Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Driving sustainable cultural transformation

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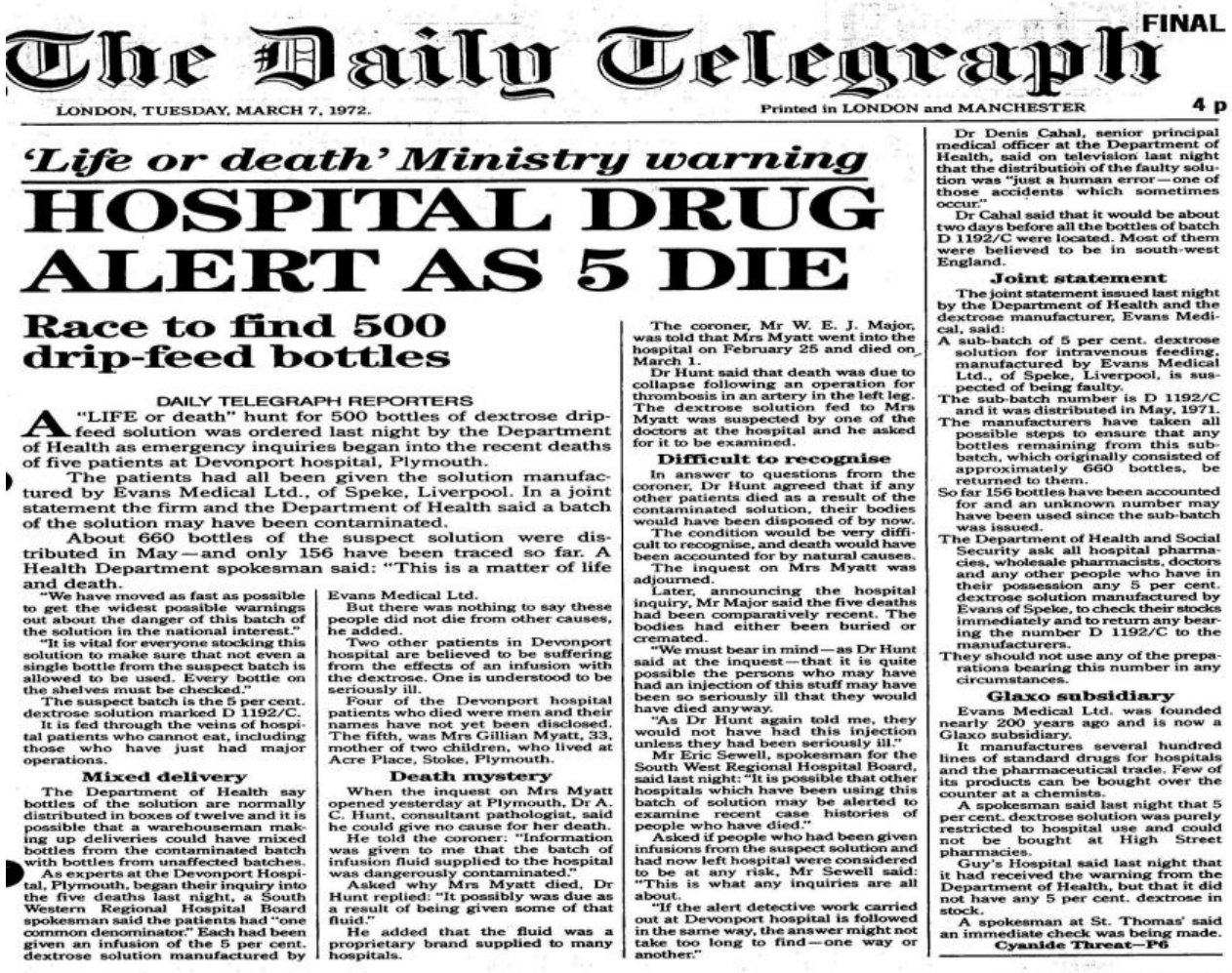
Agenda

- 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…….



The Daily Telegraph FINAL

LONDON, TUESDAY, MARCH 7, 1972. Printed in LONDON and MANCHESTER 4 p

'Life or death' Ministry warning

HOSPITAL DRUG ALERT AS 5 DIE

Race to find 500 drip-feed bottles

DAILY TELEGRAPH REPORTERS

A "LIFE or death" hunt for 500 bottles of dextrose drip-feed solution was ordered last night by the Department of Health as emergency inquiries began into the recent deaths of five patients at Devonport hospital, Plymouth.

The patients had all been given the solution manufactured by Evans Medical Ltd., of Speke, Liverpool. In a joint statement the firm and the Department of Health said a batch of the solution may have been contaminated.

About 660 bottles of the suspect solution were distributed in May—and only 156 have been traced so far. A Health Department spokesman said: "This is a matter of life and death.

"We have moved as fast as possible to get the widest possible warnings out about the danger of this batch of the solution in the national interest."

"It is vital for everyone stocking this solution to make sure that not even a single bottle from the suspect batch is allowed to be used. Every bottle on the shelves must be checked."

The suspect batch is the 5 per cent. dextrose solution marked D 1192/C.

It is fed through the veins of hospital patients who cannot eat, including those who have just had major operations.

Mixed delivery

The Department of Health say bottles of the solution are normally distributed in boxes of twelve and it is possible that a warehouseman making up deliveries could have mixed bottles from the contaminated batch with bottles from unaffected batches.

As experts at the Devonport Hospital, Plymouth, began their inquiry into the five deaths last night, a South Western Regional Hospital Board spokesman said the patients had "one common denominator." Each had been given an infusion of the 5 per cent. dextrose solution manufactured by Evans Medical Ltd.

But there was nothing to say these people did not die from other causes, he added.

Two other patients in Devonport hospital are believed to be suffering from the effects of an infusion with the dextrose. One is understood to be seriously ill.

Four of the Devonport hospital patients who died were men and their names have not yet been disclosed. The fifth, was Mrs Gillian Myatt, 33, mother of two children, who lived at Acre Place, Stoke, Plymouth.

Death mystery

When the inquest on Mrs Myatt opened yesterday at Plymouth, Dr A. C. Hunt, consultant pathologist, said he could give no cause for her death.

He told the coroner: "Information was given to me that the batch of infusion fluid supplied to the hospital was dangerously contaminated."

Asked why Mrs Myatt died, Dr Hunt replied: "It possibly was due as a result of being given some of that fluid."

He added that the fluid was a proprietary brand supplied to many hospitals.

The coroner, Mr W. E. J. Major, was told that Mrs Myatt went into the hospital on February 25 and died on March 1.

Dr Hunt said that death was due to collapse following an operation for thrombosis in an artery in the left leg. The dextrose solution fed to Mrs Myatt was suspected by one of the doctors at the hospital and he asked for it to be examined.

Difficult to recognise

In answer to questions from the coroner, Dr Hunt agreed that if any other patients died as a result of the contaminated solution, their bodies would have been disposed of by now.

The condition would be very difficult to recognise, and death would have been accounted for by natural causes.

The inquest on Mrs Myatt was adjourned.

Later, announcing the hospital inquiry, Mr Major said the five deaths had been comparatively recent. The bodies had either been buried or cremated.

"We must bear in mind—as Dr Hunt said at the inquest—that it is quite possible the persons who may have had an injection of this stuff may have been so seriously ill that they would have died anyway.

"As Dr Hunt again told me, they would not have had this injection unless they had been seriously ill."

Mr Eric Sewell, spokesman for the South West Regional Hospital Board, said last night: "It is possible that other hospitals which have been using this batch of solution may be alerted to examine recent case histories of people who have died."

Asked if people who had been given infusions from the suspect solution and had now left hospital were considered to be at any risk, Mr Sewell said: "This is what any inquiries are all about.

"If the alert detective work carried out at Devonport hospital is followed in the same way, the answer might not take too long to find—one way or another."

Dr Denis Cahal, senior principal medical officer at the Department of Health, said on television last night that the distribution of the faulty solution was "just a human error—one of those accidents which sometimes occur."

Dr Cahal said that it would be about two days before all the bottles of batch D 1192/C were located. Most of them were believed to be in south-west England.

Joint statement

The joint statement issued last night by the Department of Health and the dextrose manufacturer, Evans Medical, said:

A sub-batch of 5 per cent. dextrose solution for intravenous feeding, manufactured by Evans Medical Ltd., of Speke, Liverpool, is suspected of being faulty.

The sub-batch number is D 1192/C and it was distributed in May, 1971.

The manufacturers have taken all possible steps to ensure that any bottles remaining from this sub-batch, which originally consisted of approximately 660 bottles, be returned to them.

So far 156 bottles have been accounted for and an unknown number may have been used since the sub-batch was issued.

The Department of Health and Social Security ask all hospital pharmacies, wholesale pharmacists, doctors and any other people who have in their possession any 5 per cent. dextrose solution manufactured by Evans of Speke, to check their stocks immediately and to return any bearing the number D 1192/C to the manufacturers.

They should not use any of the preparations bearing this number in any circumstances.

Glaxo subsidiary

Evans Medical Ltd. was founded nearly 200 years ago and is now a Glaxo subsidiary.

It manufactures several hundred lines of standard drugs for hospitals and the pharmaceutical trade. Few of its products can be bought over the counter at a chemists.

A spokesman said last night that 5 per cent. dextrose solution was purely restricted to hospital use and could not be bought at High Street pharmacies.

Guy's Hospital said last night that it had received the warning from the Department of Health, but that it did not have any 5 per cent. dextrose in stock.

A spokesman at St. Thomas' said an immediate check was being made.

Cyanide Threat—P6

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

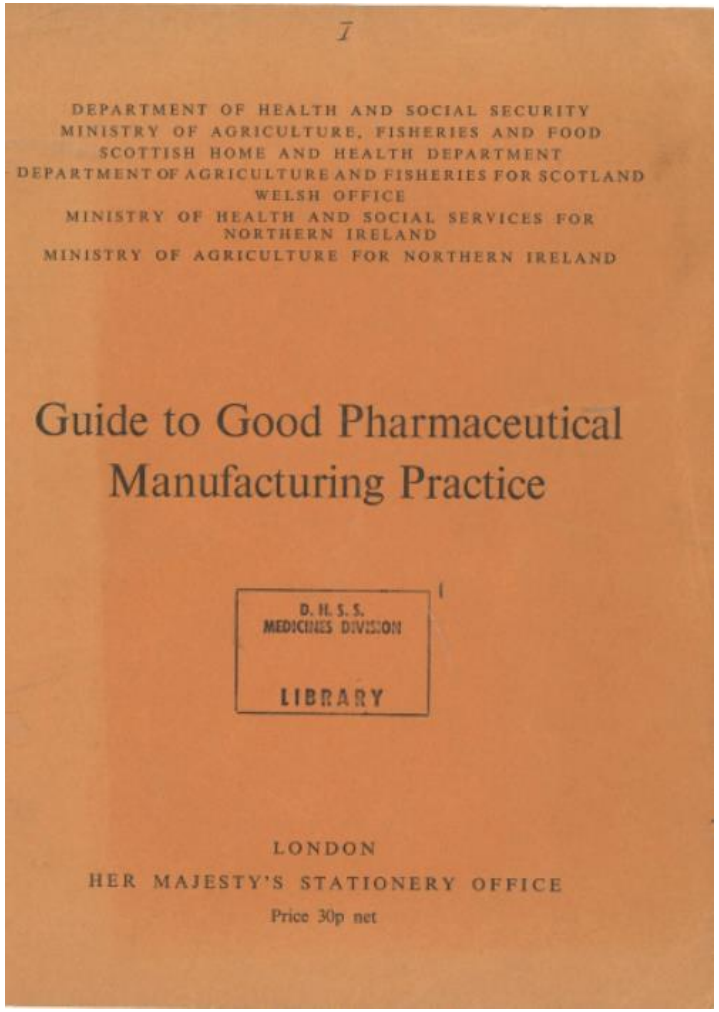
Clothier report 1972: Principal conclusions

- 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.**

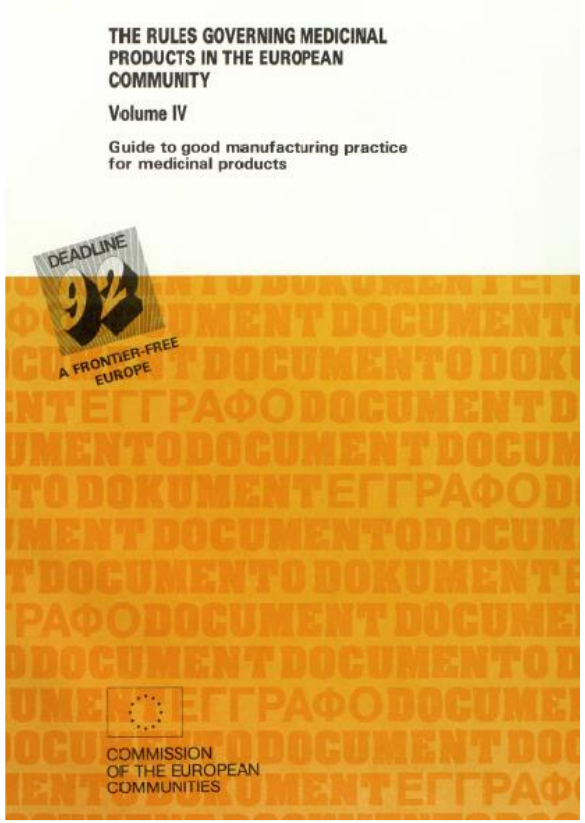
1972: ‘Forthcoming regulation’…….?



Quality Culture: 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

What does a Quality Culture require?

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:

Quality Culture and employee empowerment: global approaches

Steps to transformation

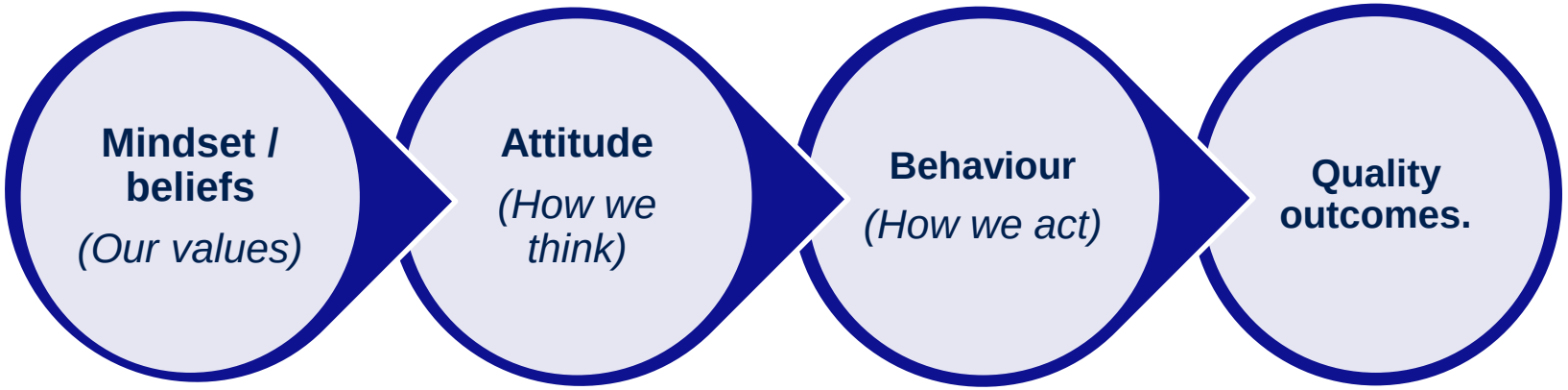
- Leadership
  - Communication
  - Visibility
  - Actions
- Empowerment of personnel
  - Ownership
  - Understanding / knowledge management
- Measurement / monitoring
- Continued focus.

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:

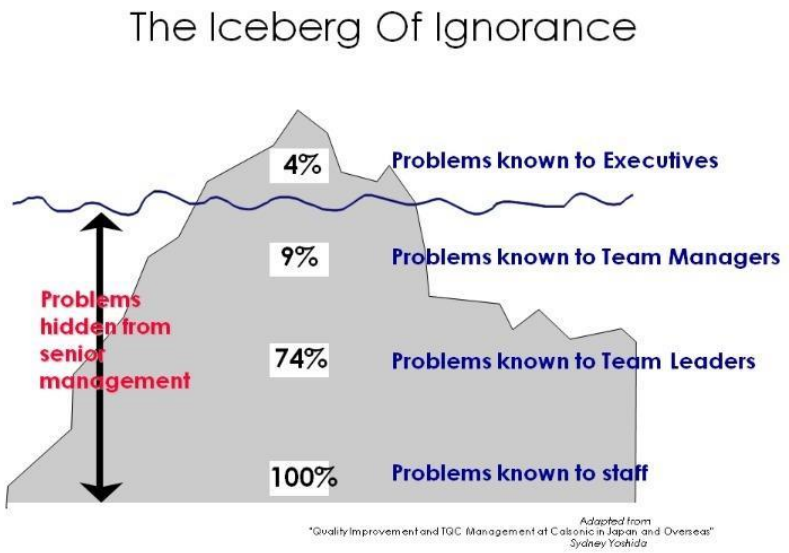
“All we’re doing is making bags of water”

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

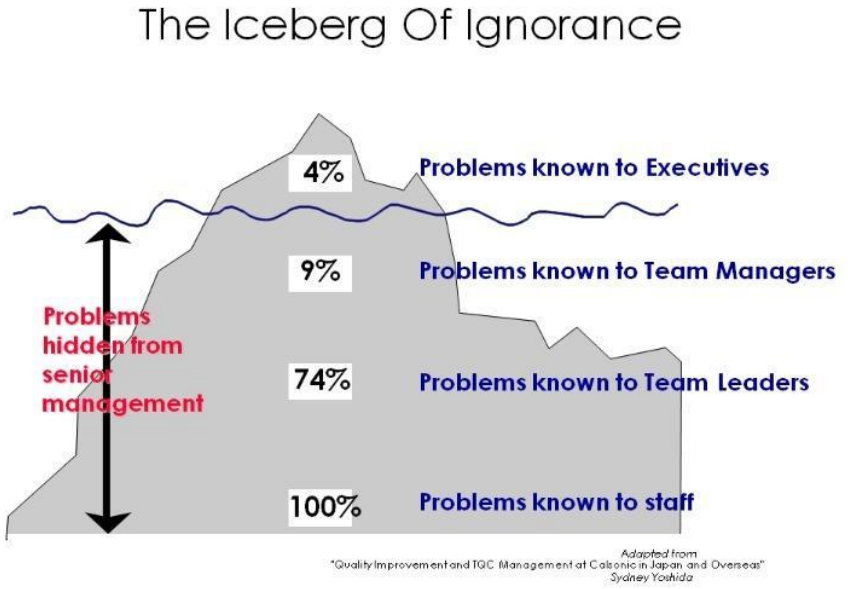
Understanding contribution

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

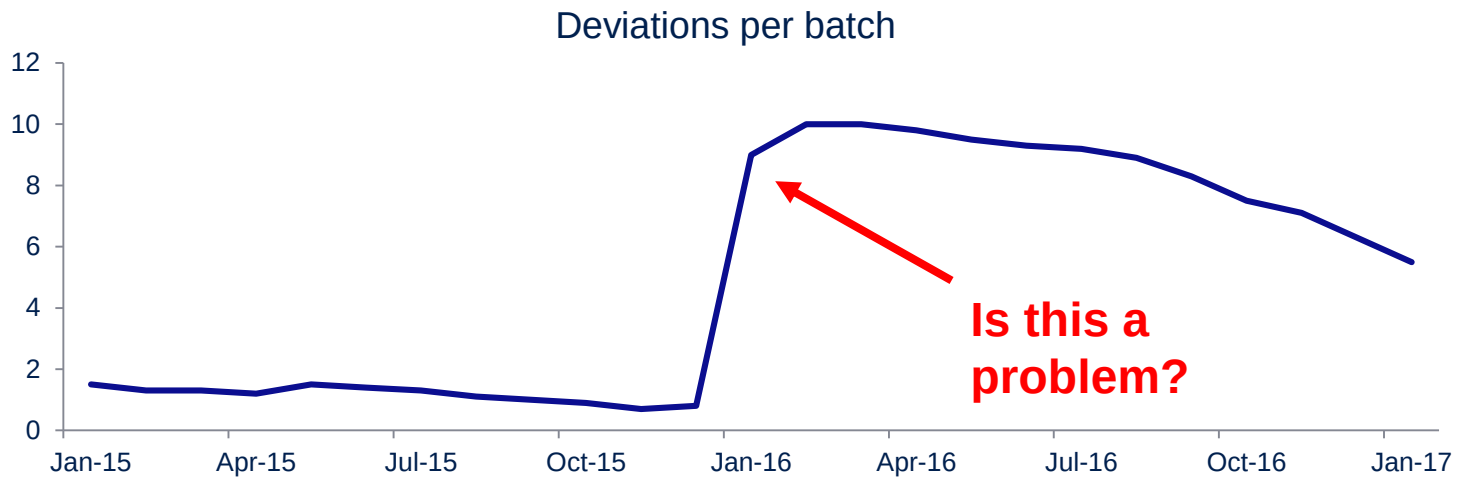
Harvard Business review October 2013.

Metrics: careful assessment

he Guardian commercial - Points Of View (360p).mp4

Metrics: careful assessment

- The need for context is paramount when interpreting metrics



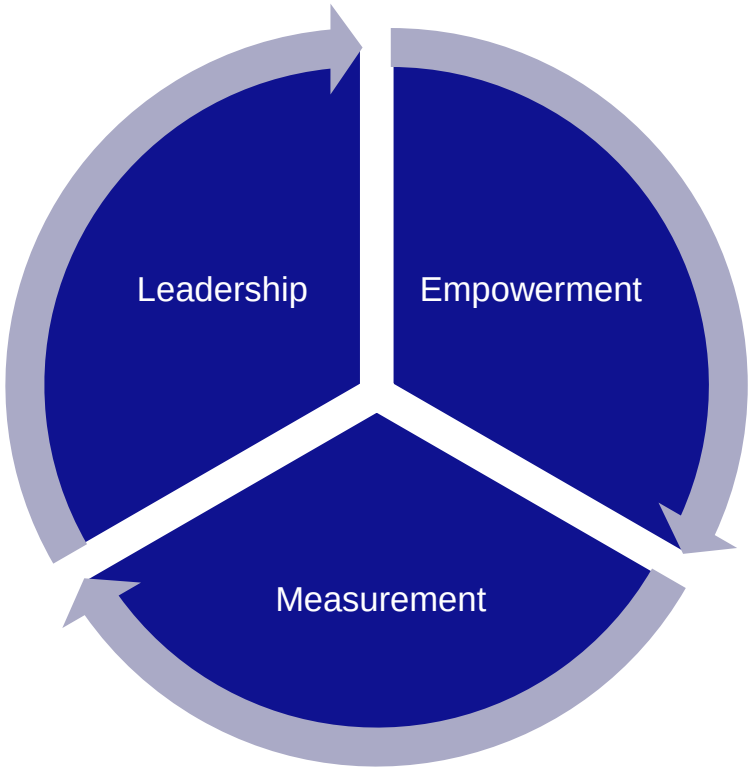
- Metrics which give context are as important as the metrics themselves
  - *Meta-metrics?*

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*

- Commitment. Knowledge. Diligence. Vigilance.

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Thank you

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