27th annual INCOSE international symposium

Adelaide, Australia

July 15 - 20, 2017

Planes, trains and endoscopes

www.incose.org/symp2017

Planes, trains and endoscopes

Meaghan O'Neil, System Design and Strategy.
INCOSE liaison with AAMI.

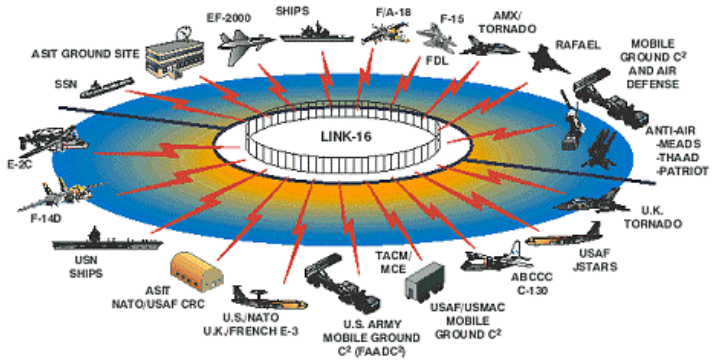
Duncan Kemp, CEng, FIET. UK MOD
Author of INCOSE UK Capability SE guide.

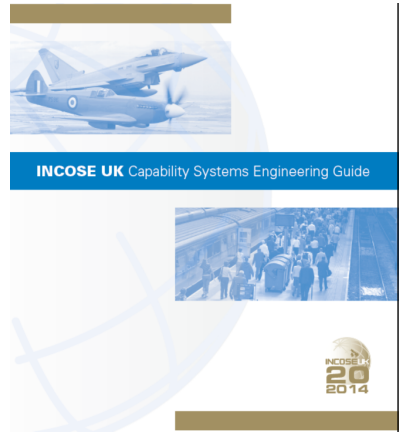
Presentation overview

- Background to Capability SE
- Healthcare acquired infections
- Understanding the problem
- Designing a solution
- Implementation planning
- Conclusions and recommendations

Background to Capability SE

Hitchins 5 layers of System
5 : Socio-economic
4: Industry wide
3: Business
2: Product/project
1: Sub-system

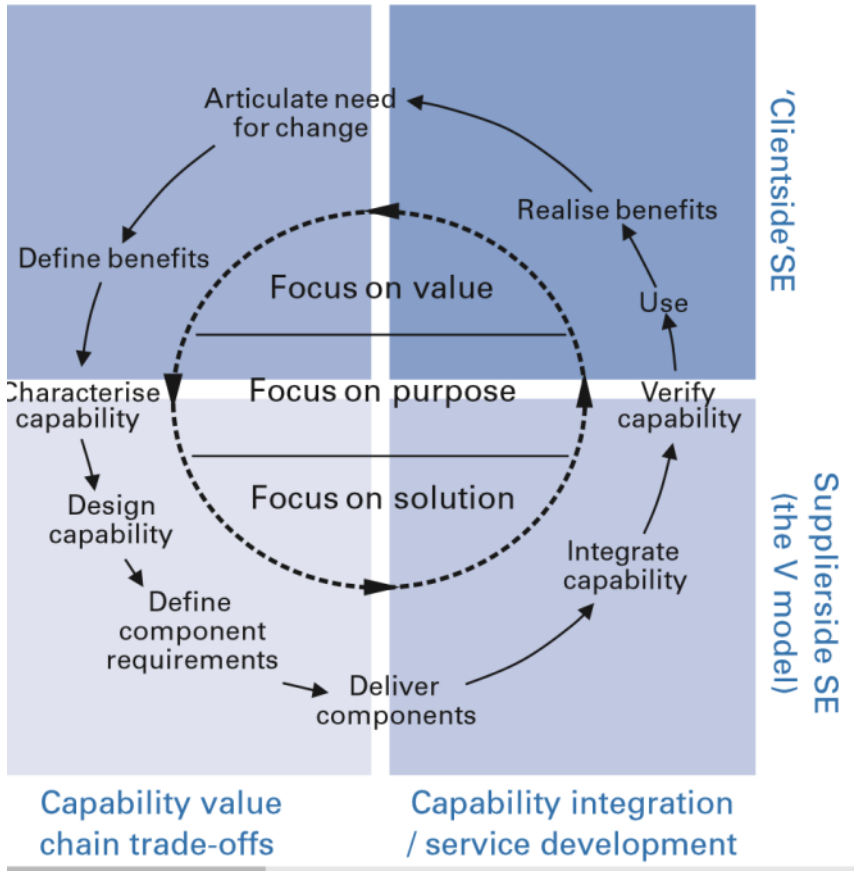




Are healthcare systems capabilities?

Characteristics of a capability:	Healthcare delivery capability characteristics:
"[Capabilities] are concerned with delivering outcomes (effects), rather than outputs (performance), a rail system moves a certain number of people, at an agreed level of safety and journey time, in order to deliver wider economic benefits.	Healthcare systems should be concerned with patient outcomes (i.e. producing healthy patients) more than number of operations to provide health benefits to society.
[Capabilities] are enduring. Today's UK Air Defence System can trace its roots back to the first World War. At no point was it replaced; rather, it evolved as elements within it changed.	Healthcare systems are enduring. Even a hospital with the most modern buildings will be using custom and practice stretching back over a century.
[Capabilities] have people in them, making them both less predictable, but more flexible than purely technological systems. During the Battle of Britain, the RAF 11 Group and 12 Group used the same equipment, but with a different operational concept, and significantly different results.	Healthcare is, fundamentally a people business. People are core to both service delivery and are also the recipients of the service. This creates significant levels of variability, variety, volume and visibility (Slack, Chambers, Johnson, & Betts, 2006).
Capabilities are often Complex Adaptive Systems. Passenger behavior changes as they use a transport capability, which in turn changes the effectiveness of the transport capability. In defense, the enemy is actively trying to subvert and disrupt the capability	Healthcare systems are complex adaptive systems (Snowden and Boone). A range of feedback loops is limiting the effectiveness of healthcare. For example, increased use of antibiotics leads to increased antibiotic resistance, which reduces the effectiveness of antibiotic drugs (World Health Organization, 2016).
Some elements are used on a daily basis, others rarely. In general, military systems are rarely used, and civil systems used on a daily basis. However there are exceptions – the UK Air Defence System is always on, and [backup train] timetables are rarely used.	Inpatient hospitals care for patients around the clock. The hospital HVAC systems are an integral part of the infrastructure and are typically always on to ensure air filtration and to maintain positive or negative air pressure as needed. In the event of a disruption, a contingency plan is recommended. These may include backup generators, not typically used in normal operation (CDC, 2003).

So what is Capability SE?



Based on

- The INCOSE UK Capability Systems Engineering Guide
- ISO 55000: Asset management -- Overview, principles and terminology
- Managing Successful Programmes
- Through Life Capability Management
- Checkland's Soft Systems Methodology
- System Dynamics and System Archetypes
- Kotter's work on organisational change

Healthcare acquired infections

First, do no harm

"When patients enter a hospital, they reasonably assume that their treatments will make them better, or, at the least, not make them worse." Dr. Lucian Leape MD

3 Risks to Patients:

1) Disease
2) Diagnosis & treatment plan
3) Implementation of plan

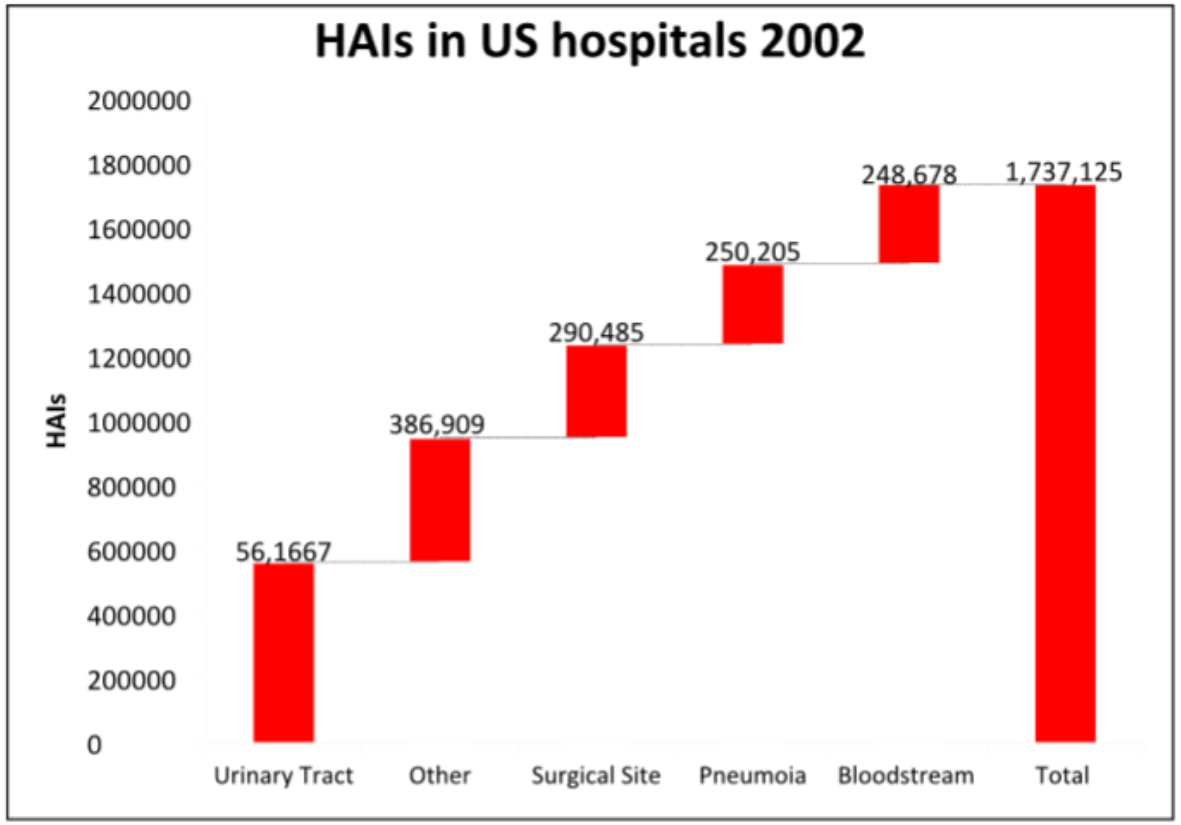
(Dekker, 2011)

Magnitude of the Problem

1:25 hospitalized patients acquire an HAI

1.7 Million HAI's occurred in 2012

99,000 Patients died of HAI



Source: 2011, CDC http://www.cdc.gov/hai/surveillance/

Operational Context

Case Study Example: Endoscopes

1

Patient A

Patient A with endogenous drug resistant bacteria) undergoes an endoscopy

2

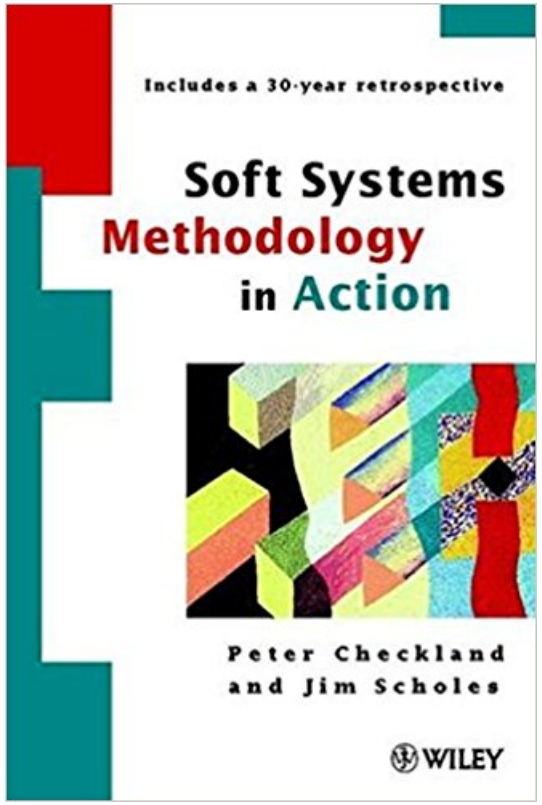
Following the first procedure, the endoscope is reprocessed. Reprocessing fails to remove the infectious agent and is returned to service

3

Patient B

An endoscopy is preformed on patient B using the contaminated endoscope, and patient B is infected resulting in an HAI

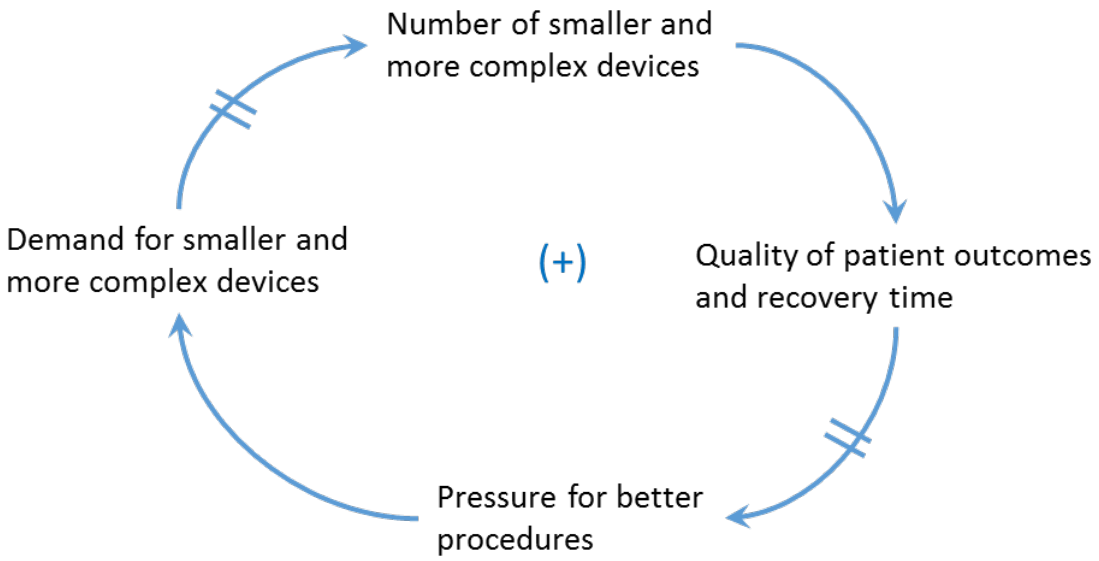
Understanding the problem



Initial SSM analysis of worldviews

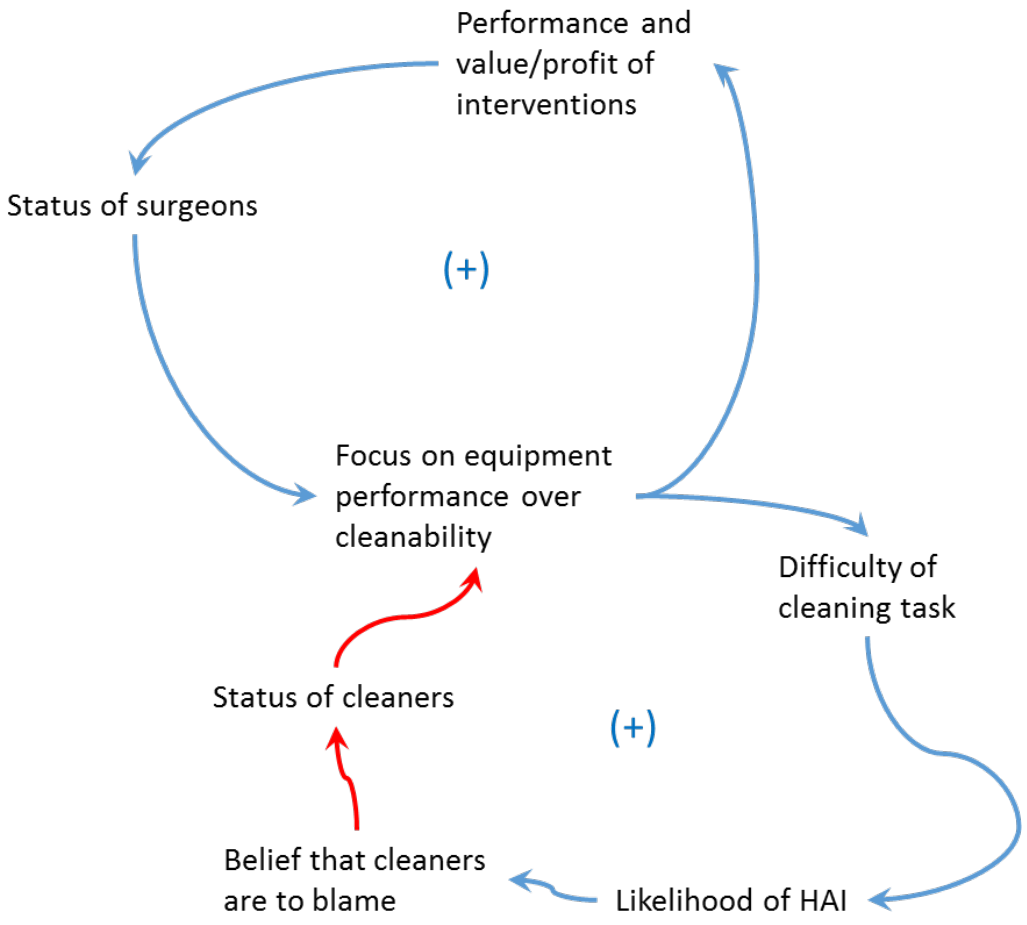
1. Healthcare Providers are seeking to deliver better and safer interventions
2. Focus on performance not cleanability
3. Healthcare Providers are responsible for the initial cleaning
4. Manufacturers are seeking to meet the demand for smaller and more complex devices that can be sold for high prices
5. Devices regulators (such as the U.S. FDA) are seeking to protect the public and help ensure the products are safe.
6. Reprocessing centers are seeking to clean the devices sent to them

Healthcare Providers are seeking to deliver better and safer interventions



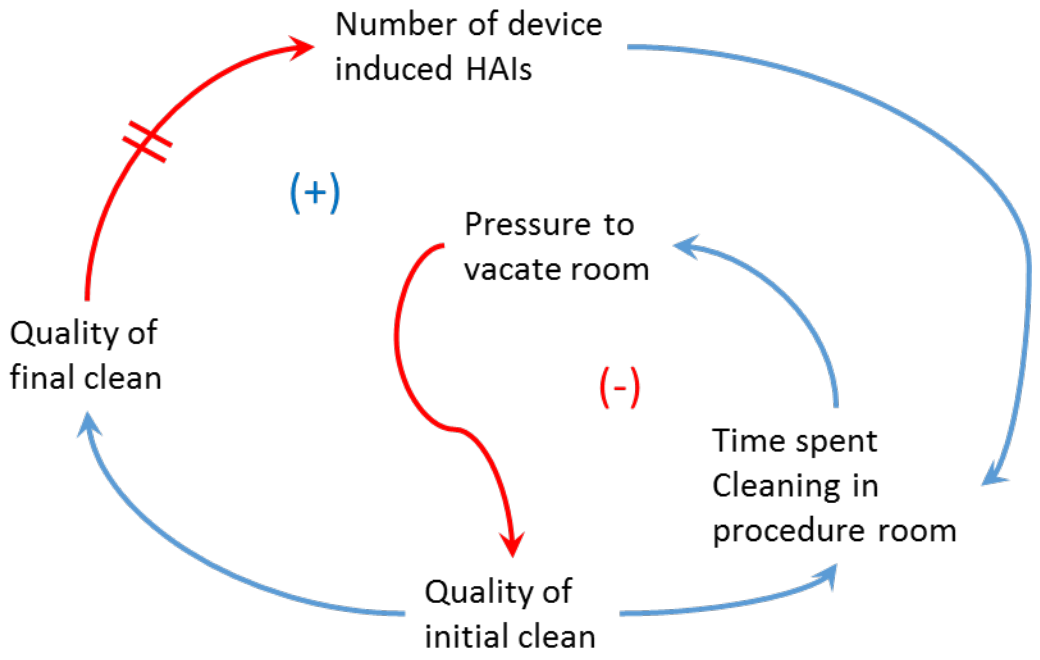
- Healthcare process effectiveness driven by
  - Smaller devices (less intrusive surgery)
  - Extra features (complexity)
- Device manufacturers, the public and healthcare providers see this as a virtuous cycle

Focus on performance not cleanability



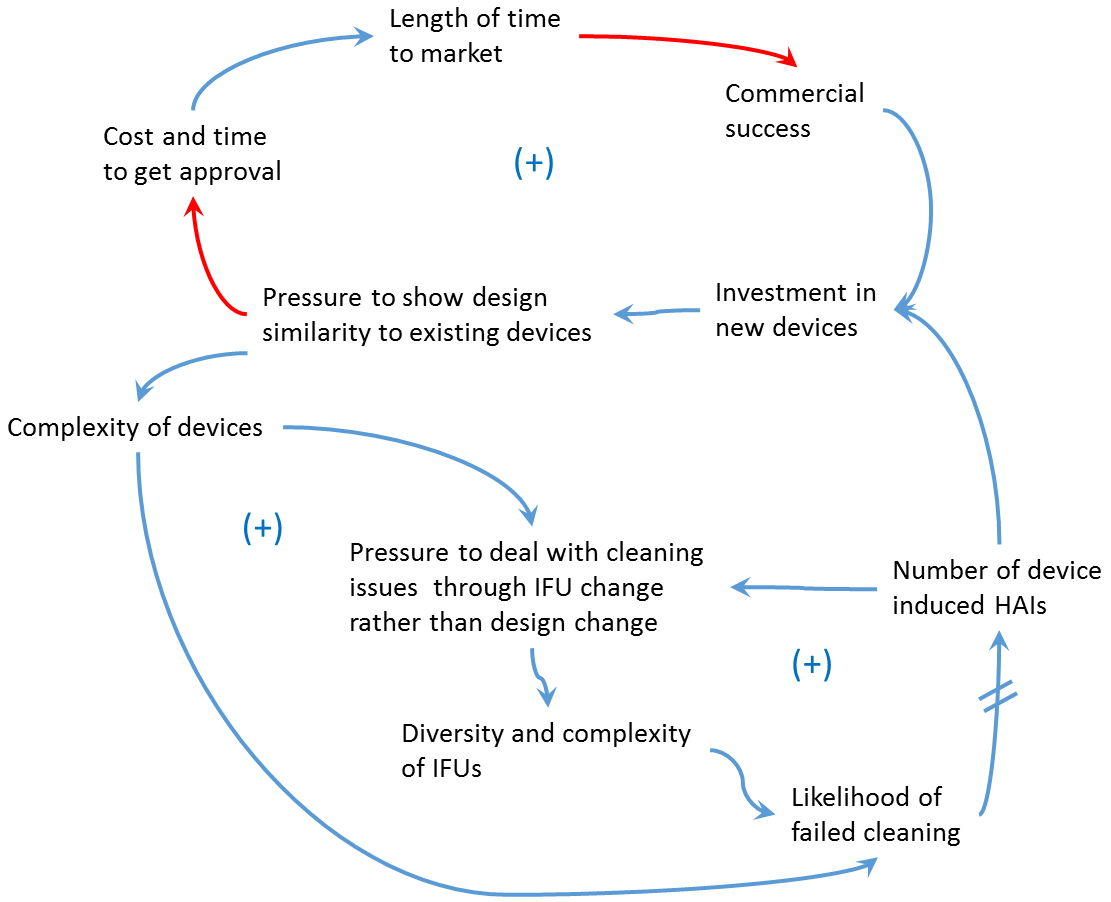
- Success to the successful archetype
- Two cycles are in conflict
- The top one dominates as
  - It operates faster
  - It aligns with the high power distance between cleaners and surgeons
- This is analogous to the situation in 1970s-1980s western defence equipment – where reliability came second best to performance

Initial cleaning and operating room occupancy



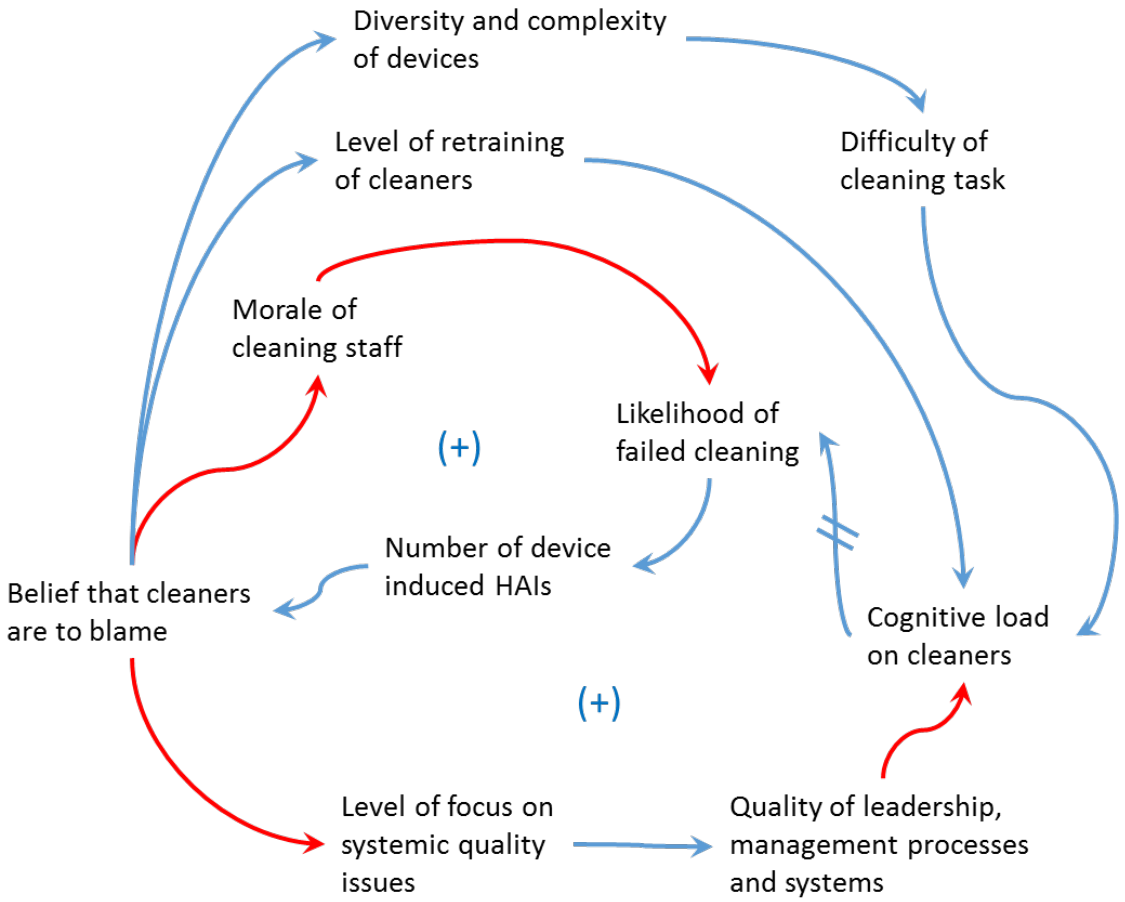
- Accidental advisories archetype
- A poor initial clean can make it nearly impossible to do a good quality final clean
- However the pressure is to optimise throughput in the procedure room
- This leads to poor initial cleans, poor final cleans and an increase in HAIs

Regulation, complexity and diversity



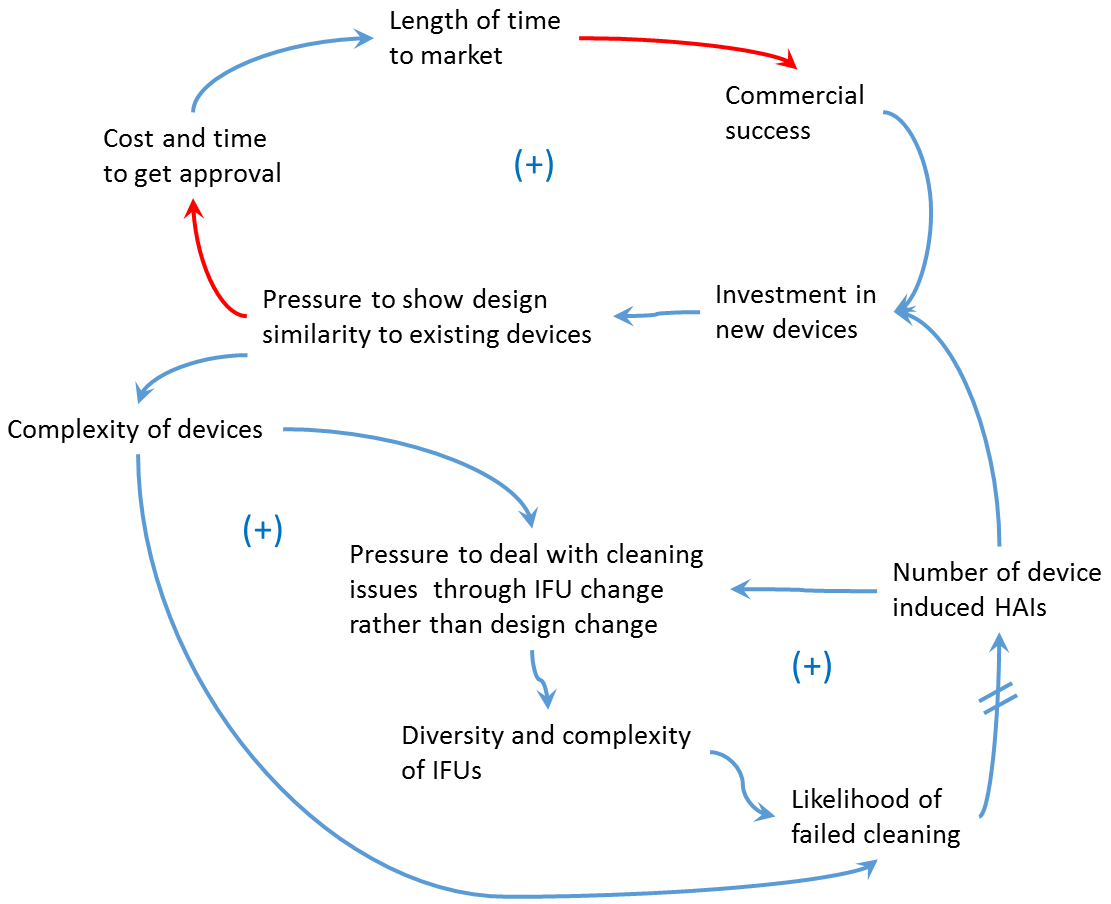
- Manufacturers want to get devices to market as quickly as possible
- Modifications to an approved product are easier to approve
- This leads to overly complex designs – as design simplifications can require new approval
- The simplest way of dealing with safety concerns is a new ‘instruction for use’
- This diversity and complexity increases the risk of HAI, which in turn drives up diversity of IFUs and investment in new devices

Leadership, blame and systemic issues



- Three mutually reinforcing cycles are at work
- The belief that cleaners are to blame increases diversity (previous slide) and retraining, increasing the cognative load on cleaners and increasing the likelihood of failure
- The belief that cleaners are at fault, reduces morale, increases the likelihood of failure and reinforces the belief that cleaners are at fault
- Finally the focus on junior staff, rather than structure and process, reduces the focus on the systemic causes

Design approach



- Looking at the 'regulation, complexity and diversity' dynamic, need to weaken the two reinforcing cycles
- This will work if we base reprocessing approach upon a small number of standard approaches
- This is done by a range of changes
  - Changing hospitals procurement preferences
  - Changing regulatory approval incentives
- Looking at all of the dynamics identifies two basic changes
  - Standard reprocessing approaches across multiple devices
  - Introducing a closed loop, 'just culture' for reprocessing

Designing a solution (1)

Required behavior We will base the reprocessing approach upon a small number of well-known standard approaches	
Culture • If we believe that a small number of standard reprocessing approaches is better than a large number • If we believe it is better to compete on product cost and functionality and collaborate on improving product safety • If we believe that complicated, non-standard, reprocessing approaches are unlikely to be followed, leading to increased infections and deaths • If we believe that cleanability is as important as functionality, performance and cost of the design	Knowledge and information • If we know the standard approaches for reprocessing • If we know the hazards introduced by cleaning and how to manage them out • If we understand the mental models of the reprocessing workers • If we understand how reprocessing is actually done • If we get regular and high-fidelity feedback from the reprocessing workers
Structures and incentives • If we know hospitals will procure equipment's using standard reprocessing approaches in preference to non-standard approaches • If getting regulatory approval incentives, the use of standard reprocessing approaches • If getting regulatory approval becomes progressively harder the more different from standard approaches we are proposing • If it is cheaper and faster to develop a product using standard reprocessing approaches than not	Systems and Processes • If hospital acquisition approaches are standard and incorporate the required incentives (possibly through a B2B purchasing portal) • If we can provide reprocessing information through a standard IT format

Designing a solution (2)

Required behavior We will create a just and closed loop reprocessing culture	
Culture • If we believe reprocessing is a fundamental enabler to achieving successful outcomes • If we believe reprocessing is a part of the hospital that is important and valued • If we believe that reducing unnecessary variation and reliance on memory will lead to better outcomes • If we believe that systemic problems need to be addressed to reduce HAI's rather than continuing to rely on training • If everyone values and respects reprocessing technicians as a core part of the care team	Knowledge and information • If we make devices easily recognized during the reprocessing process • If we make the IFUs easy to follow and accessible during reprocessing • If we know the hazards introduced by cleaning and how to manage them out • If we understand the mental models of the reprocessing workers • If we understand how reprocessing is actually done • If we get regular and high-fidelity feedback from the reprocessing workers • If everyone understands their role in ensuring proper reprocessing happens
Structures and incentives • If hospitals procure devices using standard reprocessing approaches in preference to non-standard approaches • If we incentivize reprocessing effectiveness over pure throughput • If we incentivize appropriate levels of training and certification • If everyone is incentivized to ensure that devices are effectively reprocessed • If reprocessing workers, and their employers, are incentivized to ensure that they are Suitably Qualified and Experienced to undertake their task	Systems and Processes • If hospital acquisition approaches are standard and incorporate the required incentives (possibly through a B2B purchasing portal) • If we can provide reprocessing information through a standard IT format • If we can provide systems for identifying medical devices and a corresponding IFU job aid • If standardized training and certification for reprocessing is available • If we can track device induced HAIs back to the poor cleaning that caused them

Draft implementation plan

Build and deepen guiding coalition
- Identify and align coalition of concerned AAMI, RAE, INCOSE and others
- Work with government, healthcare and device regulators and healthcare providers globally

Develop compelling case
- Capture stories, evidence and comparisons
- Develop rich media – White papers, academic papers, YouTube, TED, …

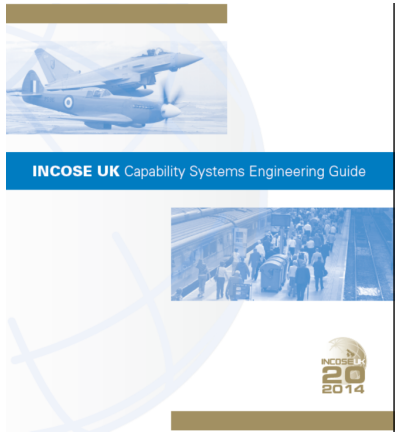
Communicate, learn and deepen case
- Identify, train and support ambassadors
- Deepen stories, evidence and comparisons
- Capture successes and learn from experience
- Develop rich media – White papers, academic papers, YouTube, TED, …
- Align AAMI, RAE, INCOSE and other work
- Change mainstream media narrative

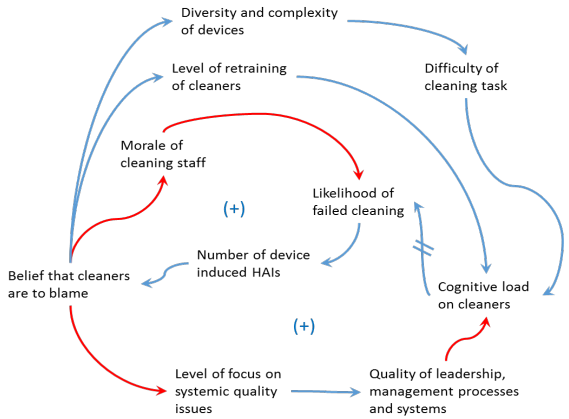
Improving device ease of reprocessing
- Define standard reprocessing methods
- Modify regulation processes and communicate changes
- Develop industry standard device purchasing processes, tools and models
- Industry wide communication and training programme in 'design for cleanability
- Develop qualifications/certifications In design for cleanability
- Measure and monitor performance and adjust approach as necessary

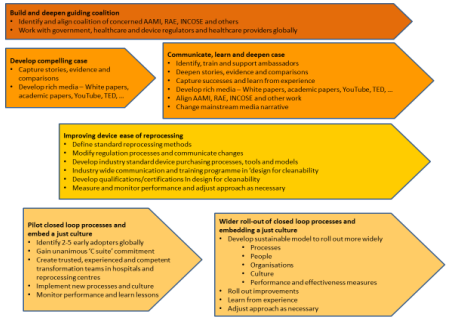
Pilot closed loop processes and embed a just culture
- Identify 2-5 early adopters globally
- Gain unanimous 'C suite' commitment
- Create trusted, experienced and competent transformation teams in hospitals and reprocessing centres
- Implement new processes and culture
- Monitor performance and learn lessons

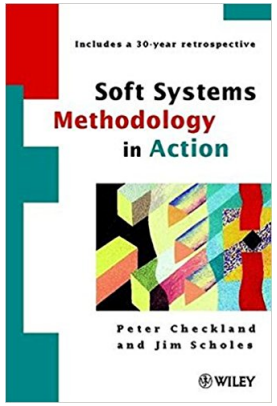
Wider roll-out of closed loop processes and embedding a just culture
- Develop sustainable model to roll out more widely
  - Processes
  - People
  - Organisations
  - Culture
  - Performance and effectiveness measures
- Roll out improvements
- Learn from experience
- Adjust approach as necessary

Summary and conclusions









Required behavior We will create a just and closed loop reprocessing culture	
Culture • If we believe reprocessing is a fundamental enabler to achieving successful outcomes • If we believe reprocessing is a part of the hospital that is important and valued • If we believe that reducing unnecessary variation and reliance on memory will lead to better outcomes • If we believe that systemic problems need to be addressed to reduce HAI's rather than continuing to rely on training • If everyone values and respects reprocessing technicians as a core part of the care team	Knowledge and information • If we make devices easily recognized during the reprocessing process • If we make the IFUs easy to follow and accessible during reprocessing • If we know the hazards introduced by cleaning and how to manage them out • If we understand the mental models of the reprocessing workers • If we understand how reprocessing is actually done • If we get regular and high-fidelity feedback from the reprocessing workers • If everyone understands their role in ensuring proper reprocessing happens
Structures and incentives • If hospitals procure devices using standard reprocessing approaches in preference to non-standard approaches • If we incentivize reprocessing effectiveness over pure throughput • If we incentivize appropriate levels of training and certification • If everyone is incentivized to ensure that devices are effectively reprocessed • If reprocessing workers, and their employers, are incentivized to ensure that they are Suitably Qualified and Experienced to undertake their task	Systems and Processes • If hospital acquisition approaches are standard and incorporate the required incentives (possibly through a B2B purchasing portal) • If we can provide reprocessing information through a standard IT format • If we can provide systems for identifying medical devices and a corresponding IFU job aid • If standardized training and certification for reprocessing is available • If we can track device induced HAIs back to the poor cleaning that caused them

- Hospitals are operational capabilities – and amenable to Capability SE approaches
- HAIs are complex problems – shown how Capability SE can help resolve these issues
- This has the potential to significantly reduce HAIs