

# Guidelines & Standards: Protecting Our Patients & Staff

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# Overview

## 1.PAST

- Good
- Bad

## 2.PRESENT

- UK TLC Survey
- Capacity planning

## 3.FUTURE

- Communication
- Mentors

# UK Transfusion Laboratory Collaborative

**SHOT** (Serious Hazards of Transfusion)

**MHRA** (Medicines & Healthcare products Regulatory Agency)

**NEQAS** (National External Quality Assurance Scheme)

**BBTS** (British Blood Transfusion Society)

**IBMS** (Institute of Biomedical Science)

**NBTC/ TLM** (National Blood Transfusion Committees/ Transfusion Lab Managers for E, S, W, NI)

**RCPATH** (Royal College of Pathologists)

**UKAS** (United Kingdom Accreditation Service)

PAST

# The good old days.....

1. SOPs?
2. Errors?
3. Validation???
4. Meetings & socialising, fun learning.
5. Cold rooms storing: blood, reagents, sandwiches.
6. Trainees worked with a senior.
7. Seniors supervised and guided trainees
8. No guidelines, standards, regulations
9. No change control



# The *bad* old days.....

1. 1hour Cross-matching .
2. Manual testing +++++
3. 32hr working day.
4. Serious patient safety errors
5. Traceability....???
6. No guidelines, regulations, standards!
7. No understanding of human factors

**THOSE WHO DO  
NOT LEARN FROM  
HISTORY ARE  
DOOMED TO  
REPEAT IT.**



*QuoteHD.com*

**George Santayana**

Spanish Philosopher

1863-1952

PRESENT



# Guidelines & Standards

Guideline Addendum

**Transfusion**

**Use of Fresh-Frozen Plasma, Cryoprecipitate and Cryosupernatant**

Issued: 10/05/2004 [Further details](#)

Guideline Addendum

**Transfusion**

**Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories**

Issued: 06/12/2012 [Further details](#)

Guideline Addendum

**Transfusion**

**Use of Anti-D Immunoglobulin for the Prevention of Haemolytic Disease of the Fetus and Newborn**

Issued: 21/01/2014 [Further details](#)

Guideline Addendum

**Transfusion**

**Administration of Blood Components**

Issued: 01/12/2009 [Further details](#)

Guideline Addendum

**Transfusion**

**The Estimation of Fetomaternal Haemorrhage**

Issued: 01/09/2009 [Further details](#)

Guideline Addendum

**Transfusion**

**Use of Irradiated Blood Components**

Issued: 18/11/2010 [Further details](#)

Guideline Addendum

**Transfusion**

**Blood Grouping and Antibody Testing in Pregnancy**

Issued: 14/03/2016 [Further details](#)

Guideline Addendum

**Transfusion**

**Transfusion for Fetuses, Neonates and Older Children**

Issued: 15/04/2016 [Further details](#)

Guideline Addendum

**Transfusion**

**Investigation and Management of Acute Transfusion Reactions**

Issued: 29/08/2012 [Further details](#)

Guideline Addendum

**Transfusion**

**Validation and Qualification, Including Change Control for Hospital Transfusion Laboratories**

Issued: 15/02/2012 [Further details](#)

Guideline Addendum

**Transfusion**

**Specification, Implementation and Management of Information Technology (IT) Systems in Hospital Transfusion Laboratories**

Issued: 01/12/2014 [Further details](#)

**Blood Safety and Quality Regulations 2005 (as amended)**

Topics: Good management, good records, Legal and professional obligations

The Regulations implement the provisions of Directive 2002/98/EC and associated Directives so that the retention periods for data relating to human blood and blood components outlined in the Directive are now part of UK law.

**The Regulations**

The retention periods are as follows:

Blood establishments must retain certain information regarding donors, establishment activity and testing of donated blood for a minimum of 15 years (regulation 7).

Blood establishments and hospital blood banks must retain data needed for full traceability for at least 30 years from the point of receipt of the blood or blood component (regulations 8 and 9).

The data that should be retained for 30 years in order to comply with the traceability requirements is as follows.

» Medical Laboratory accreditation (ISO 15189)

Medical Laboratory accreditation (ISO 15189)

UKAS provides accreditation to the internationally recognised standard ISO 15189: Medical Laboratories - requirements for quality and competence

UKAS accreditation covers the following disciplines:

MHRA

Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2017

PP

TRANSFUSION

UK Transfusion Laboratory Collaborative: minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014

BACKGROUND

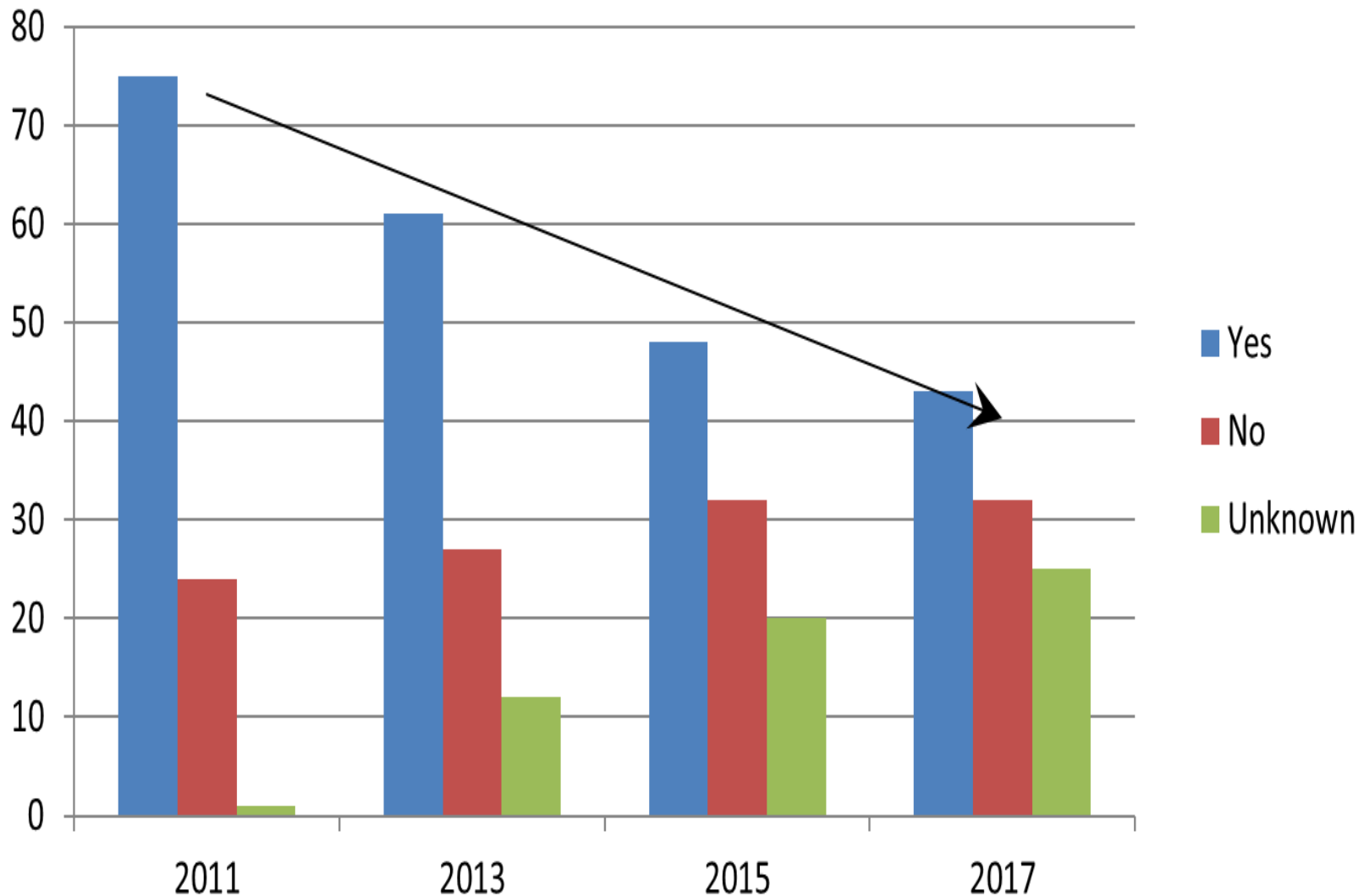
BACKGROUND

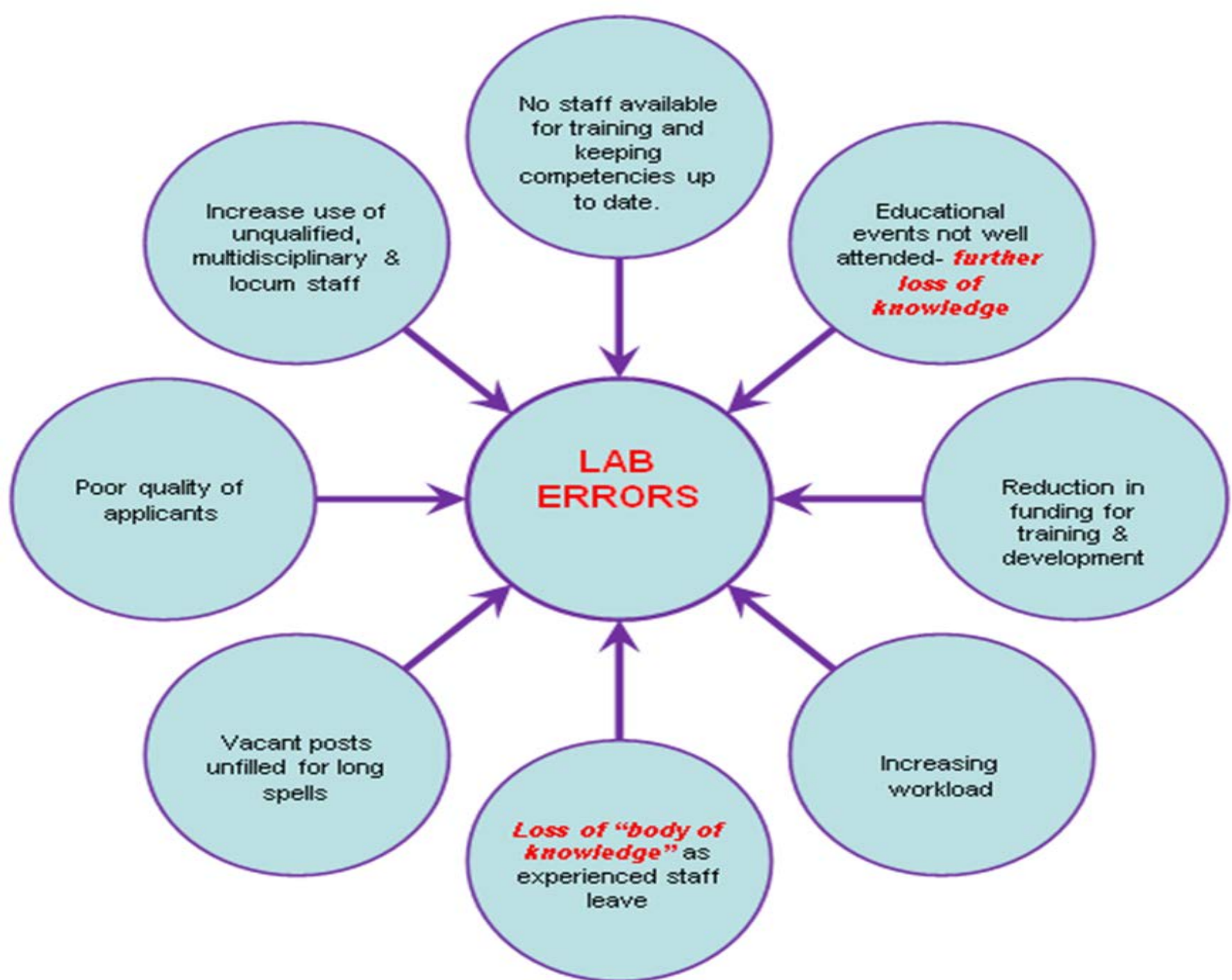
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**"It's great. I'm  
great. Everything's just great."**

**In your professional judgement does your full establishment of staff allow you to deliver all operational and regulatory activities?**





55% of laboratories do not have an agreed **staffing capacity plan** to cover core hours

*.....we are dealing with a demoralised workforce and especially demoralisation among our future workforce, which is a sign of enormous distress.*

*Dr Don Berwick*

# Define what you need

	Required WTE
<b>STAFF &amp; SKILL MIX – CORE HOURS</b>	<b>Required WTE</b>
<b>Blood Bank Manager</b>	
<b>Senior BMS- Supervision</b>	
<b>Senior BMS- Training</b>	
<b>Senior BMS- QMS support</b>	
<b>BMS or MLA- Automation</b>	
<b>BMS- Serology, review &amp; Authorisation</b>	
<b>BMS Cross-match</b>	
<b>Transfusion Practitioner- clinical interface</b>	
<b>MLA-TP and BBM support for Traceability</b>	

## Staffing Capacity Plan- Blood Transfusion Department

for XXXX NHS Hospital Trust

**Period: 1<sup>st</sup> April 2017 to 31<sup>st</sup> March 2018**

This staffing capacity plan is to identify staff levels and skill mix required to maintain safe services in the Transfusion Laboratory. This department provides both a diagnostic and a therapeutic service and must meet the requirements of the Blood Safety & Quality Regulations act 2005, as amended, which are overseen by the Medicines & Healthcare products Regulatory Agency (MHRA), via inspections and the annual Blood Compliance Report (BCR)

The UK Transfusion Laboratory Collaborative produced Standards in 2014 for Staffing levels, knowledge and skill mix required to allow the department to fulfil the requirements of the BSH Transfusion Guidelines and annual SHOT recommendations to maintain safety for both patients' and staff.

### Staffing Levels & Skill Mix Required: Table 1

Table 1		Staff Levels				
Staff & Skill Mix: CORE hours	Required w/e (define)	Q1 Apr - Jun	Q2 Jul-Sep	Q3 Oct-Dec	Q4 Jan-Mar	
Blood Bank Manager		Adequate	Adequate	Adequate		
Senior BMS- Supervision		Inadequate	Inadequate	Inadequate		
Senior BMS- Training		Inadequate	Inadequate	Inadequate		
Senior BMS- QMS support		Inadequate	Inadequate	Inadequate		
BMS or MLA- Automation		Adequate	Adequate	Adequate		
BMS- Serology, review & Authorisation		Adequate	Adequate	Adequate		
BMS Cross-match		Adequate	Adequate	Adequate		
Transfusion Practitioner- clinical interface		Adequate	Adequate	Adequate		
MLA-TP and BBM support for Traceability		Adequate	Adequate	Adequate		
MLA Reception		Inadequate	Inadequate	Inadequate		
Trainees	supernumary	N/A	N/A	N/A	N/A	
<b>Nights &amp; Weekend Shifts</b>						
BMS- Transfusion+ Haematology		Adequate	Adequate	Adequate		
MLA Support		Inadequate	Inadequate	Inadequate		
Transfusion Advisory Support (Senior/BBM)	24/7 cover	Inadequate	Inadequate	Inadequate		
Overall staffing level for the financial year 1 <sup>st</sup> April 2017- 31 <sup>st</sup> March 2018 for BCR reporting		Inadequate for task to maintain safety standards.				

Evidence for the above classification of staffing levels can be found:

1. Weekly shift rotas
2. Number of lab based incidents reported
3. Audit schedules

4. Cleaning schedules
5. Equipment PPM.
6. Training folders
7. Document reviews
8. UKAS and MHRA Non-conformances
9. Staff vacancies, sickness/absence.

### Actions taken:

Actions	Q1	Q2	Q3	Q4
Escalated to Senior Management via Quality Team	Yes	Yes	Yes	
Staffing concerns raised at HTC	Yes	Yes	Yes	
Added to Trust risk register as a Live Risk	No	No	Yes	
<b>Reference: Datix 1234</b>				
Business case made for additional staffing resources?	No	No	In progress	
Funding approved?	N/A	N/A	N/A	
Vacancies available to recruit into?	N/A	N/A	N/A	
Staff recruited & training in progress?	N/A	N/A	N/A	

*This Capacity Plan and associated Risk Register entry may be requested for review by the regulators and must be kept up dated.*

### Capacity Plan produced by:

\_\_\_\_\_ Date \_\_\_\_\_  
Blood bank manager

Q1 Review \_\_\_\_\_ Date \_\_\_\_\_

Q2 Review \_\_\_\_\_ Date \_\_\_\_\_

Q3 Review \_\_\_\_\_ Date \_\_\_\_\_

Q4 Review \_\_\_\_\_ Date \_\_\_\_\_

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# Culture Concerns

- Reports of threats , bullying and blame.
- False declarations on Annual BCR
- Post inspection commitments not supported
- Incidents and errors not reported
- Staff losing their jobs over raising issues
- Risks not raised
- Capacity plans ignored

# Impact of Errors & Culture



*Drive out fear from an organisation-  
as fear is toxic to safety &  
improvement*

W. Edwards Deming

- Right staffing levels
- Right skill mix
- Right knowledge
- Right supervision
- Right equipment
- Right procedures
- Right resources

*Patient and Staff Safety*

FUTURE

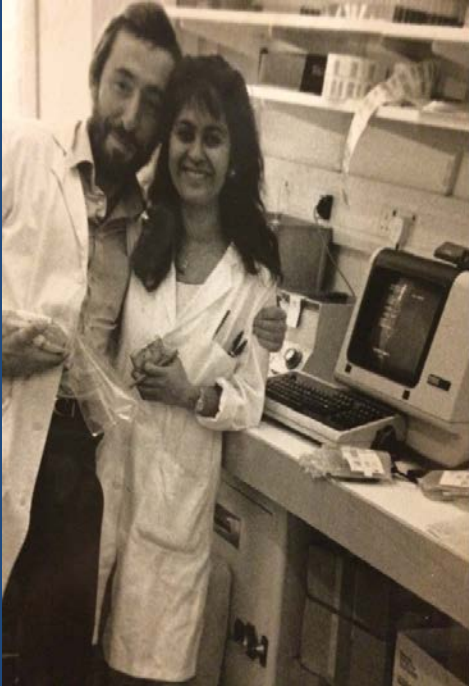
All anyone asks for is a  
chance to work with pride.

W. Edwards Deming

# Communication & Support

- Attend external meetings
- Connect colleagues: Risk teams, BBMs, Quality teams.
- Participate on forums: [MHRA Blood Forum](#), [PathlabTalk](#), [IBMS](#)
- Tell us what is happening: [UKTLC email TBA](#)
- Share documents -JPAC website soon.
- Write your capacity plans
- Find mentors to listen and advise.

# Friends & Mentors



**Keith Prior**

*Barbara Morris*

**BILL CHAFFE**

**Joan Jones**

Gwen Guthrie

**UKTLC team**

*Many others!*



# Forums

## MHRA Blood Forum

<http://forums.mhra.gov.uk/forum.php>

## PathLabTalk:

<https://www.pathlabtalk.com/forum/index.php>

## IBMS members Forum:

<https://www.ibms.org/membersarea/login/login.asp>

The background of the slide is a grayscale photograph of a rugged coastline. In the foreground, dark, jagged rock formations rise from the sea. The middle ground shows waves crashing against the shore, with white foam visible. In the background, a range of mountains or hills stretches across the horizon under a hazy, overcast sky. The overall mood is serene and powerful.

Human interaction is the key  
force in overcoming resistance  
and speeding change.

Atul Gawande

“[quartzfancy](#)”

*Bring joy and pleasure  
back into our working  
lives.*