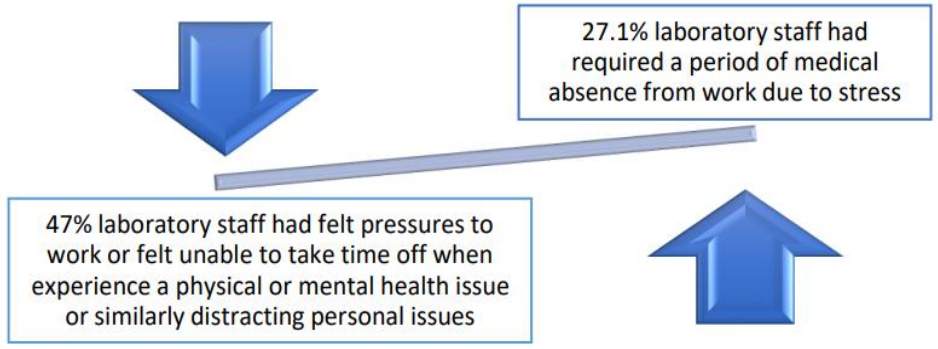


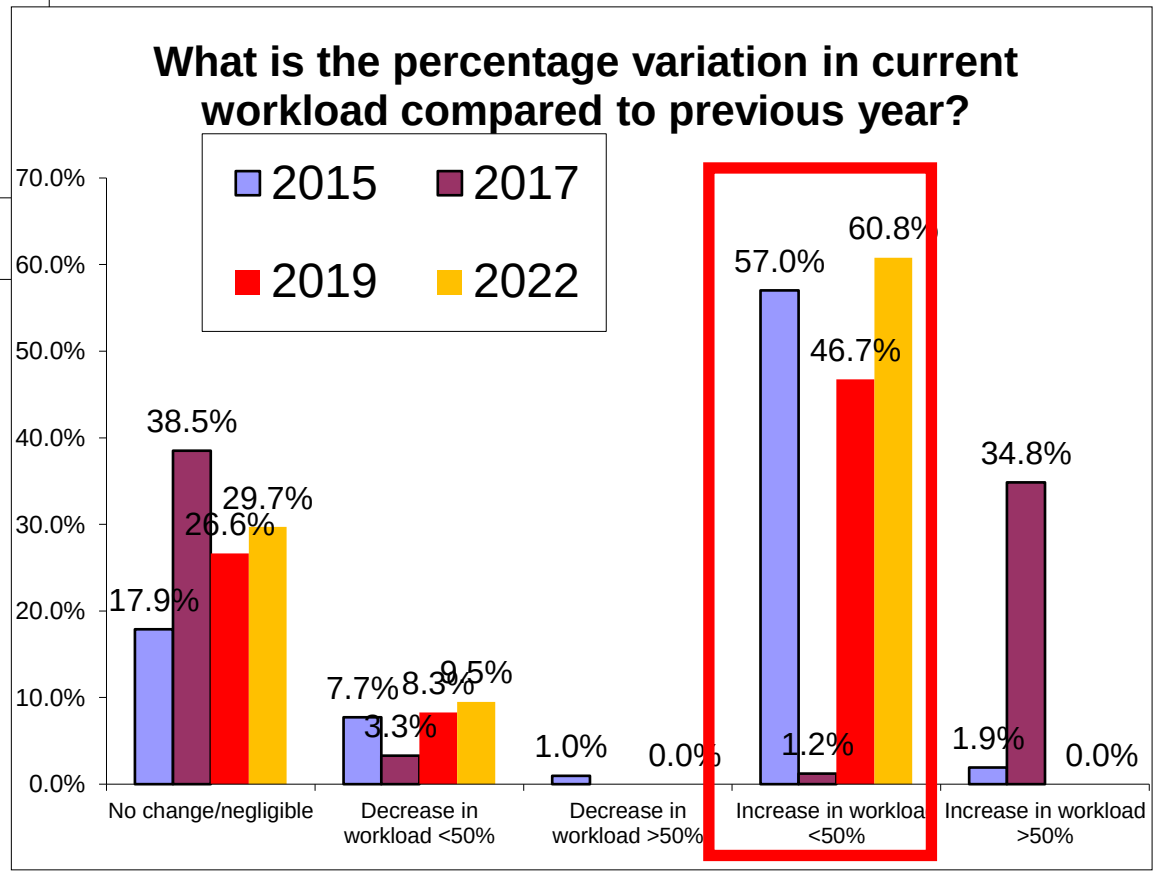
Varied assessment experiences





Nearly 1 in 5 laboratory staff do not feel psychologically safe in their workplace.
Over 2 in 5 felt concerns raised are not acted upon or felt unsafe to raise safety concerns





Do the 2022 standards improve patient care?

Is this ‘good value for money’ for NHS patients?

Why?

- NHSE 2021 position statement - NHS England, NHS Improvement and the CQC are committed to, and strongly endorse, participation in accreditation schemes for diagnostic services
- Needed for some clinical trials work
- Community diagnostic centres – “must meet accreditation standards for their modalities within two years of being operational”
- Used in CQC inspection methodology

- Drive quality care for patients and continuous improvement

What happens if we don’t have standards and accreditation?

7.2.2 Information for patients and users

"The worst treatment disaster in the history of the NHS"

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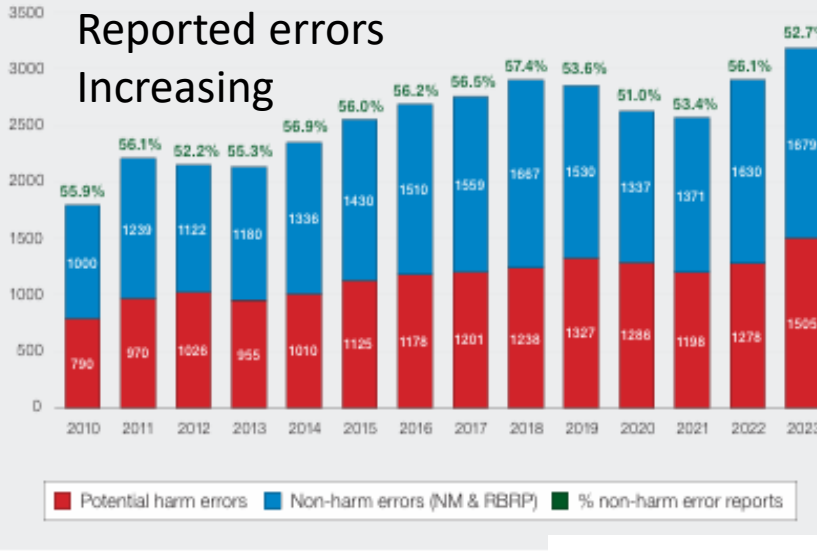
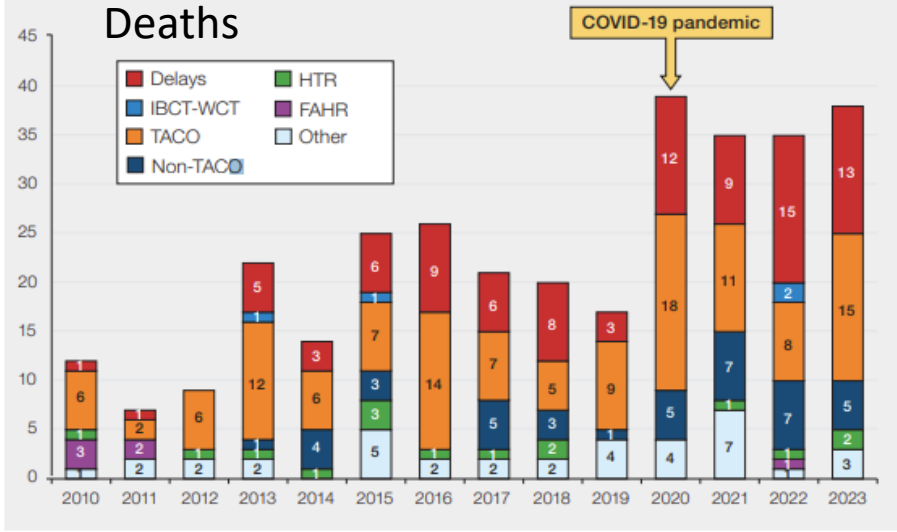
SHOT Serious Hazards of Transfusion

Reported errors Increasing

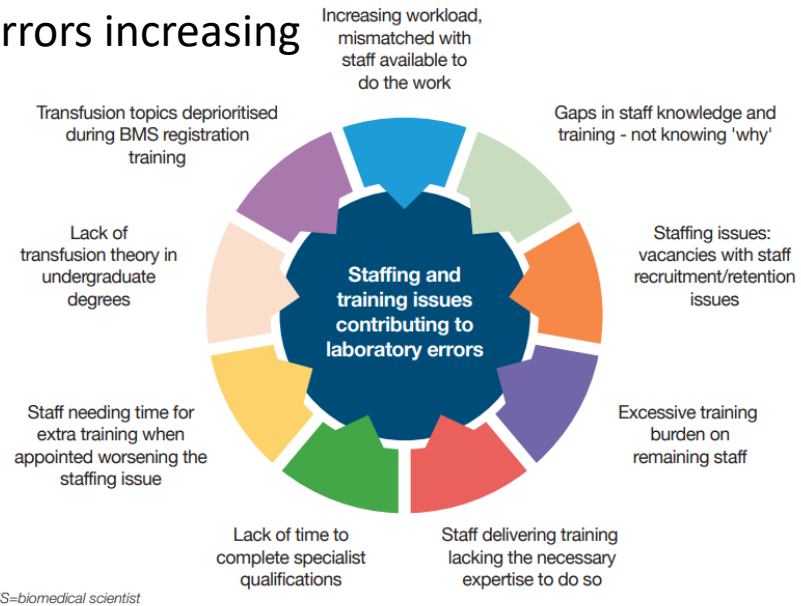


Deaths



ABO incompatible transfusions *

Lab errors increasing



BMS=biomedical scientist

Many of these items are covered in the standards and can support improvement/investment

*Annual SHOT report 2023

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Summary thoughts

- ISO 15189:2022 risk-based approach is good
- Transition has not been difficult to achieve (except resource challenges)
- Mostly QMS findings
- Standards that support good patient care and quality laboratory services
- Ensure everything is documented in a policy/SOP
- Be pragmatic
- Build into existing processes
- Be brave to challenge lack of standardised approach

Questions