Building a strong Quality Culture and how to measure it

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Director Inspection Enforcement and Standards

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Agenda

Quality Culture

• Lessons from history
• What MHRA looks for
• Does “one size fit all”?
• Measuring Quality Culture
• Hallmarks of a Quality Culture
• PDA Assessment Initiative
Quality Culture: Nothing new......
Report of the Committee appointed to inquire into the circumstances, including the production, which led to the use of contaminated infusion fluids in the Devonport Section of Plymouth General Hospital

Chairman
C. M. CLOTHIER, ESQ., Q.C., B.C.L., M.A. Oxon.

Presented to Parliament by the Secretary of State for Social Services by Command of Her Majesty
July 1972
Clothier report 1972: Principal conclusions

• The Committee heard of **no imminent technological advance** in the field of production of intravenous fluids **which will eliminate the need for skillful men devoted to their work**.

• The Committee considers that **too many people believe that sterilization of fluids is easily achieved with simple plant operated by men of little skill under a minimum of supervision, a view of the task which is wrong in every respect**.

• The Committee considers that the lessons of the past are apt to be forgotten and that **public safety** in this as in many other technological fields **depends ultimately on untiring vigilance both in industry and by government**. **Forthcoming regulation of the industry by license and inspection will not of itself guarantee freedom from similar disasters**.
1972: ‘Forthcoming regulation’…….?
Quality Culture: what MHRA looks for

• Confidence that the company is (and will remain) in control
• Understanding of how quality attributes impact the patient
• Confidence in quality-related decision making
• Maturity of organisational mindset:

Compliance-driven: “I do this because I have to”

Excellence-driven: “I know this is important to the patient, because…..”
What does a Quality Culture require?

- Knowledge
- Transparency
- Management commitment
- Diligence
- Vigilance

Visibility to the patient
Regulatory action: the road to ruin!

- Data Integrity (basic ALCOA)
- Serious PQS failure
- Quality defects with public health impact

- Mgmt oversight and resourcing – ICH Q10
- Failing PQS
- Quality defect investigations and actions

- Failing PQS
- Risk based investigations and actions
- Personnel knowledge / experience

Common themes; increasing severity.
Quality Culture: does “one size fit all”?
Measuring Quality Culture
Metrics: careful assessment

- The need for context is paramount when interpreting metrics.
- Understanding the context is as important as the metrics themselves.

Deviations per batch

Is this a problem?
Metrics: careful selection

- Careful selection of metrics is required
  - What behaviours do the metrics demonstrate?
  - What behaviours do the metrics influence?
  - What is the relevance of each metric to product quality or patient safety?

“The only true measures of quality are the outcomes that matter to patients”

Michael E. Porter and Thomas H. Lee, MD
The importance of context

"Investigations closed within 30 days"

On time
- Poor investigations?
  - Poor quality?
- Poor decision making?
  - Supply disruption?

Late
- Good investigations?
  - Improved quality?
- Good decision making?
  - Consistent supply?
  - Patient benefits?
Metrics: careful selection

• Is the company monitoring the right things?
  • NOW
  • IN FUTURE

Adapted from "Quality Improvement and ISO Management at Colombo, Jaffe and Overseas" by Susan Yoshida
Hallmarks of a Quality Culture

1. Values clear from the top – CEO and Board
2. Leadership by example – walking the talk
3. True priorities understood and owned – patient first
4. Openness and transparency – processes in place
5. Responsibilities defined and understood – training
6. Doing what is right is more important than looking good
7. Learning from mistakes is our most valuable investment – continuous improvement
Aspiring to Measure Quality Culture

Assessment tool (performed on-site)

Survey tool (online)

Objective & verifiable (Mature Quality Attributes)

Behaviors and feelings (leadership & self)

For details contact Denyse Baker (baker@pda.org)
Survey developed to measure quality culture behaviours

30 questions for staff at sites
- How often have you observed site leadership
- Assess your own behaviours
- Overall assessment of the site

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<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Seldom</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost always</th>
<th>N/A</th>
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<tbody>
<tr>
<td>1. Driving and recognising staff on continuous improvement activities at your plant?</td>
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<td>2. Encouraging staff to share knowledge and expertise to solve plant problems?</td>
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<td>3. Making it easy to promote fast escalation of quality issues?</td>
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<td>4. Communicating a values set of values driving the culture, and hold staff accountable on work conduct?</td>
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<td>5. Providing technologies that are needed for current requirements?</td>
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<td>6. Ensuring continuous learning is available at all levels?</td>
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<td>7. Proactively consider quality and embed quality into their work and decisions?</td>
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<td>8. Provides support and resources for staff to deliver quality results?</td>
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<td>9. Ensuring staff understands their individual impact on quality and safety?</td>
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<td>10. Establishing and reviewing excess functional quality goals and metrics?</td>
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<td>11. Sharing information on product quality performance with employees and key partners (e.g., suppliers)?</td>
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<td>12. Encouraging “speaking up” (talking) quality issues?</td>
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<td>13. Promoting staff based on results and appropriate behaviors?</td>
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Survey developed to measure quality culture behaviours
On-site Assessment - 5 categories

- Leadership Commitment
- Communication & Collaboration
- Employee Ownership
- Continuous Improvement
- Technical Excellence
On-site Assessment - 12 attributes

1. Leadership Commitment to Quality
2. Enabling Capable Resources
3. Quality Communications
4. Collaboration with Auditors
5. Understanding Quality Goals
6. Safety Culture
7. Leadership Commitment
8. Management Review and metrics
9. Clear Quality Objectives
10. Internal Stakeholder Feedback
11. Utilization of new proven technologies
12. Maturity of Systems
Back to 1972........

• Clothier report’s principal conclusions of 45 years ago are still relevant today
  • *No technological advances which eliminate the need for skillful personnel devoted to their work*

• Commitment. - from senior management
• Knowledge. - through development of staff
• Diligence. - from all involved
• Vigilance. - relevant metrics to inform good decisions
THANK YOU FOR YOUR ATTENTION

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