



Lecture 2: Quality Behavior

Martin Haerer, Ph.D., Holopack Verpackungstechnik

Quality Behaviors

How are they measured?





QUALITY MATTERS!

“Quality is the result of a carefully constructed cultural environment.

It has to be the fabric of the organization, not part of the fabric.”

Philip B. Crosby

CULTURE AND BEHAVIOR

Culture is not something you “fix”, cultural change is what you get after you put in new processes or structures in place.

Makes intuitive sense to look at culture as an outcome – not a cause or a fix.

Reworking fundamental practices will inevitably lead to some new values and behaviors.

Quality Culture

Can you quantify and measure a culture?



Is there a set of Mature Quality Attributes that are a surrogate for Quality Culture behavior?

1. Is there a relationship between Quality Culture Behavior scores and Mature Quality Attribute scores?
2. Which Mature Quality Attributes relates to Quality Culture behavior?



Can Quality Attributes be used as a proxy for Quality Culture?



Nice Hypothesis. How do you prove it?

And what are Quality Attributes?

What are Quality behaviors?

PDA launched a global study to answer this

- Draft Survey June / July 2014
- Launched Sept 4th – Oct 20th 2014
- Two surveys (Executive & Open to All Survey)
- Three Sections
 - A. Demographic (product, site, size)
 - B. Quality Culture / Behavior
 - C. Mature Quality Attributes



137 Global Responses Received from the Survey

What is a Quality Attribute?

- Quality Attributes:
 - Objective characteristics of a quality system
 - Can be verified
 - A tangible program or system
 - Can be audited
 - Often verified in regulatory inspections
- Examples include:
 - Deviations reporting
 - Change control system
 - CAPA system
 - Complaints management system
 - Environmental monitoring program

55 Quality Attributes were identified

Traditional Quality Attributes

Mature Quality Attributes

Traditional Quality Systems

Deviation, Complaints
Change Control, Disposition,
CAPA, Specifications,
Environmental Monitoring, etc.

Enhanced Quality Systems

(Q8, 9, 10, 11)
MR Programs, Risk
Management Programs,
Knowledge Management
Programs, QbD Programs,
Quality Manual, etc.

Other Systems

Quality Goals,
Rewards and Recognition
programs,
Safety Prevention Program,
Personal Development Program,
Cost of Quality, etc.

Seven Areas of Questions

1. Prevention Programs
2. Quality Management and Issue Escalation
3. Training and Personnel Development
4. Quality System Management
5. People and Communication
6. Continuous Improvement
7. Site Metric Reporting



These 7 areas identified **55** Mature Quality Attributes

What is a Quality Behavior?

- Quality behavior:
 - Action that need to be observed or experienced
 - Difficult to quantify or audit
 - Behaviors are the characteristics of the culture
- Examples include:
 - Communication & Transparency
 - Rewards and Recognition
 - Engagement
 - Cross Functional Vision

Seven Areas of Behavior Questions

1. Communication & Transparency
2. Commitment & Engagement
3. Technical Excellence
4. Standardization of Criteria or Requirements
5. Cross Functional Vision
6. Rewards and Recognition
7. Speak Up for Quality Culture

These 7 areas identify 42 specific behaviors

Behaviors, not attributes define the culture

The **behaviors** and **beliefs** are characteristic for a particular social group.
(Webster's dictionary)

Culture/values indicate what is important to the enterprise,
thus, impacts their decision making.

The importance of culture:

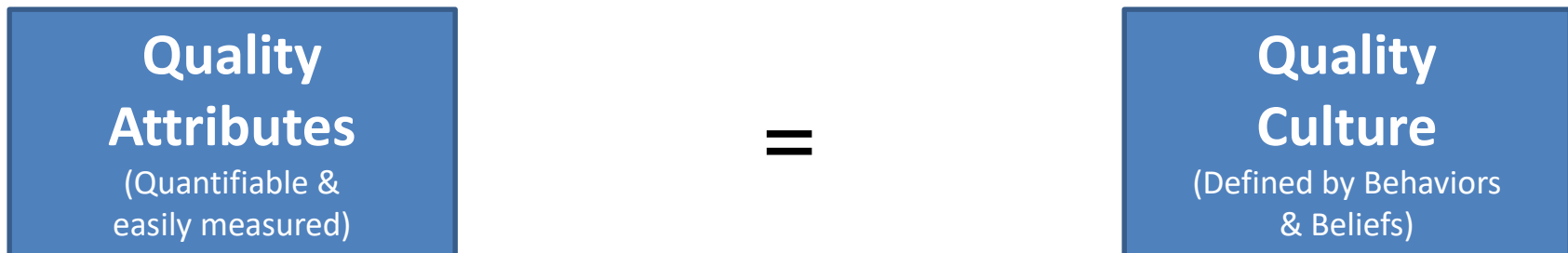
- The root cause of many of quality problems
- Essential for continuous improvement of the quality systems

Can Attributes be used as a proxy for Quality Culture?

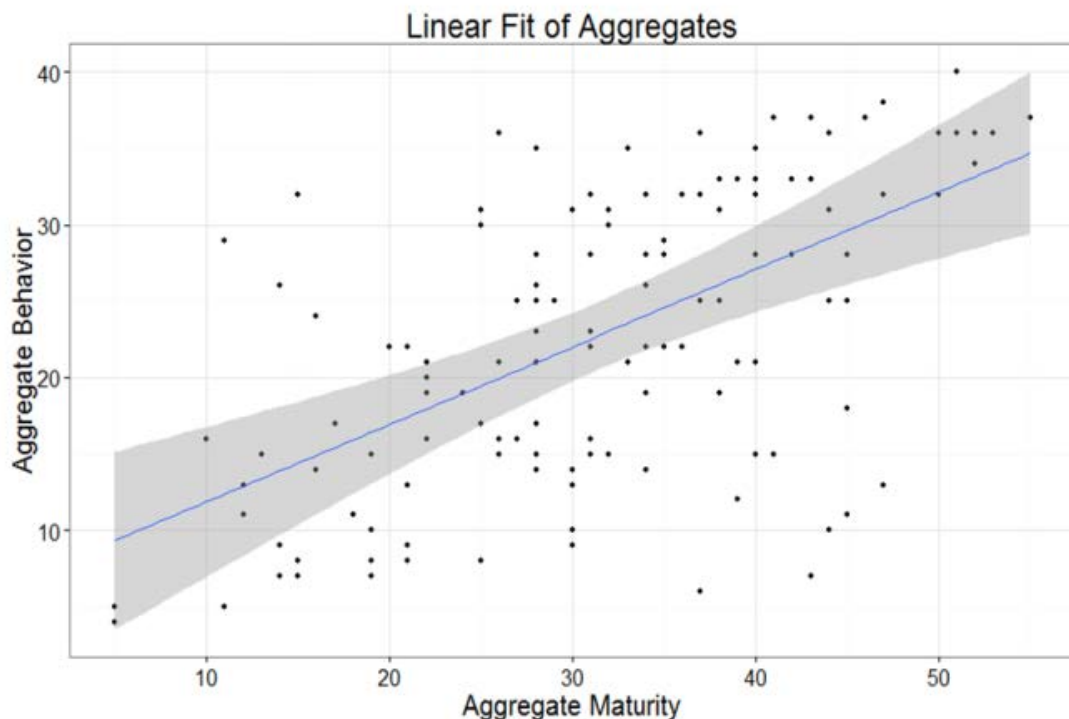
- IF....



- Then...



Strong correlation between attributes and behaviors



Sum of:

- 55 Attributes
- 42 Behaviors

Correlation

$$R^2 = 0.3378$$

Behavioral studies with R^2 value > 0.25 = large effect statistically & practically significant

Attributes are a good proxy for Quality Culture!

Quality Attributes - Quality Culture

1. Collecting Error Prevention Metrics
2. Management communication that quality is everyone's responsibility
3. Utilization of new proven technologies
4. Clear performance criteria for feedback and coaching
5. EH&S Environmental program with trained staff (risk assessments, emission controls, spill prevention and response)
6. Site has formal quality improvement objectives and targets
7. Quality topics included in at least half of "all hands" meetings
8. Collecting Management Review Metrics
9. Collecting Employee Turn Over Rate Metrics
10. Program to show how employee's specific goals contribute to overall quality goals

Investigation matrix

What's measured and what role does culture play?



Some of the signs of poor Quality Culture

- Lack of processes/systems for managing the QS
- Short term focus
- Reliance on QA department for managing the QS

Investigation Quality - Metrics

KPIs are used to:

- evaluate success of a particular activity
- measure progress toward a strategic goal
- determine that a required level of performance is being maintained
- measure or drive performance improvement

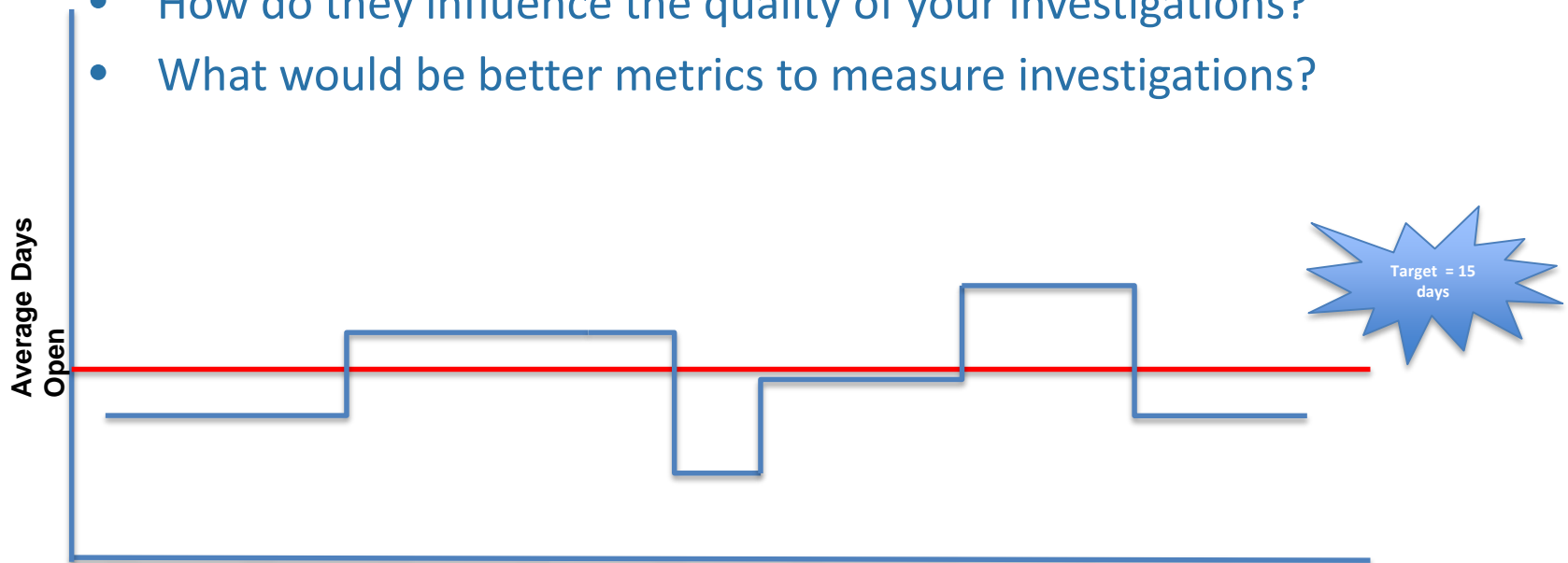


Possible Metrics

1. Number of 483 (regulatory) observations
2. Successful (passing) regulatory inspections
3. Hours of training
4. Number of completed validation reports
5. Number of SOPs
6. No documentation errors
7. Number of CAPAs completed

Investigation Quality - Metrics

- What metrics are currently used in your company?
- How do they influence the quality of your investigations?
- What would be better metrics to measure investigations?





Investigation Quality - Metrics

1. All failures, non-conformances and deviations are entered in the system (audit)
2. Number of failures, non-conformances, OOS, OOT, deviations
3. Investigations are started immediately (24 hours) and completed in a timely manner.
4. % of problems fixed permanently by corrective action
5. % of high risk CAPAs completed on time
6. % of product quality problems identified that do not reoccur
7. Effectiveness of correct action
8. All required deficiencies, after risk and root cause analysis are presented to management
9. Number of failure investigations where the cause is a non-validated process

Investigation Quality - Purpose

- Why do an investigation?
- Why are investigations important?
- Whom are they important to?
- Are all investigations equal?

