Culture Transformation – Best Practices

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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
• 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: New GMP concept?

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
Quality culture: where to focus?

- Management initiatives?
  - ‘Right first time’
  - ‘SOP compliance’
  - ‘Lean’ initiatives
  - ‘Quality culture’ programmes

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


- Changing behaviours?.

8
Don’t just say it….. show it!
What influences quality culture?

- Enablers:
  - Motivated People
  - Facilities, equipment & methods
  - Leadership
  - Patient-centred objectives

- Organisational behaviours:
  - Continuous improvement
  - Visibility of issues
  - Risk-based decisions

- Quality culture & Compliance
  - Quality Outcomes
Leadership: MHRA GMP inspection findings

- Key ICH Q10 requirements
  - Para 1.5: Senior Management has ultimate responsibility for effective PQS......active participation and commitment at all levels.....
  - Para 1.6: Management review of PQS.....identify opportunities for continuous improvement.....
  - These deficiencies rarely occur in isolation.
Leadership: MHRA GMP inspection findings

Deficiencies linked to leadership failure Jan 2018-Sept 2019

- Maintain state of control
- Continual improvement
- Change management
- Root cause analysis
- Investigations
- QRM
- Personnel resources
- Document controls (DI)
- Contemporaneous records (DI)

Critical  Major
Steps to behavioural transformation
Steps to behavioural transformation

- Environment
- Monitoring
- Leadership
- Momentum

Behavioural transformation
Leadership’s role

• Communication of priorities and values
  • To personnel
  • To shareholders
  • To clients
  • To regulators
QA Director, large volume parenterals:

“All we’re doing is making bags of water”
Leadership's role

- Commitment to change and quality improvement
- Visibility
  - Absent vs dominant leadership
- Actions
  - Displaying the desired behaviours
  - Leading by example.
‘Enabling environment’

• Create a physical and psychological environment that supports achievement of organisational goals.

• Address demotivating factors:
  • Poor training
  • Unnecessary complexity
  • Inadequate facilities and equipment
  • Problematic methods
  • Lack of management interest to fix problems.
‘Enabling environment’

- Invest in people
- Educate and develop, don’t just train
  - Understanding of their role and contribution
    - to the patient
    - to the business
- Evidence of positive outcomes from individual contribution
- Empower to effect change.
‘Enabling environment’

- Simplify SOPs and working practices
- Prioritise actions
  - Risk acceptance (‘zero risk’ does not exist)
- Provide adequate resources
  - Capacity vs demand
  - Reliable methods
  - Properly functioning equipment and facilities.
Monitoring

- 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?
Maintaining momentum

- Ongoing reinforcement of transformation steps
  - Leadership
    - Values
    - Behaviours
  - Enabling environment
  - Monitoring
    - Changes to metrics if required.
Delivering Success

Galbraith’s Star Model

Developed by Jay Galbraith in 1960s, the star model is widely accepted because of the approach that seamlessly links competitive advantage to strategy to structure, people, lateral processes and reward mechanisms.

Benefits
- Description of important organizational elements
- Recognition of the interaction between the elements

Limitations
- Does not “call out” some key elements including inputs/outputs culture
Quality Culture and employee empowerment: global approaches
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
Back to 1972……..

• Clothier report’s principal conclusions of 48 years ago are still relevant today
  • No technological advances which eliminate the need for skillful personnel devoted to their work

• Leadership commitment. Enabling environment. Motivated personnel.
Thank you

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