



Medicines & Healthcare products
Regulatory Agency



Building Quality Metrics

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Indicators of mature Quality Culture:

- Led from the top, empowered from below
- Communication of priorities
 - To personnel
 - To shareholders
 - To clients
 - To regulators
- Relevant monitoring
 - Critical review of what metrics are monitored, and the environment in which they are being monitored.

Metrics: careful selection



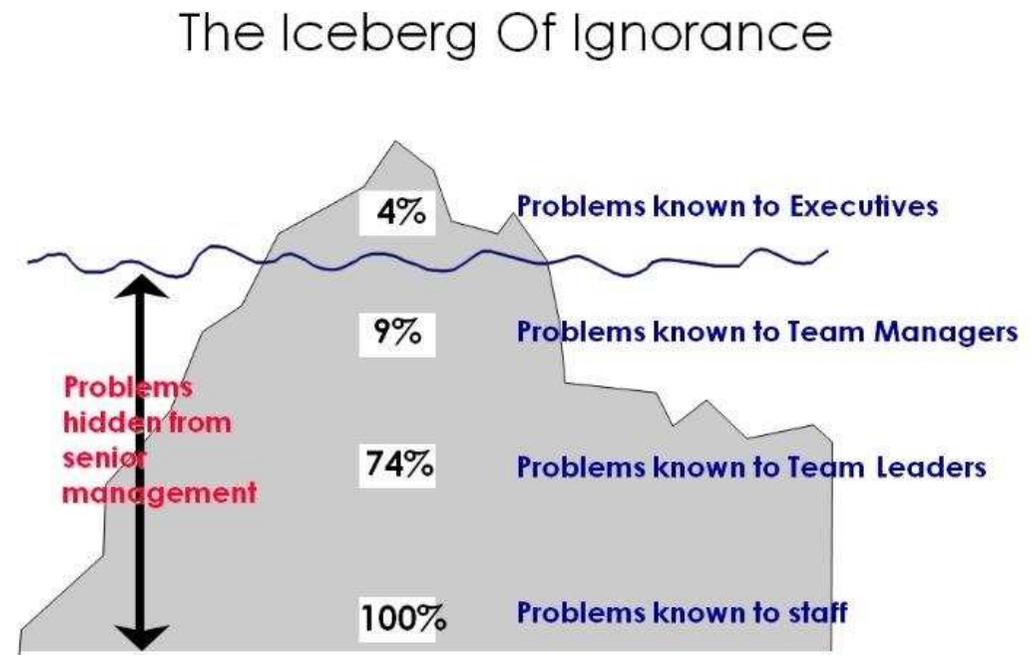
- Careful selection of metrics is required
 - What behaviours do the metrics demonstrate?
 - What behaviours do the metrics influence?
 - What is the relevance of each metric to product quality or patient safety?

“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 selection

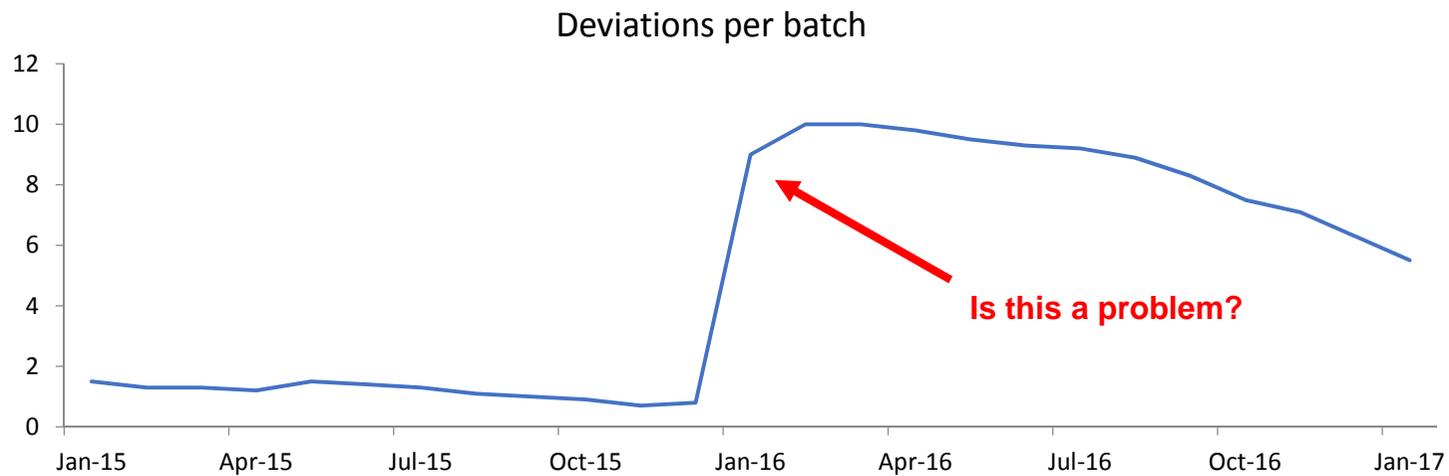
- Is the company monitoring the right things?
- NOW
- IN FUTURE



Adapted from
"Quality Improvement and TQC Management at Colsonic in Japan and Overseas"
Sydney Yoshida

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?*

The importance of context



MHRA and quality metrics

- Metrics used to augment existing regulatory processes
 - Risk-based inspection intel
 - Compliance management
 - Regulatory action
- Focus on flexible metrics based on compliance specifics
 - Behavioural and performance indicators
 - Company-derived metrics
 - Regulator-derived 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.

Summary

- Public health emergencies and regulatory action cases provide useful quality culture indicators
- Requirements of a quality culture are diverse, and may not be common in a global setting
- Importance of staff engagement and communication
- Careful selection and assessment of metrics is required to enable good decision making
 - Biggest challenge is the measurement of behaviour using compliance and processed-based metrics.

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