Driving sustainable cultural transformation

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Agenda

- Learning from the past: 1970s quality culture
- Quality Culture requirements and indicators
- Steps to sustainable transformation
  - Leadership
  - Personnel empowerment
  - Monitoring
  - Maintaining momentum
- Reflections on quality culture actions in 2018.
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’…….?
EU GMP January 1989*:
“...attainment of quality objectives is responsibility of senior management....requires commitment at all levels in the company”.

* Harmonised with international GMP
Implementing a quality culture
What does a Quality Culture require?

- Knowledge
- Diligence
- Transparency
- Management commitment
- Vigilance

Visibility to the patient
Quality Culture: MHRA indicators

• 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….”
Quality Culture and employee empowerment: global approaches
Steps to transformation

- Leadership
  - Communication
  - Visibility
  - Actions
- Empowerment of personnel
  - Ownership
  - Understanding / knowledge management
- Measurement / monitoring
- Continued focus.
Steps to transformation: Leadership
Leadership’s role

• Quality culture is ‘led from the top, empowered from below’

• Significant impact to the organisation’s quality culture
  • ‘Sets the tone’ for the organisation’s mindset and beliefs
QA Director, large volume parenterals:

“All we’re doing is making bags of water”
Leadership: communication

- Communication of priorities and values
  - To personnel
  - To shareholders
  - To clients
  - To regulators

- Build understanding among leaders and workforce
  - What are we trying to achieve?
  - Why is it important?
  - Reduces working by rote
  - Removes some of the incentive to short cut / falsify / ignore issues
Leadership: visibility

- Absent leadership
  - Unaware of issues
  - Failure to act

- Dominant leadership
  - Creates fear
  - Prevents personnel ownership

- Balance is important.
Leadership: actions

- MHRA inspection case study:
  - Falsification of analytical results
  - Microbiology plates destroyed before recording results
  - Falsification of calibration certificates
  - Batch records falsified
  - Company ‘in denial’ when investigating issues
  - Multiple attempts by senior management to mislead the inspectors

- Attempts to blame individuals
- Evidence of management coercion of personnel.
Leadership: actions

• MHRA inspection case study analysis:
  • ‘Absent’ senior management
  • Culture of saying ‘yes’ to any management request
  • Contract personnel did not report problems (fear)
  • Poor investigations – blamed individual junior personnel
  • Poor training
  • Significant under-resourcing of personnel

• Statement of non-compliance issued. Supply continuity impact.
Leadership: actions

- MHRA inspection case study remediation:
  - Change in organisational leadership
  - Over 140 additional staff employed
  - New environment of open and honest actions
  - Visibility of issues
  - QRM improvements.
Steps to transformation: Empowerment of personnel
Each employee requires……..

- Understanding of their role and contribution
  - to the patient
  - to the business

- Evidence of positive outcomes from individual contribution

- Investment in personal knowledge and experience
  - Knowledge shared throughout organisation

- Relevant to all personnel, including contract workers.
Successful empowerment

Visibility to the patient

Knowledge sharing

Understanding contribution
Steps to transformation: Measurement / monitoring
Monitoring

• Relevant monitoring
  • Critical review of what metrics are monitored, and the environment in which they are being monitored

• Is the company monitoring the right things?
  • Now
  • In the future.
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
Metrics: careful assessment
Metrics: careful assessment

- The need for context is paramount when interpreting metrics
- Metrics which give context are as important as the metrics themselves
  - *Meta-metrics?*

![Graph showing deviations per batch](Image)

*Is this a problem?*
Quality metrics – future considerations

• Enhancing personnel ‘ownership measures’
  • ‘Empowerment measures’ – ability to influence change

• Selecting and reviewing relevant metrics
  • Product / patient, process, compliance and behaviour
  • Providing context for metrics interpretation

• Challenges:
  • **Industry**: approaches to communicating variable metrics and contextual information
  • **Regulators**: normalising diverse metrics as inputs to risk-based inspection planning.
Steps to transformation: Continued focus
Maintaining momentum

- Ongoing reinforcement of transformation steps
  - Leadership
    - Values
    - Behaviours
  - Empowerment
    - Training, understanding
    - Access to senior management
  - Monitoring
    - Changes to metrics if required.
Benefits from quality culture focus

• Reputational
  • Business benefits

• Operational
  • Identify and fix problems more effectively
  • Improved quality, consistent supply, less waste

• Regulatory
  • Risk based regulation – regulatory relief
  • Ability to use modern flexible concepts (ICH Q12 etc).
Reflection: In the last year......

• What have you done in the last year to demonstrate quality culture behaviours?

• How have you changed your behaviour to influence those around you?

• Have you empowered your personnel?

• Have you measured outcomes?

• What are you continuing to do?
Summary

• Organisational culture influences quality outcomes
• Requires continuous reinforcement through senior management behaviour and employee empowerment
• Empowerment is achieved by sharing knowledge, understanding of task objectives, and ‘visibility to the patient’
• There may be different geographic approaches to achieving the different elements of empowerment; overall outcomes are the same.
Back to 1972........

- Clothier report’s principal conclusions of 47 years ago are still relevant today
  - *No technological advances which eliminate the need for skillful personnel devoted to their work*

Thank you

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