

Quality Mindset

Part 2 of 3
Complexity



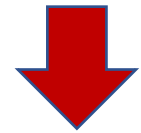


Agenda

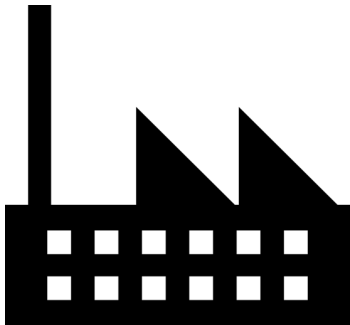
Worldviews:-
Complexity in action

World-views

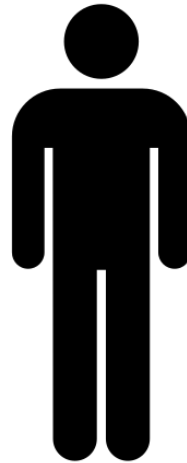
Order ←————→ Non-order



Organisations



Ourselves

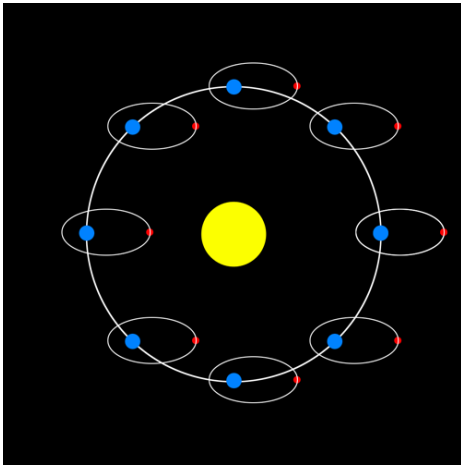


What has physics got to do with management ?

Order



Newtonian Mechanics



- ❖ Inputs – Outputs
- ❖ Forces and opposite forces



Management Science

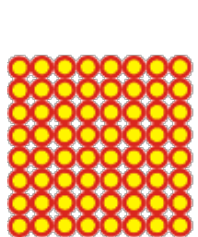
Organisations, people and processes can be treated as machines with inputs and outputs. The future can be predicted – “machine thinking.”

- ❖ KPIs
- ❖ Agency theory of management
- ❖ Standardise / Best Practice
- ❖ Performance Management
- ❖ Scorecards
- ❖ Change Plans
- ❖ Process Excellence
- ❖ Lean

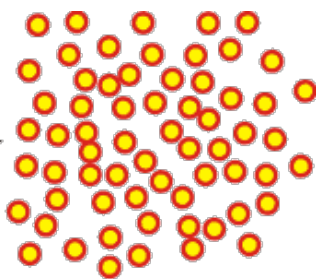
Non-order



Laws of Thermodynamics

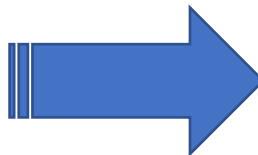


Highly Ordered
Low Entropy



High Disorder
High Entropy

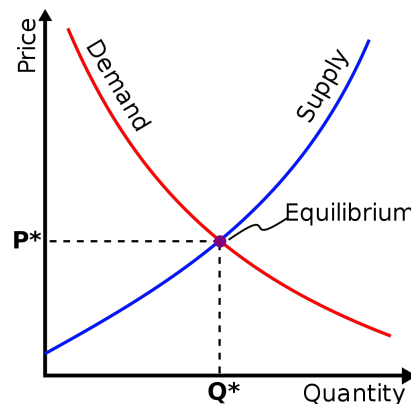
- ❖ Everything moves to equilibrium
- ❖ Entropy increases – Disorder increases



Economic theory (Neoliberalism)

Market forces are supreme.

- ❖ Invisible hand of the market ensures supply v demand.
- ❖ Trickle-down economics ensures wealth is shared.



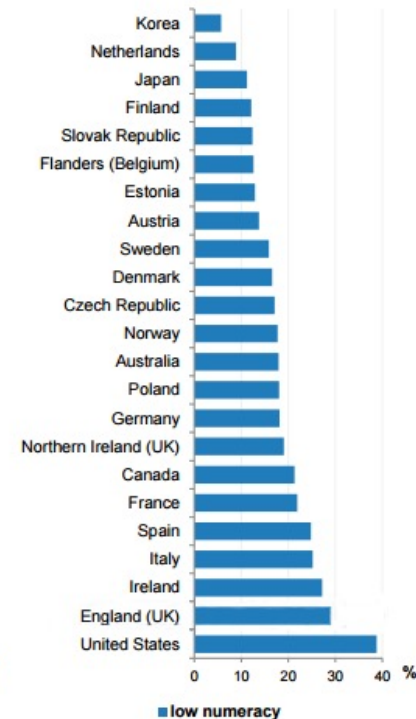
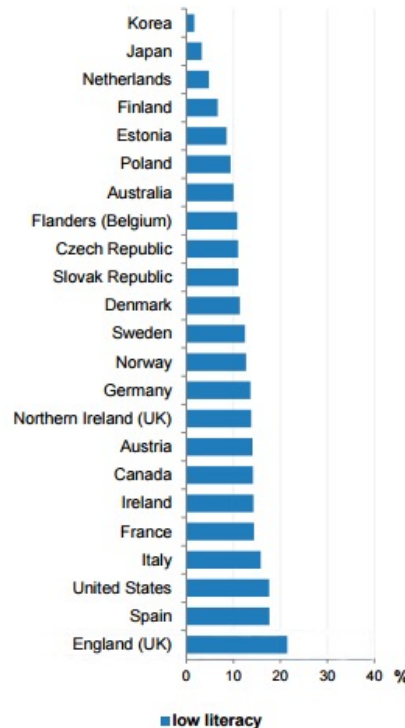
What is the success rates of both extremes of world-view thinking ?

Order (Machine thinking)



- ❖ Numeracy and literacy rates in England.
- ❖ Key target in education.
- ❖ Targets and measures do not always translate into success.
- ❖ Schools and children are not machines

Percentage of 16-19 year-olds with low literacy and numeracy (below level 2)

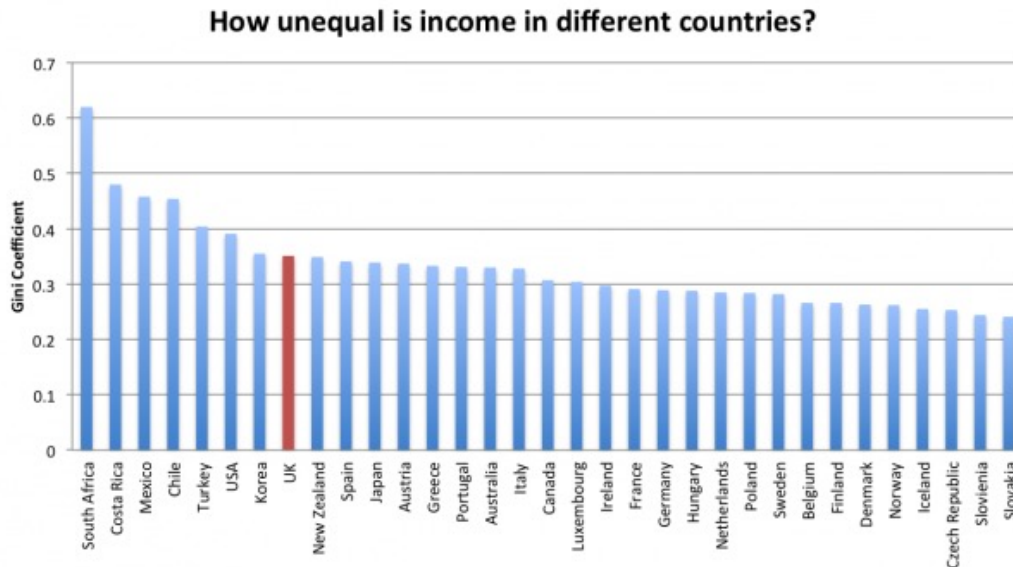


Note: Adults who obtained their highest qualification outside the host country: those with foreign qualifications and 1st generation migrants, who obtained their highest qualification prior to entering the host country, are excluded.

Source: OECD calculations based on the Survey of Adult Skills (PIAAC) (2012) (database).

What is the success rates of both extremes of world-view thinking

Disorder (Equilibrium / Market forces)



- ❖ Inequality UK 3rd worst in OECD countries.
- ❖ No evidence of trick-down of wealth.
- ❖ Top 26 billionaires own 50% of global wealth.

World-views



Complexity

The middle ground –
Not too tight but not too loose

Clear principles, but allowing local
variation

Eg: Hospice movement in U.K. World
recognised care with bespoke
solutions

Drawbacks in lean thinking

- ❑ Manufacturing approaches have not always delivered their **full** potential in healthcare organisations. *
- ❑ Organisations are complex, changing and evolving systems and **not** machines.
- ❑ Your Quality System is a complex adaptive system.
- ❑ You will need to apply **newer** thinking around how Quality Systems and organisation actually behave to **improve**.

*

Kaplan GS, Patterson SH, Ching JM, *et al* Why Lean doesn't work for everyone *BMJ Quality & Safety* 2014;**23**:970-973

Some Continuous Improvement Methodologies

Observe, Plan, Do, Check, Act: (O) PDCA:- *Observe, Plan, Do, Check, Act.* Deming Cycle.

"Observe the current situation." One of the foundations of lean.

Six Sigma / Process Excellence:- 1980/90s Motorola, GE

Focus of reducing variability and getting a process under control

DMAIC:-

Define:- Define Problem

Measure:- Measure current state

Analyse:- Experiment / Study

Improve:- Define fix

Control:- Make sure it stays fixed

Lean:- Based on Toyota Production System.

Focus on reducing waste and meeting customer expectations.

Concepts include:-

Value, Value-stream and Flow

Hugely successful over the last 25 years

Tend to see organisations / processes as machines with inputs and outputs.

Very engineering based.

Embracing complexity



Proponents of **Complexity** theory.

Ilya Prigogine – 1917-2003

Nobel laureate:- complex systems



Open systems:- new characteristics can emerge and new patterns form that are shaped by the particularities of the situation and the past

Jean Boulton

Peter Allen

Cliff Bowman

Complex Systems
Research Centre,
Cranfield University
U.K.



Complex is not the same as Complicated



A car key
is **Simple**



A car is
Complicated



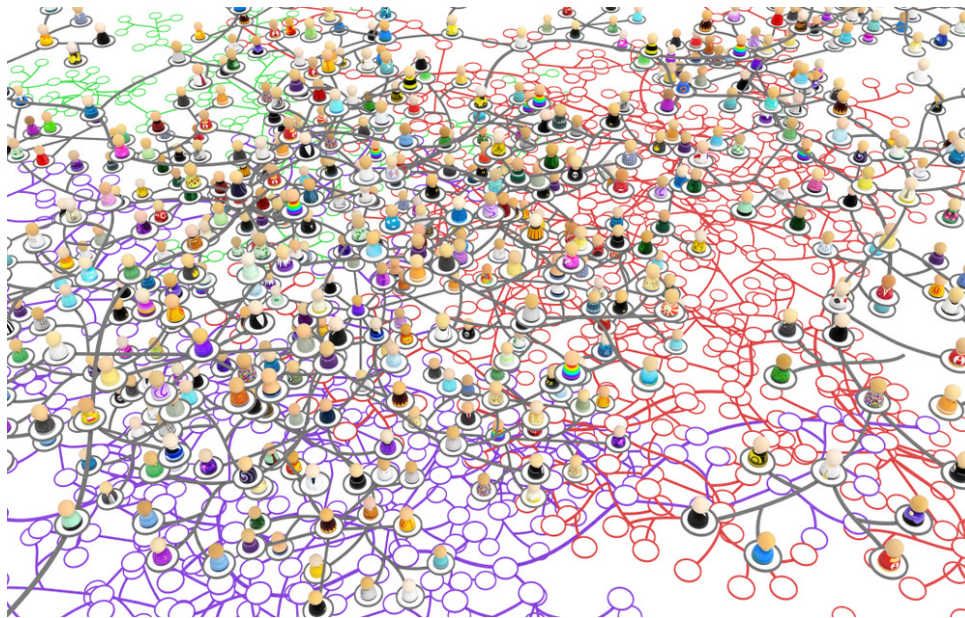
How traffic behaves
is **Complex**

Complexity isn't a theory !

It just describes and accepts how things are
at times.

Have we chosen the “wrong” science –ie:
Mechanics – to describe human systems ?

Your Quality System is at times a: Complex Adaptive System



Designing quality management systems as complex adaptive systems

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Abstract

Complex adaptive systems research adds to the theory of how to design systems that are resilient to change in turbulent environments. This paper reports a case story about using complex adaptive systems theory for designing a quality management system in a politically turbulent organization. The story explains how the quality management system evolved rapidly, exploiting the turbulence of the organization, but collapsed after six years. Through an analysis and discussion of what went wrong, three key issues are identified and explained; (1) topology of quality man-

Quality management systems from the perspective of organization of complex systems

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Abstract

The aim of this model is to analyse quality management systems from the standpoint of the organization of complex systems introduced by Robert Rosen. The concept that an organized system, under certain conditions, can be modelled as a living system introduces unsuspected tools to analyse its behaviour. The model is oriented towards the understanding of the implications of

Treat it as such

As your QMS is a **complex** system, this is the reason..

- ❑ Your non-conformances haven't reduced to zero.
- ❑ Your complaints haven't been completely eliminated.
- ❑ Your human errors haven't been eradicated.

Even after **1000s** of man-hours of investigation and effort.

Supplement your approach..

- ☐ It's not that you haven't been applying **enough** effort.
- ☐ Maybe you've been applying the **wrong** effort in the **wrong** way ?

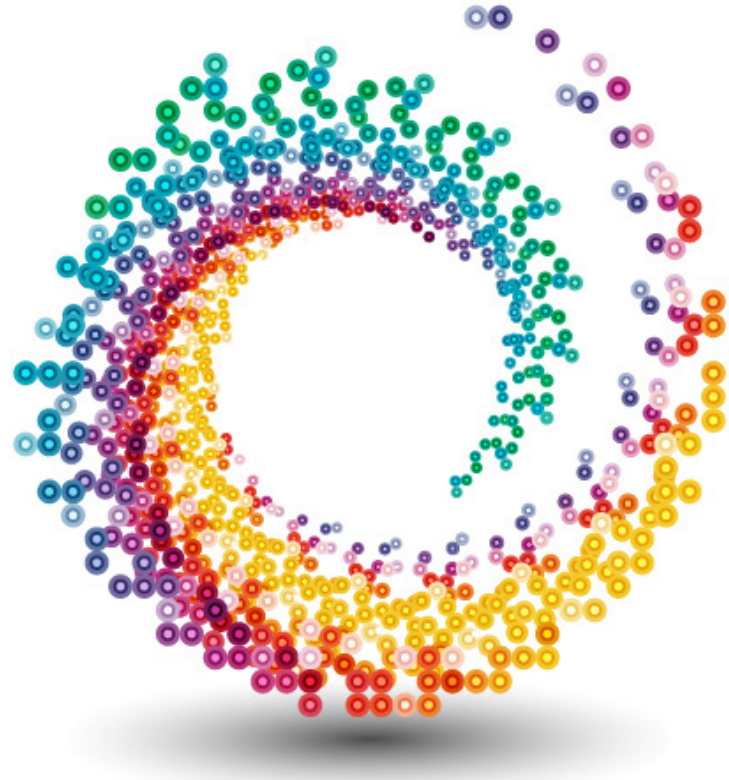
Behaviours of complex systems

- Cause and effect are confounded or have no meaning.
- The system is constantly changing and hard to predict. Even the act of measuring can change the system's behaviour.

There is no such thing as a root cause in a complex system

How **complex** systems behave....

- ☐ Systemic
- ☐ Path-dependent
- ☐ Sensitive to context
- ☐ Emergent
- ☐ Episodic





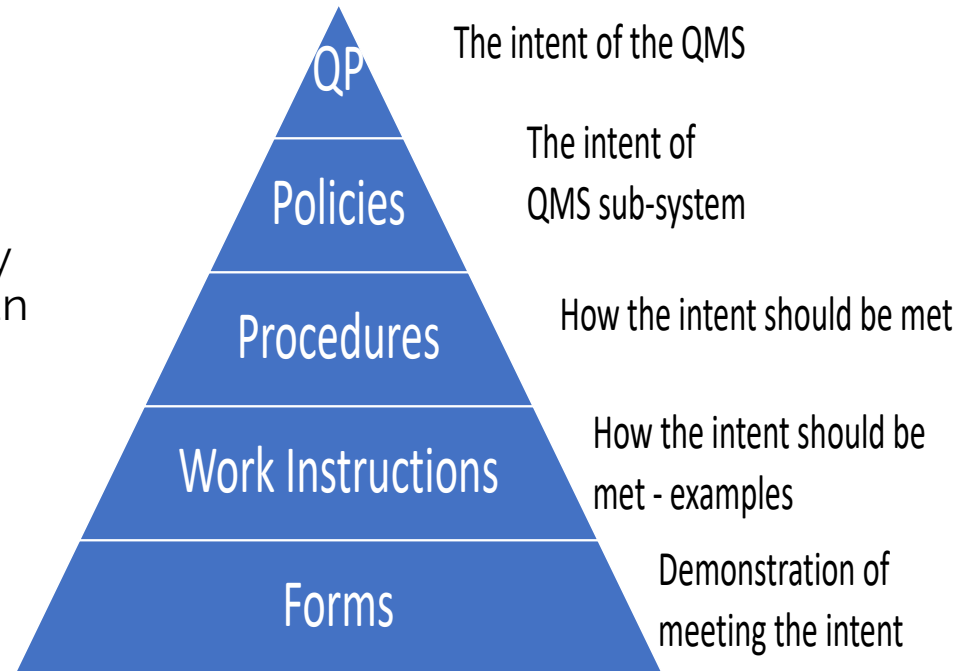
The Quality System as a Complex Adaptive System.

Systemic

- The processes within the QMS are connected. Poor design of products and manufacturing systems can result in surges in the non-conformance system post launch of a new product.
- Weak or inadequate supplier controls can result in generation of defects and audit deficiencies. Inadequate staff training can result in non-conformances, scrap and potentially customer complaints.
- Errors in documentation can have no impact, or in the case of specifications huge repercussions on the quality of products manufactured and direct impact on patient health.
- All parts of the QMS are interlinked and even small changes, or more often lack of focus in one area, can have repercussions on other parts of the system.

Scalar

- The QMS operates on many levels. This scalar nature can also be seen with documentation.



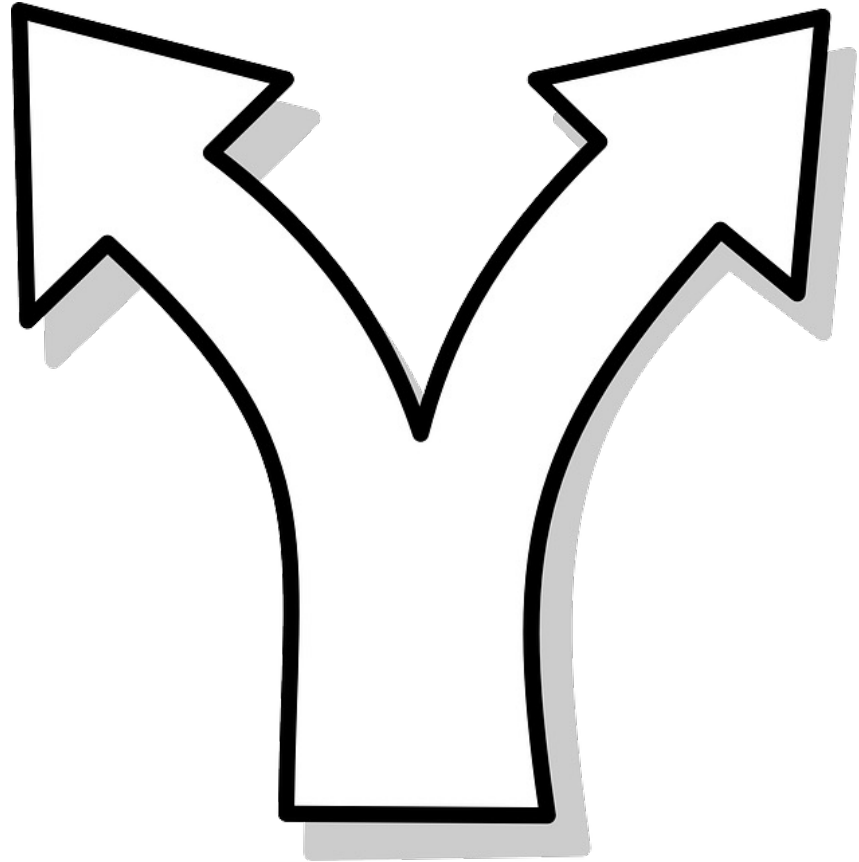


Variety, divergence and self organisation

- Complex systems exhibit variety. This does not necessarily mean this is good or bad. It just happens.
- The history of quality management within a single organisation is itself a story of evolution. If an organisation is small then a single individual may have to wear many quality hats: design, supplier, compliance, regulatory affairs.
- As the business grows - and in line with how quality management has evolved - specialisms begin to evolve – and to some extent self-organise, another feature of complex systems - each accountable for a specific area of the QMS.

Divergence... can cause a problem

- Another example of the system evolving can be seen with documentation.
- Often documentation differs in how it describes the intent or even describes another intent entirely. It often reflects how the manager thinks the process is executed, as opposed to current practice.
- This divergence between 'what is written' and 'what is really done' causes compliance issues as documentation diverges from reality.



Divergence... can create new opportunities

- Divergence can create new possibilities and support innovative approaches.

The word 'innovation' is rendered in a playful, overlapping style. The letters are in various colors: blue, pink, green, and red. The letters are arranged in a way that they appear to be layered on top of each other, creating a sense of depth and movement. The 'i' is blue, 'n' is pink, 'o' is green, 'v' is pink, 'a' is green, 't' is red, 'i' is pink, 'o' is orange, and 'n' is blue.

FUTURE

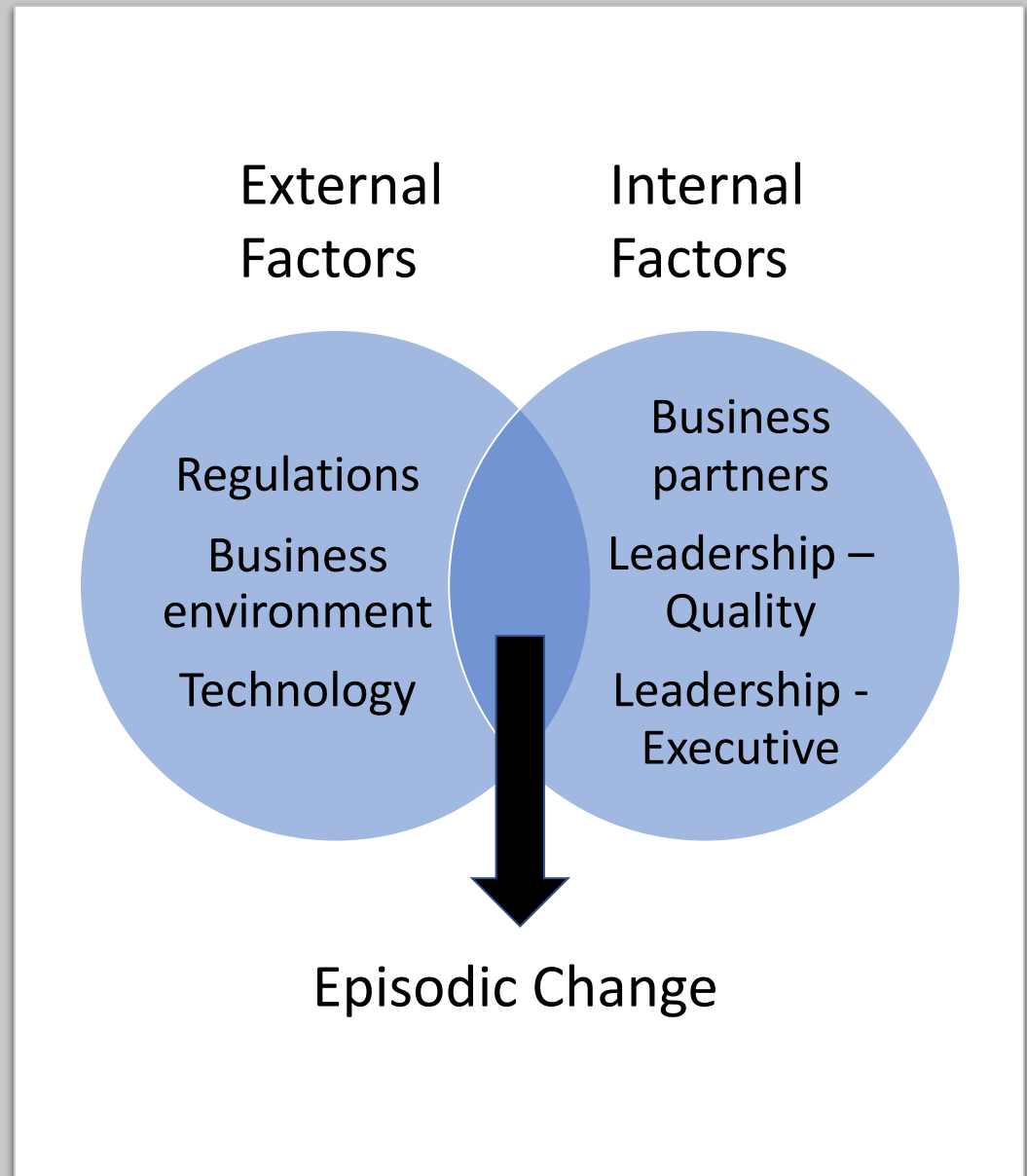


Contingency and more than one future

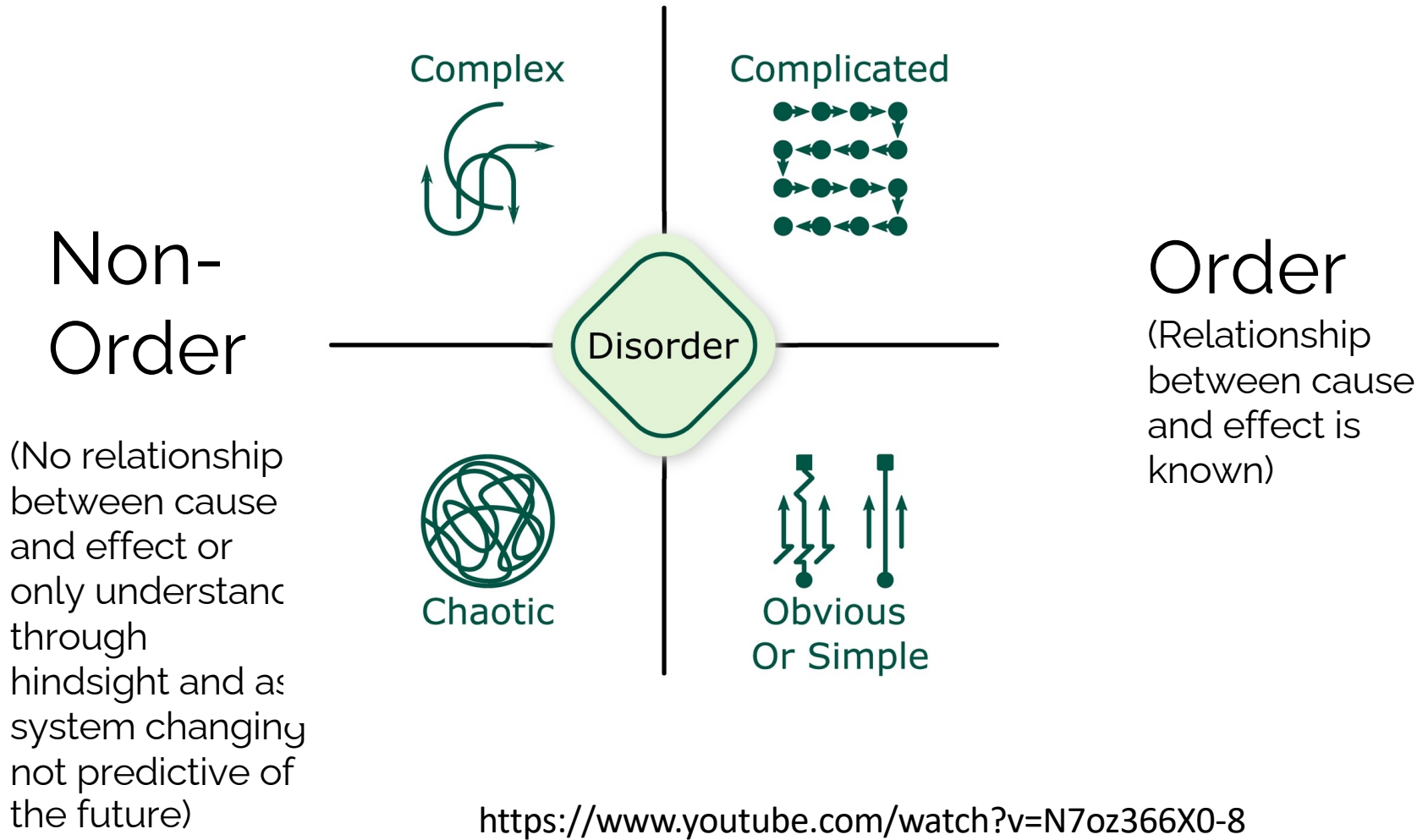
- Almost all organisations are as they are for historical reasons. The QMS is no different. At a macro -level every QMS has a history. If you examine the content of documentation often it has been shaped by the past. Islands of very specific direction sit within a sea of general guidance, the result of CAPA events bolted on to documentation and procedures.
- Without addressing this the QMS may eventually collapse under its own weight of compliance deadwood and be unable not so much to adapt, but to simply exist. The challenge is to know when to prune back and when to let grow.
- One important aspect is that you as a leader have huge influence over the direction the quality system takes and how it is viewed, executed and maintained.

Episodic change

- Change is generally a constant, but one aspect of complex systems is how they respond to external stimuli.
- They may stay relatively unchanged for long periods then go through a phase of rapid transformation as the system reaches a tipping point and the system is driven towards a new equilibrium.
- Several factors can increase the potential for this tipping point to happen.

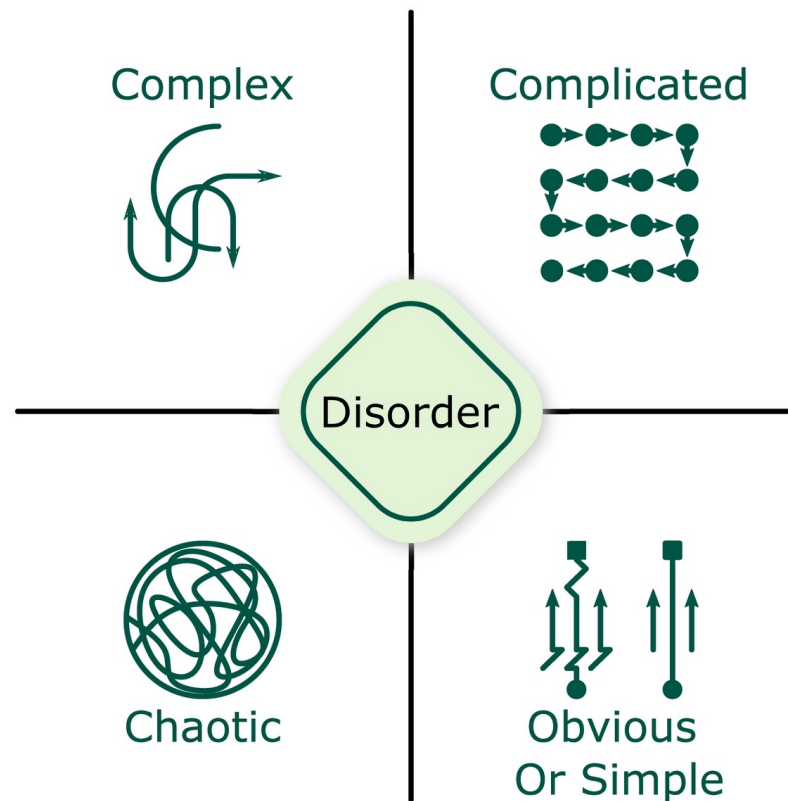


Cynefin ® Framework – Decision / sense-making framework developed by David Snowden



How does this help me in practice ?

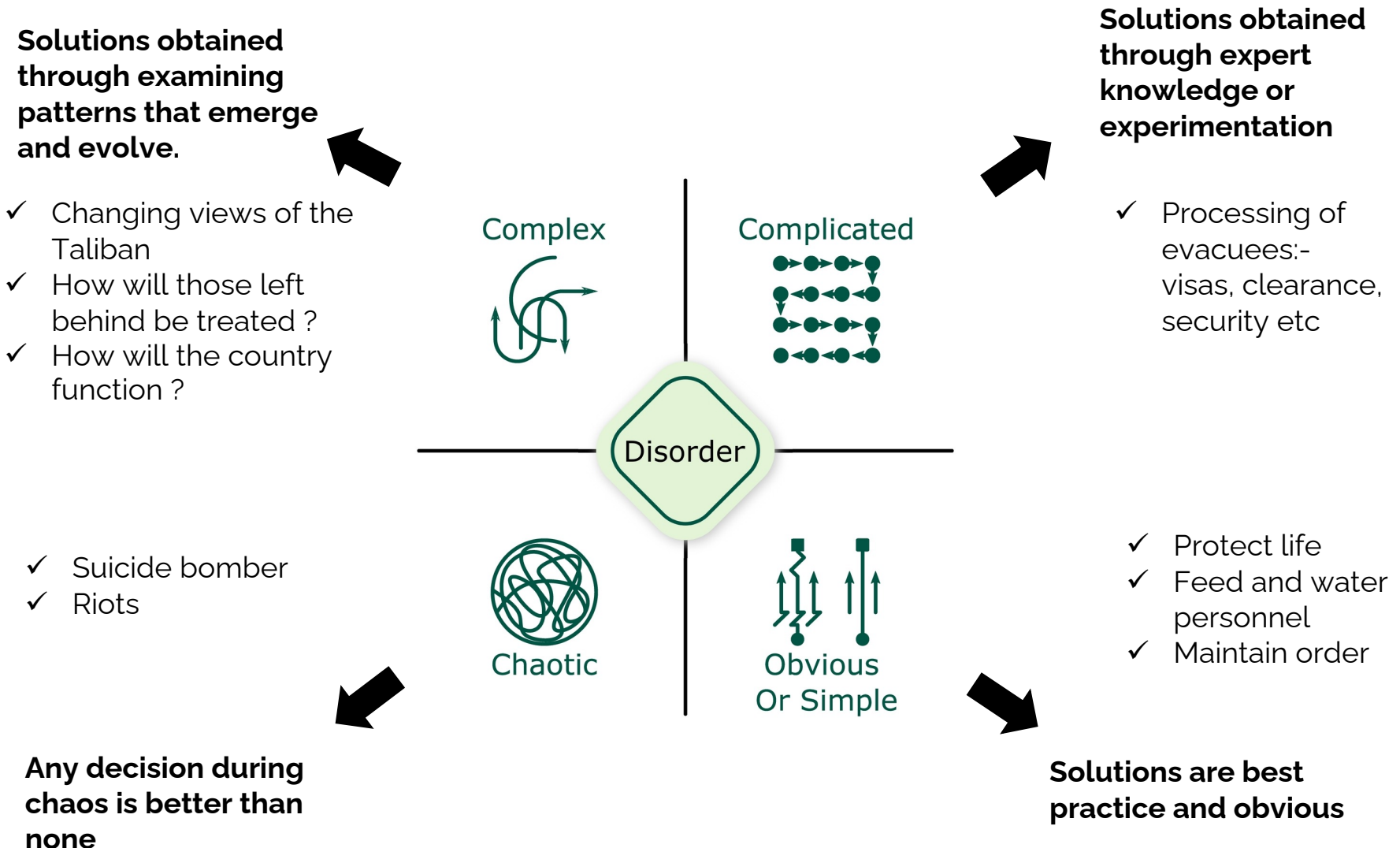
Cynefin Framework





Evacuation of Kabul Airport 2021

Evacuation of Kabul Airport 2021

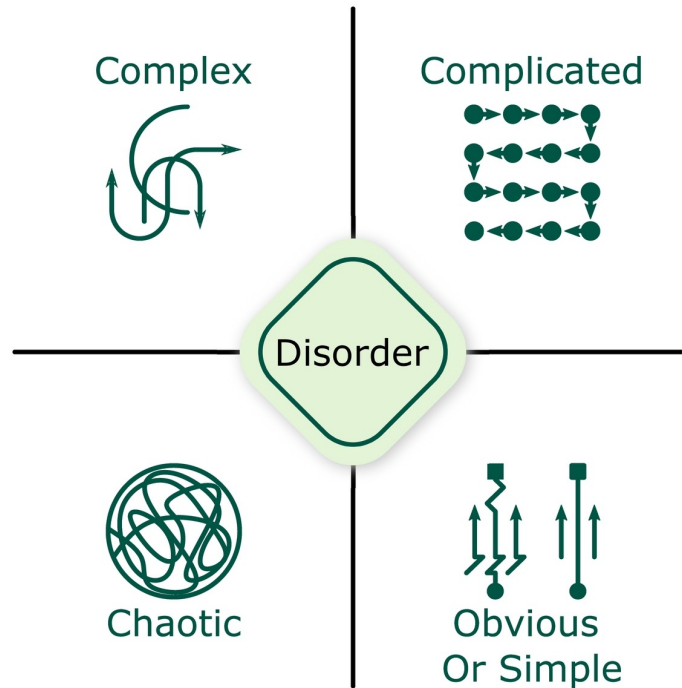


A Quality System example

Solutions obtained through examining patterns that emerge and evolve.

- ✓ What is the culture of quality ?
- ✓ What are the behaviours ?
- ✓ Who are the stakeholders of influence ?
- ✓ Flagrant breaches of GDP and GMP

Gain control



Solutions are through expert knowledge eg: Regulatory Affairs, External consultants

- ✓ IVDR / MDR compliance
- ✓ Regulatory requirements for new markets



- ✓ Reduce variability, waste
- ✓ Improve control
- ✓ Improve OTIF / LIFR



Solutions are best practice eg: lean, PEx etc

Applying the Cynefin framework makes for **better** decision making

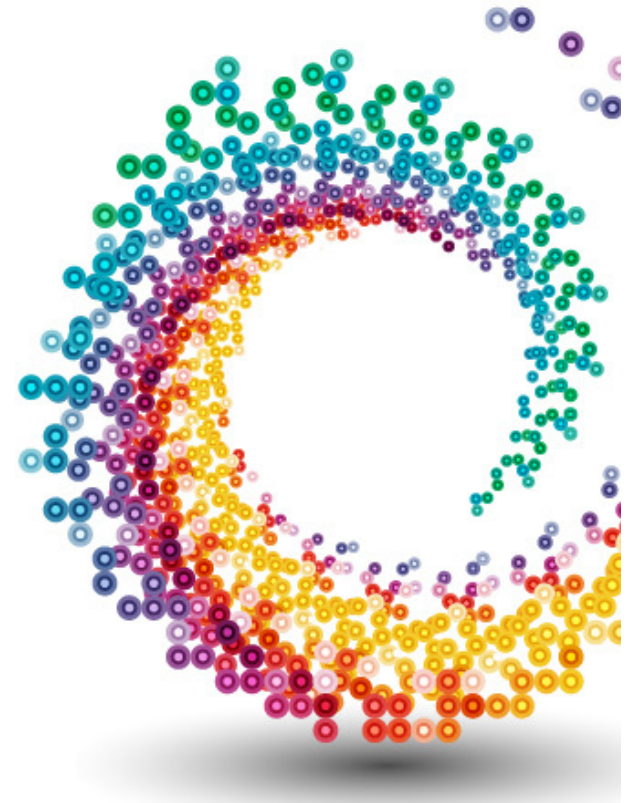
Snowden, D. and Rancati, A. (2021)
[Managing complexity \(and chaos\) in times of crisis. A field guide for decision makers inspired by the Cynefin framework,](#)
Publications Office of the European Union,
Luxembourg, 2021, ISBN 978-92-76-28843-5, JRC123629.



Approaches for dealing with the QMS as a CAS

Treating the QMS as a complex adaptive system - or by extension the Quality organization itself - for it to be truly successful you must exploit four key aspects. You need the ability to:

- Balance Innovation and Control
- Manage Risk
- Model Appropriate Leadership
- Continually Pursue Improvement



Balancing Innovation and Control



Balancing Innovation and Control

- Increased control generally comes at a resource cost. Hard wiring aspects of the QMS, for example through electronic systems involves a cost which must be balanced against the benefit. Standardization for standardization's sake, especially across a business enterprise, may feel the purest approach, but is often not adding value for the customer.
- In the eyes of the FDA, noncompliance with internal procedures indicates a weak or even nonfunctioning QMS, which equates in their eyes to noncompliance with federal law. Overly prescriptive or complex procedures become rich pickings for external auditors. Organizations can quickly struggle to comply with their own self-imposed and sometimes contradictory documentation. Clear, simple, and not overly prescriptive procedures are generally best. If the procedure is prescriptive, then the business will need to provide resources to comply with them. Again, control comes at a cost.



Managing Risk

Managing risk involves dealing with probability and uncertainty.

Complex system do not always obey normal distributions and predicted levels of confidence.



Model appropriate leadership

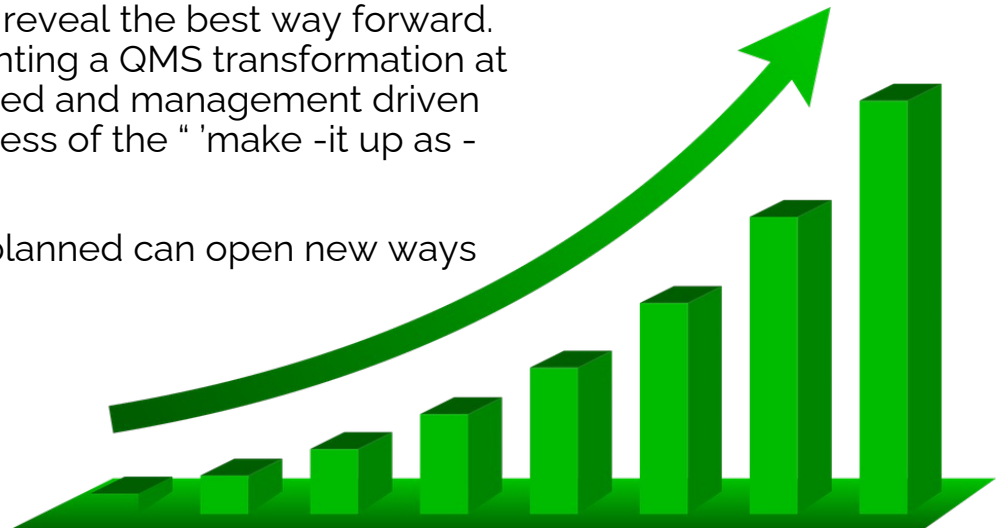
- With respect to the QMS, the quality system is more than a combination of its parts. This does have consequences for where you see the QMS residing; from a philosophical point of view i.e., ownership is collective rather than residing within the Quality function or owned by the VP of Quality.
- For an effective QMS, the responsibility for quality should be shared. This needs to be actively explained to the organization. All individuals have a direct responsibility for quality and the quality system is not a system owned and executed solely by the Quality organization.
- A servant leadership style often fits best with your need to ensure the QMS and the Quality organization serves the needs of its different customer groups.



Continually pursue improvement

- Despite its complex behavior, the quality system is not some nebulous entity that is impossible to change, and we should give up. Quite the opposite, improvements can be made. Learning a new language or skill requires practice and success generally builds more success. Improving the QMS is no different.
- Successes should form the foundation for further advances, but these returns must be cultivated. They do not happen without planning, effort, and action to reinforce advances made. An organization that sees continual improvement as an essential and ongoing activity is better placed than one that is wrapped up in the specific methodology in how this can be achieved.
- Sometimes a planned approach does not reveal the best way forward. Øglund noted his puzzlement in implementing a QMS transformation at “the apparent failure of the highly structured and management driven development method” and the rapid success of the “ ‘make -it up as - you go along’ approach”
- Sometimes approaches that were never planned can open new ways of thinking.

More of this in the next module



Summary

The world can operate at multiple levels, often simultaneously. Being able to recognize these and responding appropriately is the key to success. At times Quality needs to take a step back, at other times observe or experiment to understand. Certain situations require Quality to enforce control.

- As a complex adaptive system, a quality system can be unpredictable and changing. The comfort blanket of cause-and-effect may not be available.
- Understand the system by observation.
- Be able to differentiate the clear, complicated, complex and the chaotic.
- Make your decision making contingent on the presentation of events.
- Deciding not to act can still be the correct decision.
- Use the customer as your reference point for decision making.