ERASMUS+ KA2 Strategic Partnership
2017-1-FI01-KA203-034721
HELP – Healthcare Logistics Education and Learning Pathway

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Concepts in Risk & Safety

By air mail

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HELP presentation - 2020

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Overview

Historic Overview

- Changing nature of risk
- Timeline

Traditional Risk Analysis Methods

- Some methods explained

Emerging Safety Paradigms:

-Systems & complexity thinking

- Safety-II

- Resilience Engineering

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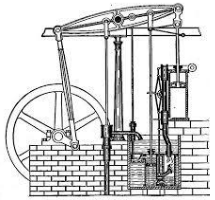
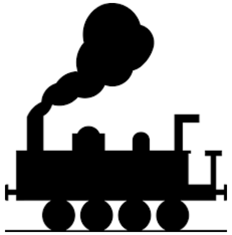
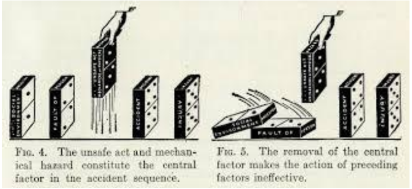
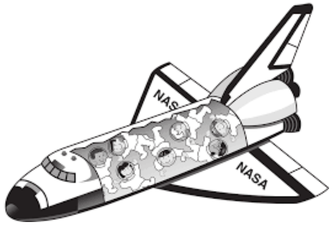
Ages of Safety









Safety Management

Age of Human Factors

Age of Technology

1800 — 1980 — 2000

Single Root Cause Accidents

- 1769 Industrial Revolution
- 1893 Railroad Safety Act (1st safety legislation)
- 1931 Industrial Accident Prevention (First safety science theory by Heinrich)

Socio-Technical Accidents

- 1979 Three Mile Island
- 1984 Bophal Leak
- 1986 NASA Challenger Crash
- 1987 Herald of Free Enterprise
- 2003 NASA Columbia Crash
- 2011 Fukushima

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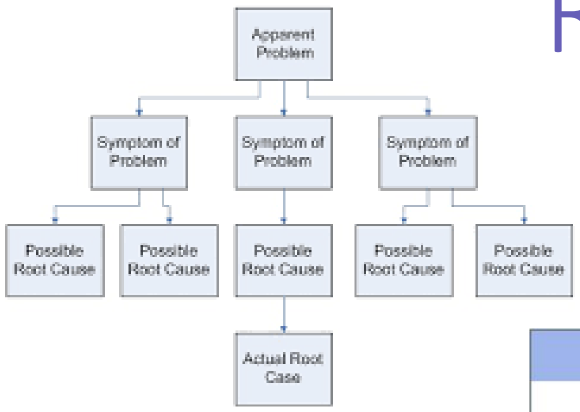
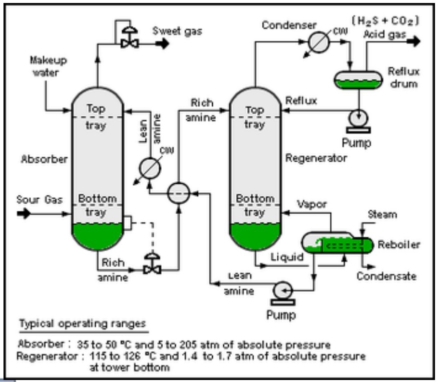
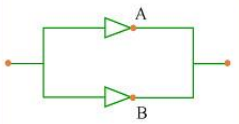
Risk Methods





FMEA FOR A SYSTEM OF TWO AMPLIFIERS IN PARALLEL



Critical	Failure probability	Failure mode	Failures by mode (%)	Effects: Critical	Effects: Noncritical
A	1×10^{-3}	Open	90		x
		Short	5	5×10^{-5}	
		Other	5	5×10^{-5}	
B	1×10^{-3}	Open	90		x
		Short	5	5×10^{-5}	
		Other	5	5×10^{-5}	

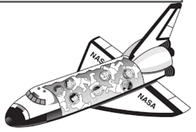
Probability	Probability and Impact Matrix								
0.9	0.09	0.18	0.27	0.36	0.45	0.54	0.63	0.72	0.81
0.8	0.08	0.16	0.24	0.32	0.4	0.48	0.56	0.64	0.72
0.7	0.07	0.14	0.21	0.28	0.35	0.42	0.49	0.56	0.63
0.6	0.06	0.12	0.18	0.24	0.3	0.36	0.42	0.48	0.54
0.5	0.05	0.1	0.15	0.2	0.25	0.3	0.35	0.4	0.45
0.4	0.04	0.08	0.12	0.16	0.2	0.24	0.28	0.32	0.36
0.3	0.03	0.06	0.09	0.12	0.15	0.18	0.21	0.24	0.27
0.2	0.02	0.04	0.06	0.08	0.1	0.12	0.14	0.16	0.18
0.1	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
Impact	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9

< 1945
First Root Cause models
RCA

1949
Failure Mode and Effect Analysis
FMEA

1960
Hazard and Operability Study
HAZOP

1980s
Probabilistic Risk Assessment
PRA



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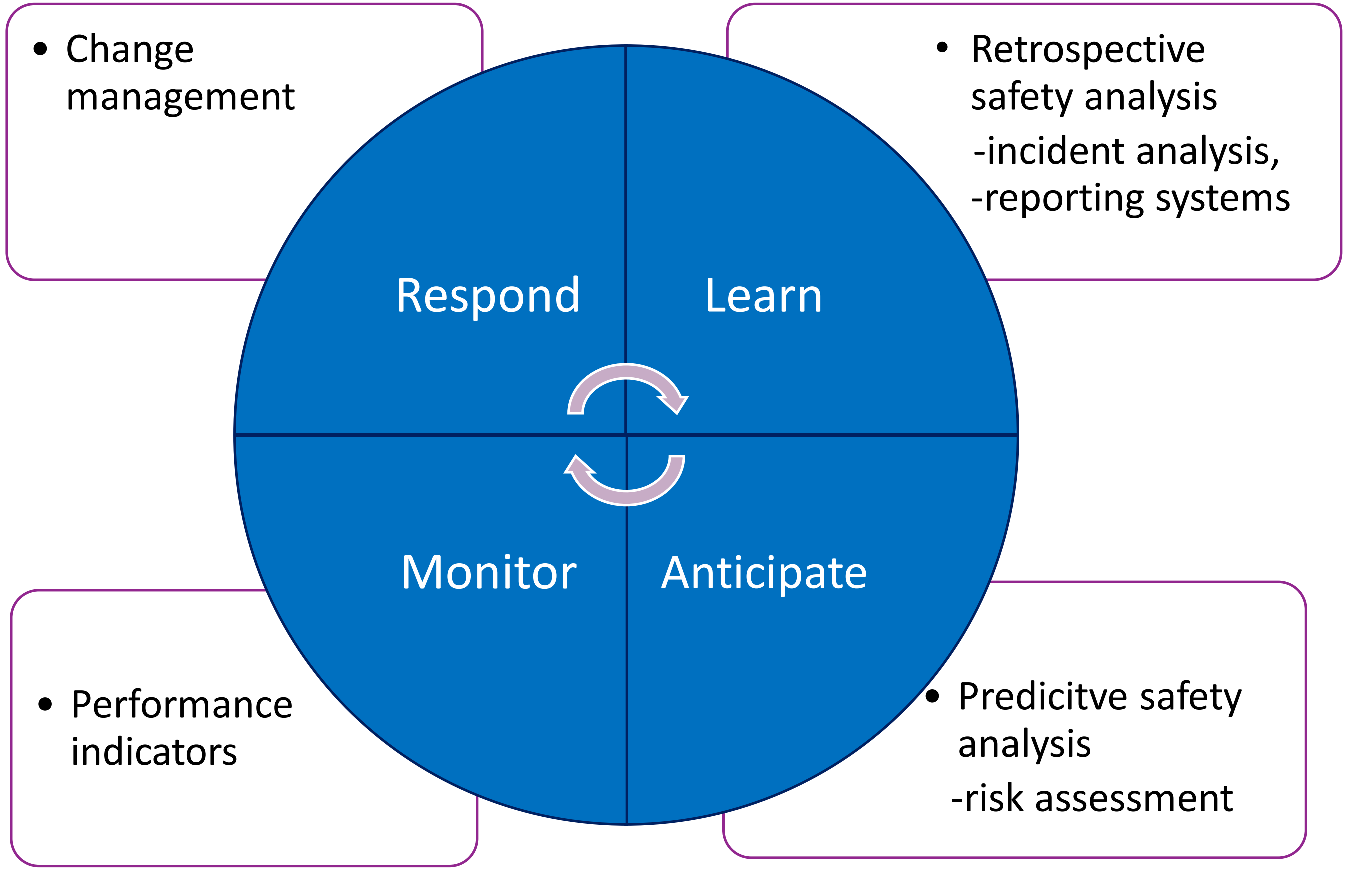
Safety cycle



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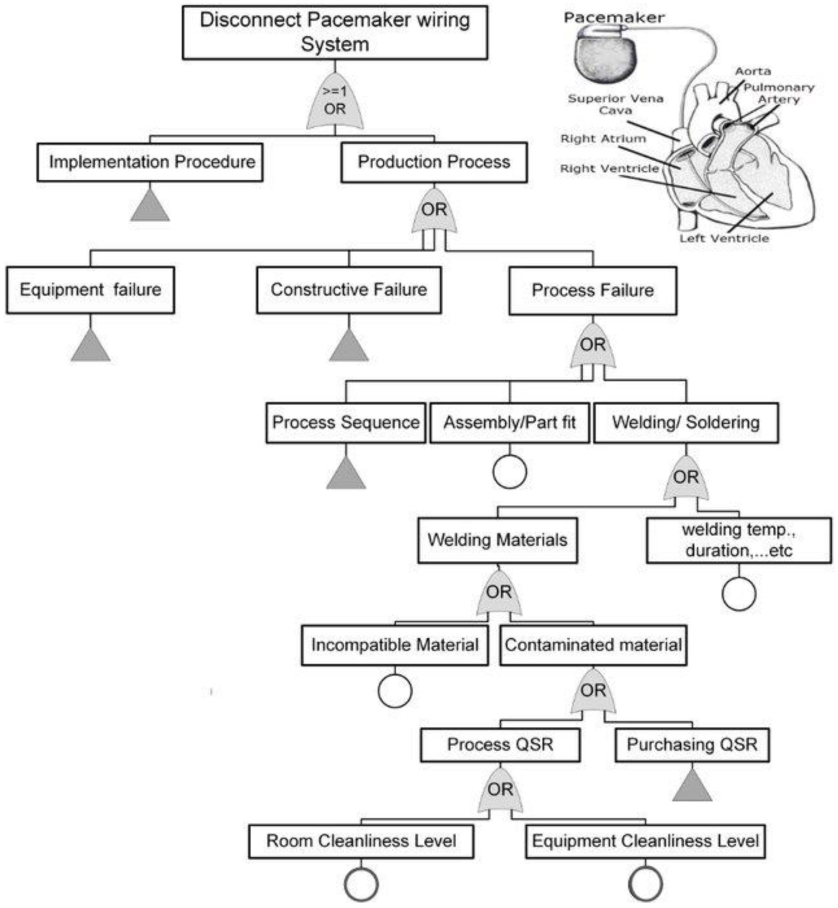
Root Cause Analysis (RCA)

on a disconnected pacemaker



(Ibrahim & Chassapis, 2014)

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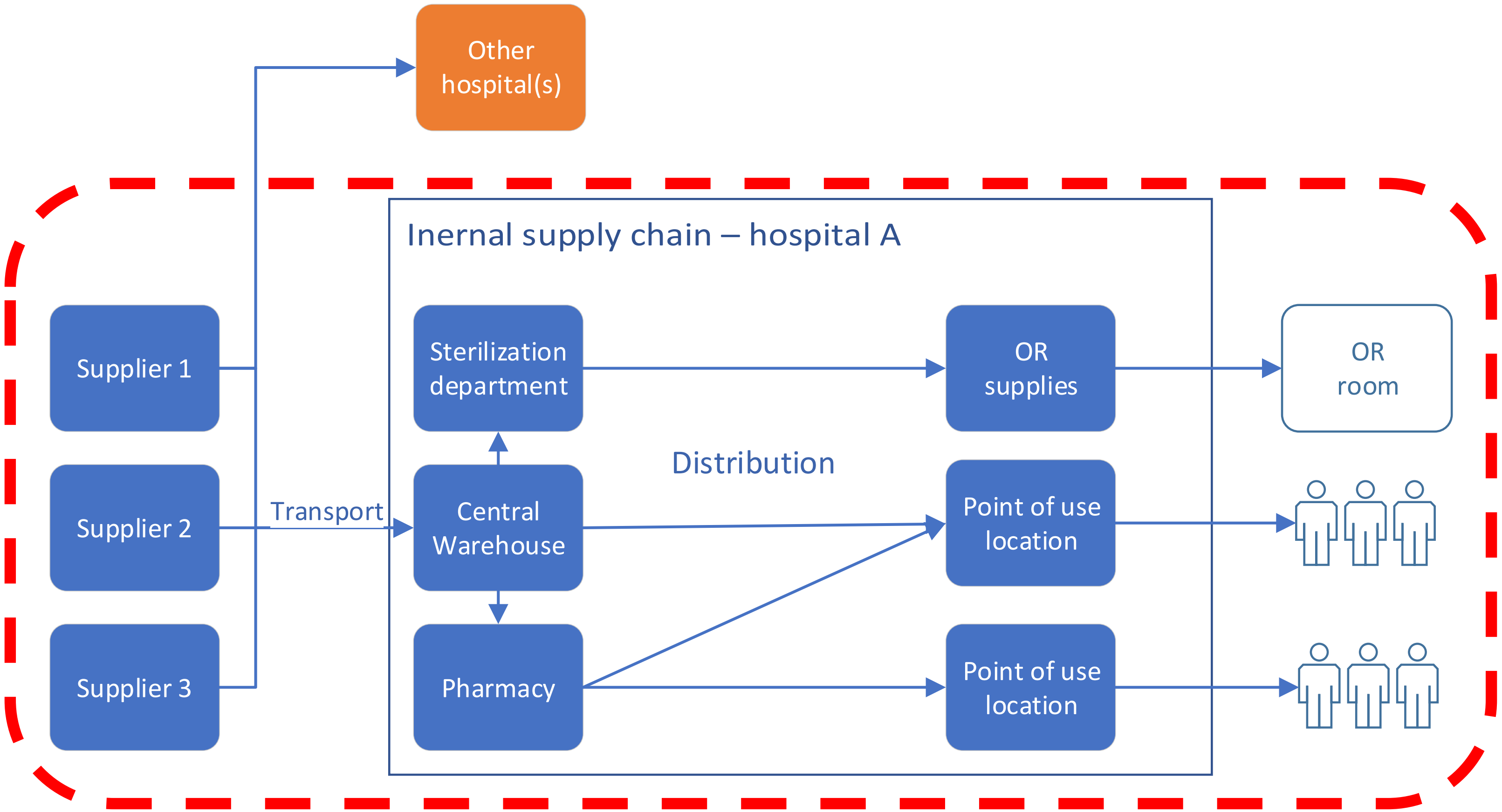
Root Cause Analysis



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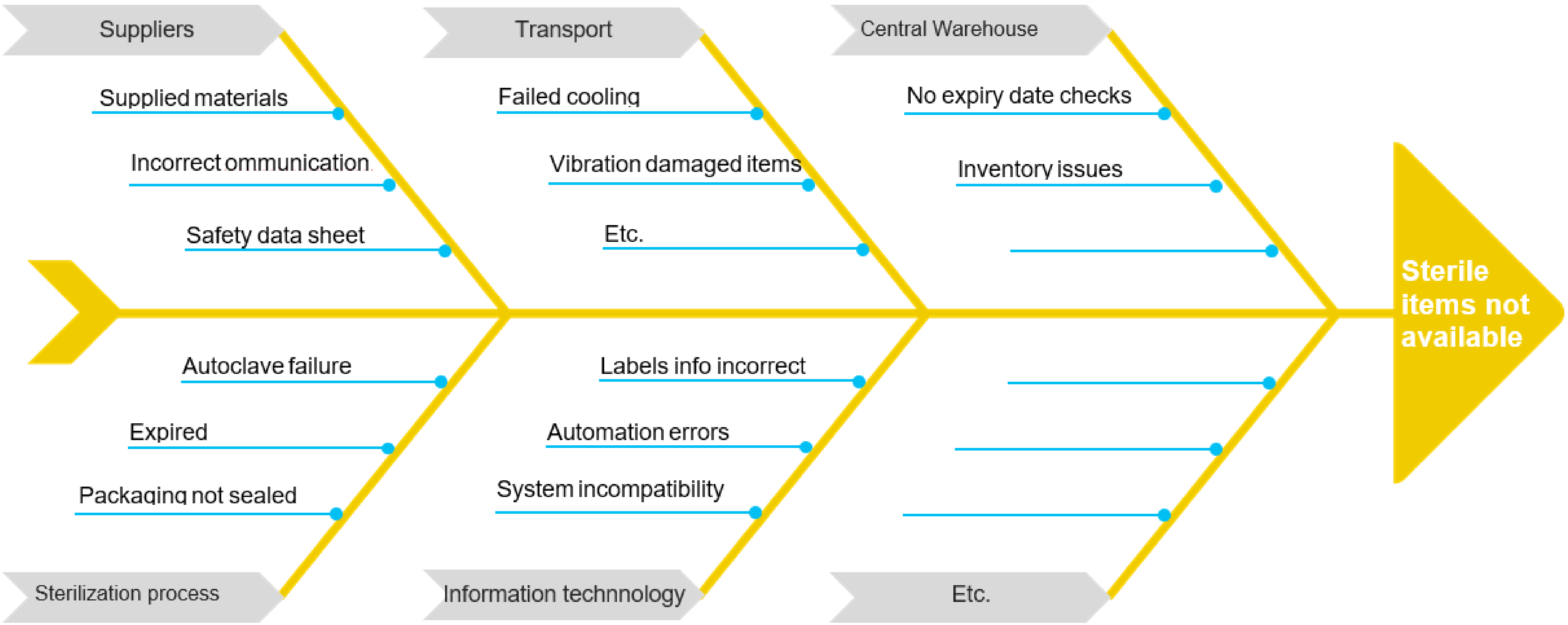
Root Cause Analysis (Fishbone)



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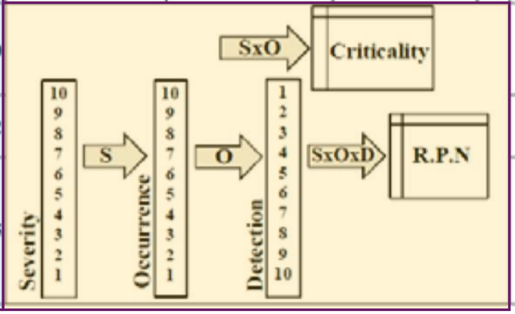
Failure Mode Effect and Analysis - FMEA

on a disconnected pacemaker

Item/Part / Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Class	Potential Cause(s) / Mechanism(s) of Failure	Occurrence	Current Production Controls Prevention	Current Production Controls Detection	Detection	R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken	Severity	Occurrence	Detection	R. P. N.
Pacemaker Regulates heart beat Transmits signals between heart and electronic circuit.	Signals to\from heart must be continuous. (Any error in reporting the heart rhythm and response by the adequate signal represent a threat).	Separation of wires connecting the electronic circuit to other pacemaker components, such as the battery.	The wiring separation will prevent signal transfer. The device will not be able to sense or respond to such event.	9	Critical	1- wrong soldering material is used.	8	Material Control Purchasing Control	QSR.	3	216	Suppliers control (selection criteria). Auditing Control. Statistical process control. Sampling and Testing Control. Working environment control	Medtronic Design and manufacturing team. Regulatory Team. QSR Team.	CAPA Control ICH Q9. Risk Management techniques implementation and verification, ongoing control and monitoring. Validation documents control.				0
				10		2- The material become contaminated during processing.	8	cleanroom Practices.	QSR.	4	320	Expected Improvement after applying suitable controls	Risk Reduction due to more ability to detect it	which reflect on its occurance probability.	10	2	2	40
				8		3- The wires material/charactristics are not suitable.	5	Design controls supplier Control	QSR.	5	200							0
				8		4-The wires are under extra tension.	6	Process Control	QSR.	4	192							0
				9		5- Overheated wires and connections due to compact size.	7	Design and process controls	QSR.	5	315							0



Adapted from (Ibrahim & Chassapis, 2014)

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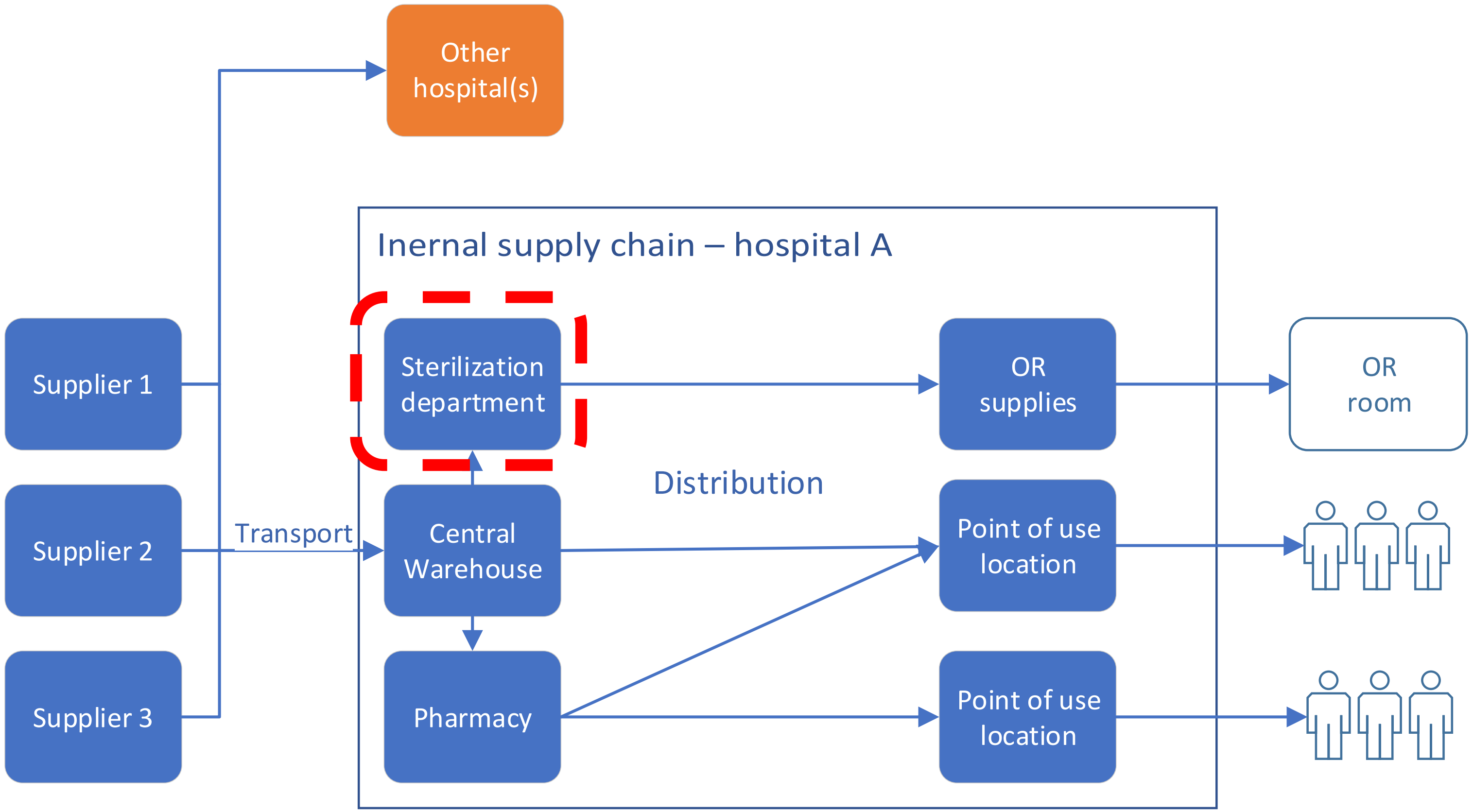
FMEA



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Sterilizer – autoclave

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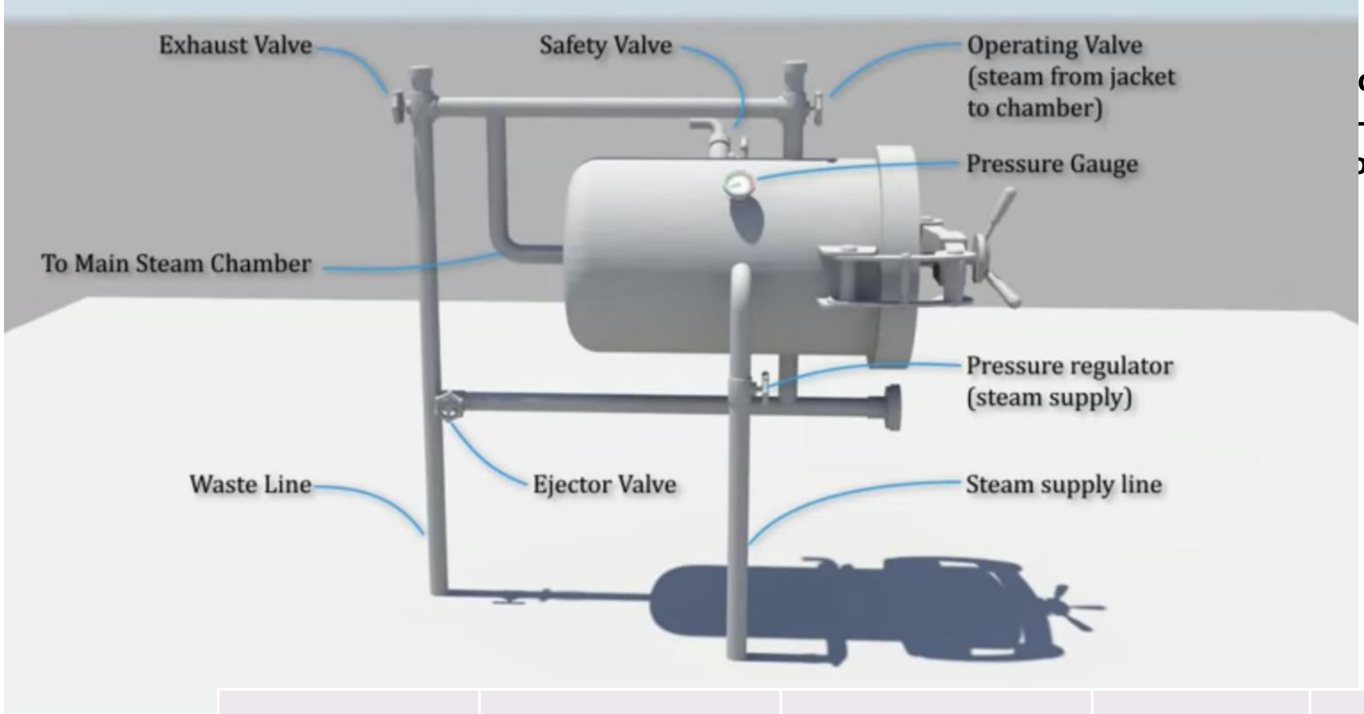

FMEA

Component	Function	Potential Failure Mode	Potential effects	Potential causes	Severity	Probability	Detection	RPN
Pressure regulator	regulate pressure	loss of integrity	pressure loss	corrosion	2	2	2	2*2*2=8
		blocked	pressure build up	contamination of water to produce steam	4	3	1	4*3*1=12

Figure: Community College Consortium for Bioscience Credntials

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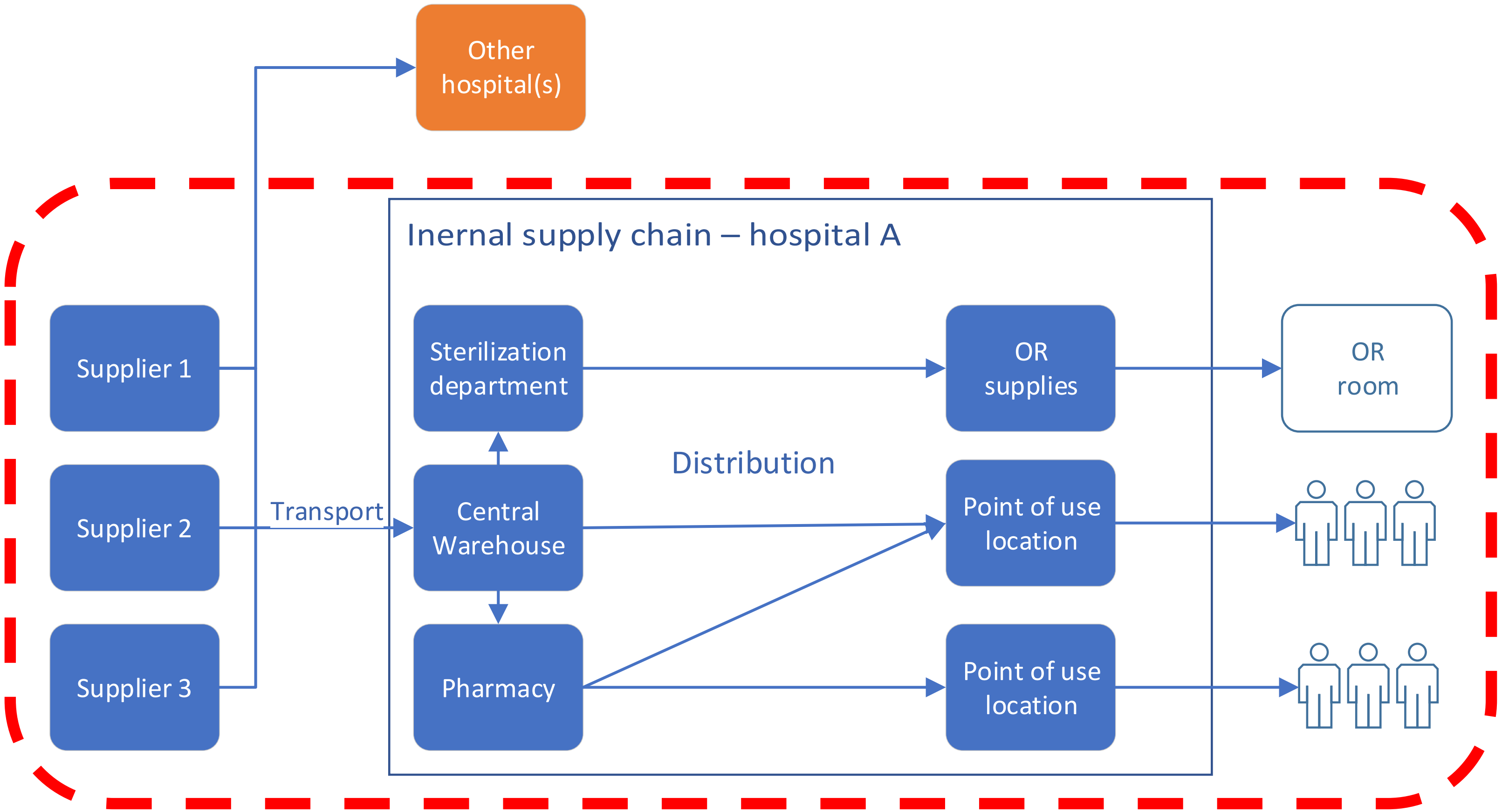
FMEA



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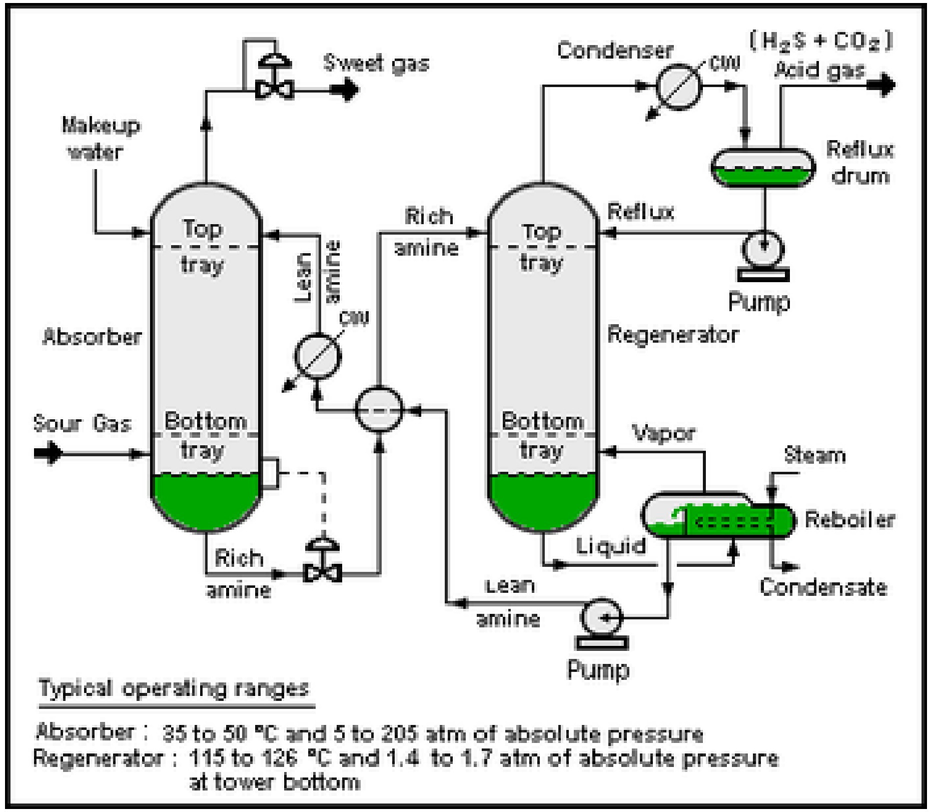
Hazards and Operability Study - HAZOP



- Typical for petrochemical industry
- Operational parameter guide words on flow, pressure, temperature, level, ...
  - E.g. high flow, low flow, reverse flow, contamination, etc.

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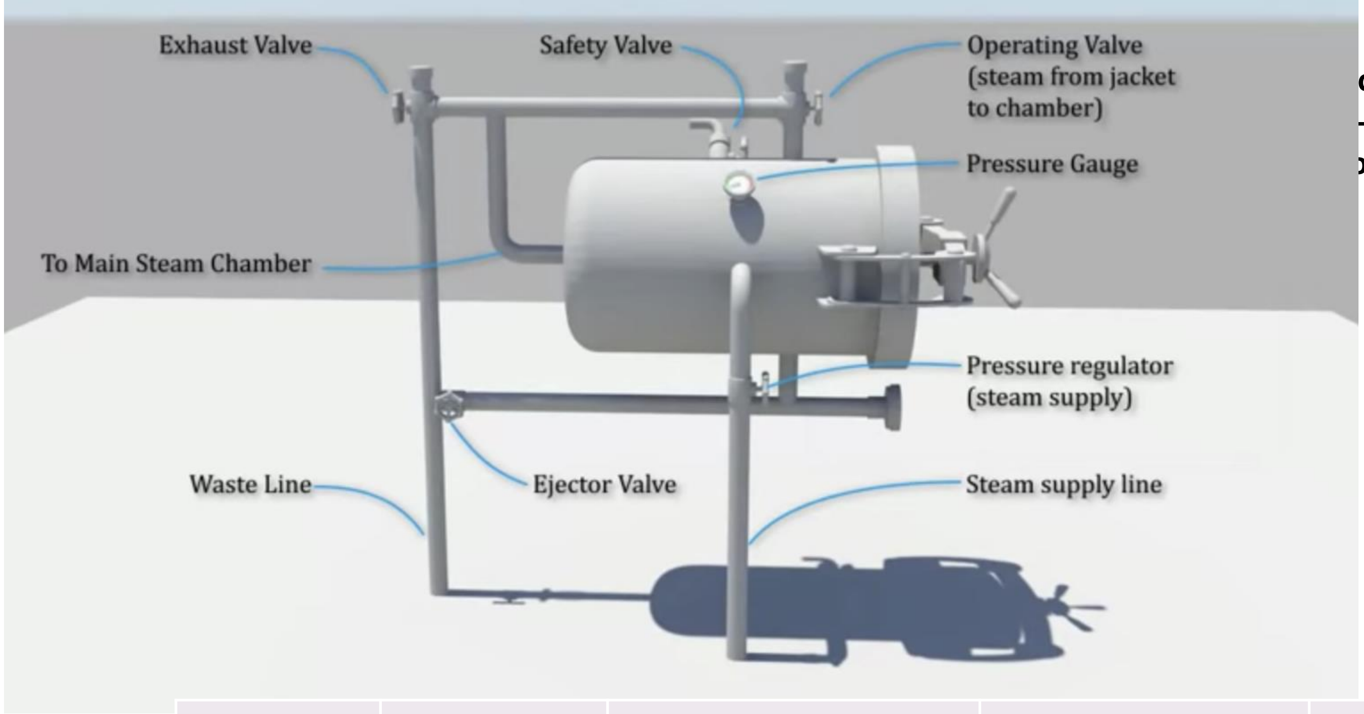

HAZOP

Study node	Process parameter	Guide word	Deviation	Possible causes	Possible consequences	Action required
Steam supply line	Pressure	more	high pressure	pressure controller is broken	overpressure	pressure gauge warning
		less	low pressure	pressure controller is broken	no sterilization	log process parameters & generate warning
		early	unexpected pressure	supply valve cannot be fully closed	operator hazard	inspect intervals for supply valves & operator protection
	Flow	no	no flow	steam is not generated	no sterilization	log process parameters & generate warning
		reverse	reverse flow	pressure build up in autoclave vessel	operator hazard	install safety valve

Figure: Community College Consortium for Bioscience Credntials

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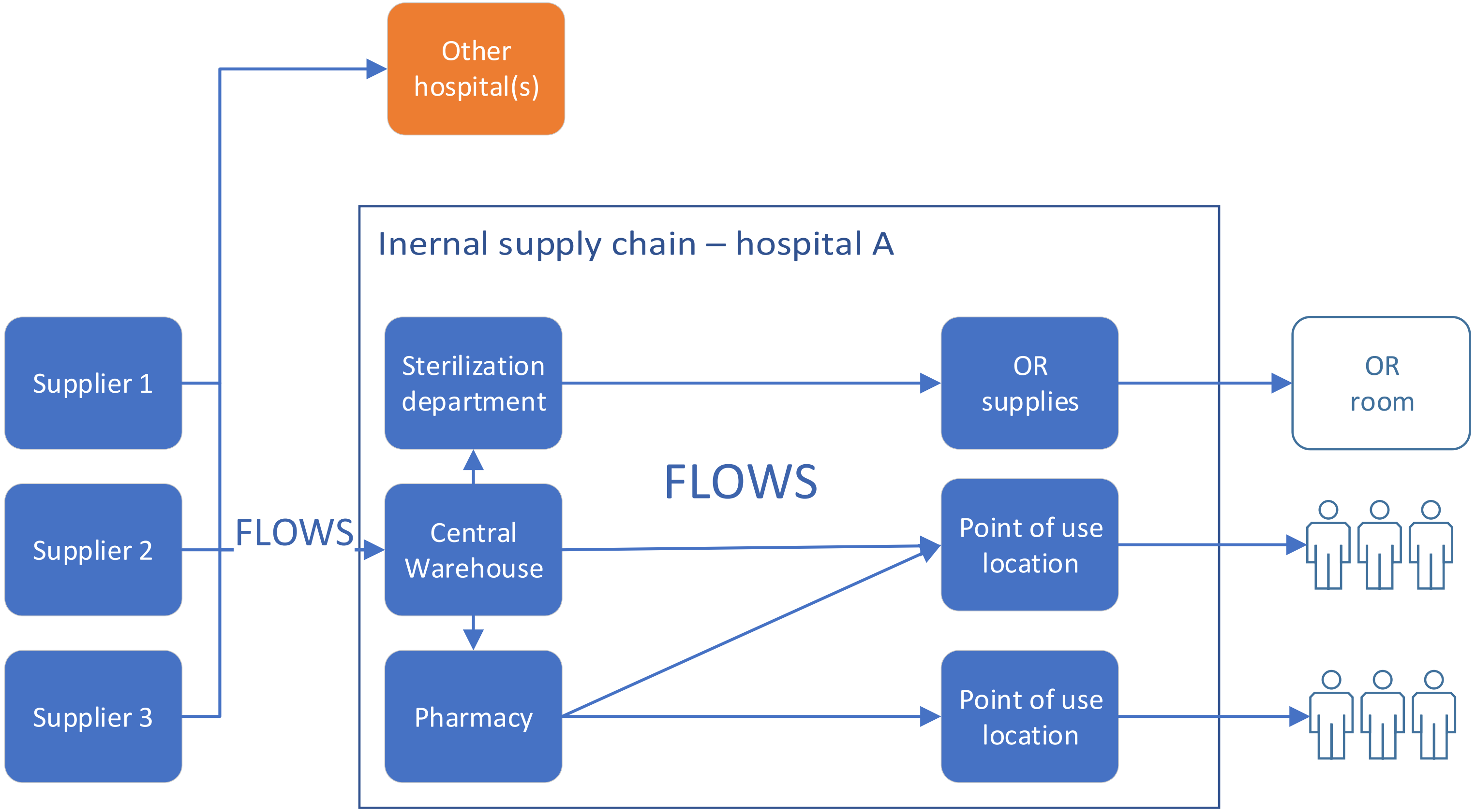
HAZOP?


Other hospital(s)
Inernal supply chain – hospital A
Supplier 1
Supplier 2
Supplier 3
FLOWS
Sterilization department
Central Warehouse
Pharmacy
FLOWS
OR supplies
Point of use location
Point of use location
OR room

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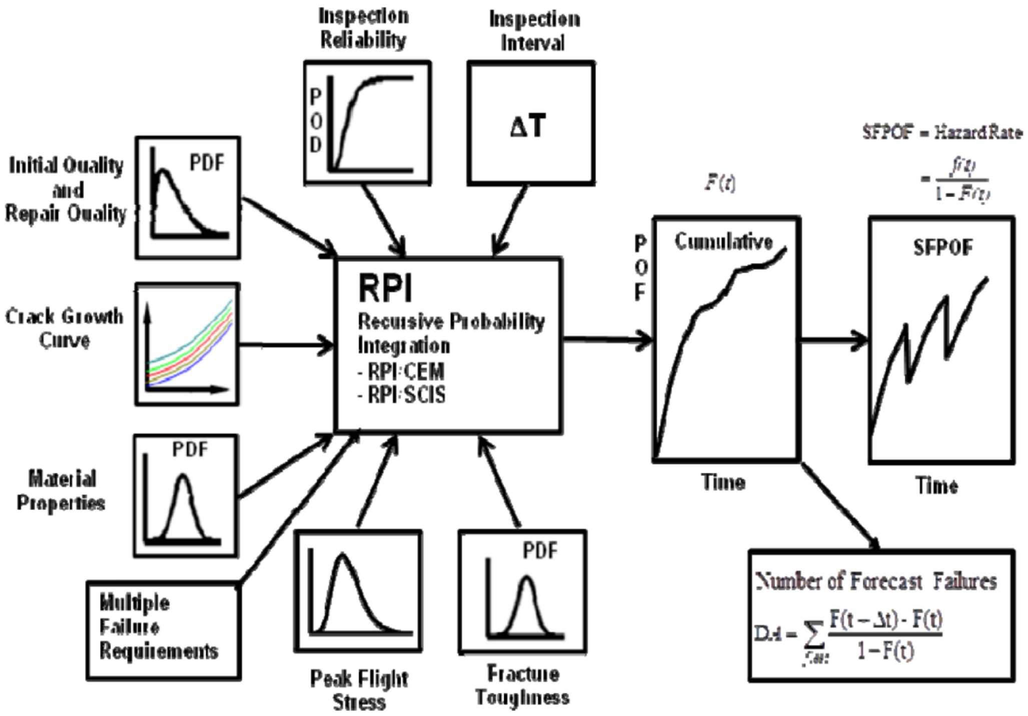
Probabilistic Risk Assessment - PRA

Multiple parameter example

Simple parameter example

Probability	Probability and Impact Matrix								
0.9	0.09	0.18	0.27	0.36	0.45	0.54	0.63	0.72	0.81
0.8	0.08	0.16	0.24	0.32	0.4	0.48	0.56	0.64	0.72
0.7	0.07	0.14	0.21	0.28	0.35	0.42	0.49	0.56	0.63
0.6	0.06	0.12	0.18	0.24	0.3	0.36	0.42	0.48	0.54
0.5	0.05	0.1	0.15	0.2	0.25	0.3	0.35	0.4	0.45
0.4	0.04	0.08	0.12	0.16	0.2	0.24	0.28	0.32	0.36
0.3	0.03	0.06	0.09	0.12	0.15	0.18	0.21	0.24	0.27
0.2	0.02	0.04	0.06	0.08	0.1	0.12	0.14	0.16	0.18
0.1	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
Impact	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9



Right-hand figure (Shiao, Y-T Wu, Ghoshal, Ayers, & Le, 2012)

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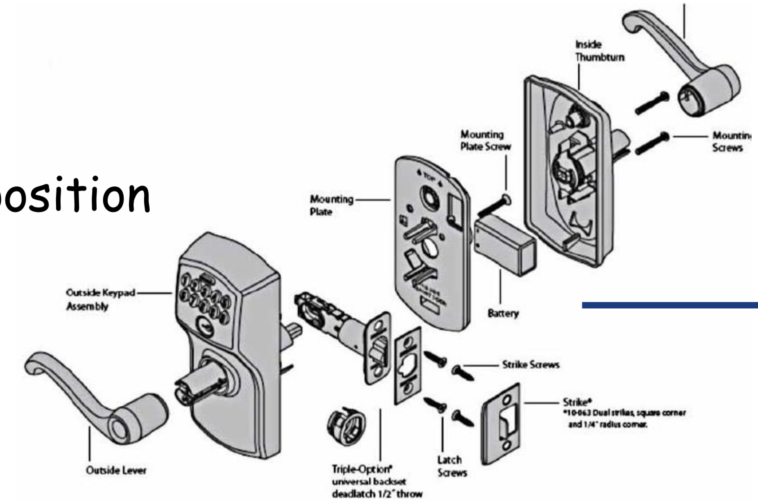
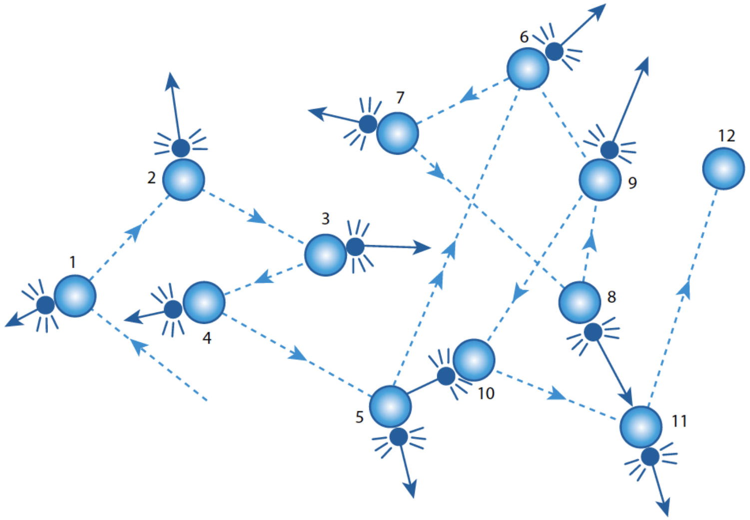
Systems Thinking

“Systems thinking marks the changing perspective from decomposition by analytical reduction to the analysis and design of the whole, as distinct from the components. It provides a means for studying emergent system safety properties”

Decomposition
RCA
FMEA
HAZOP





Systems thinking methods

Quote: (Adriaensen, Decré, & Pintelon, 2019), figures: (Eurocontrol, 2013)

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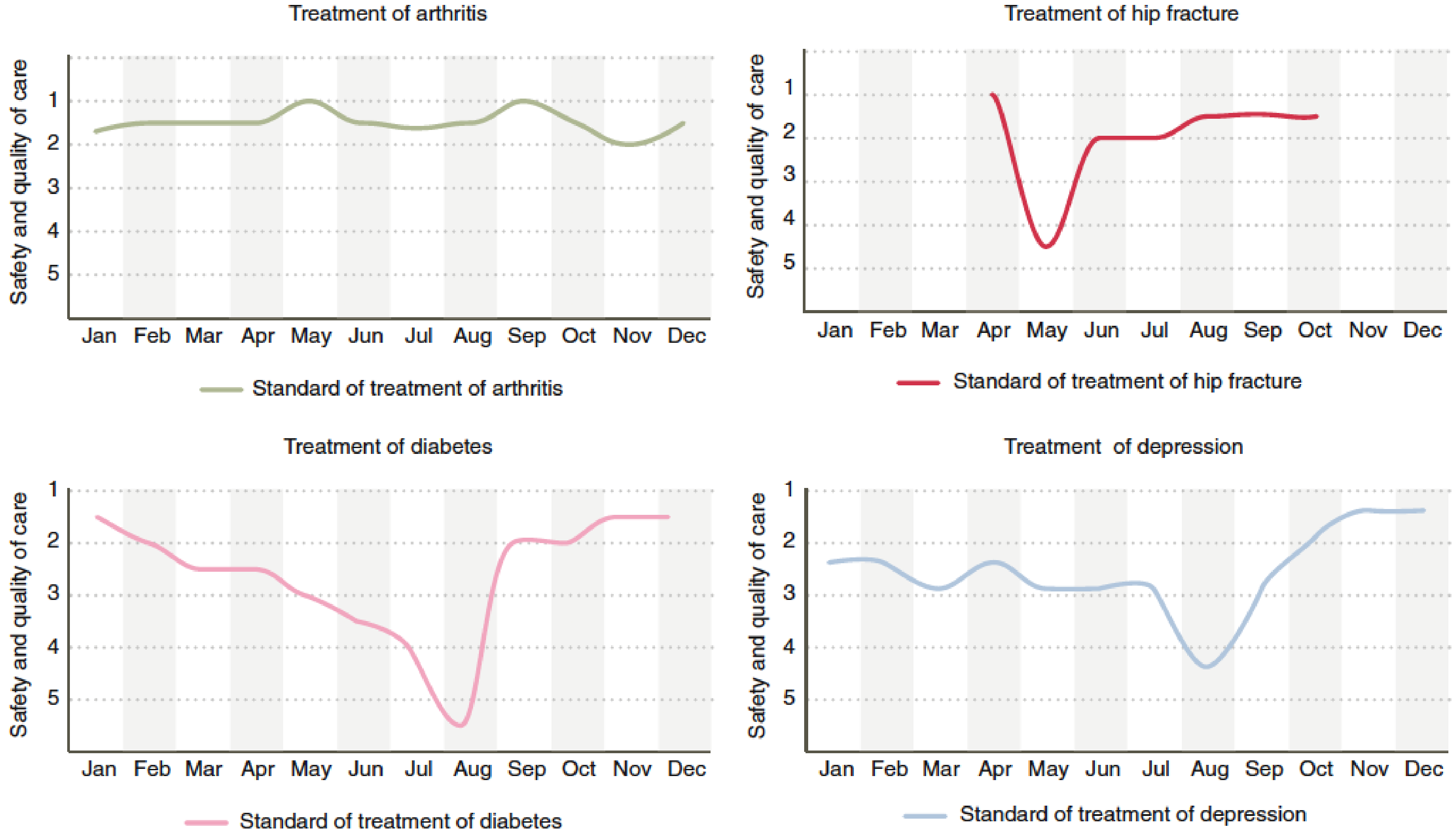
Resonance & Emergence



(Vincent & Amalberti, 2016)

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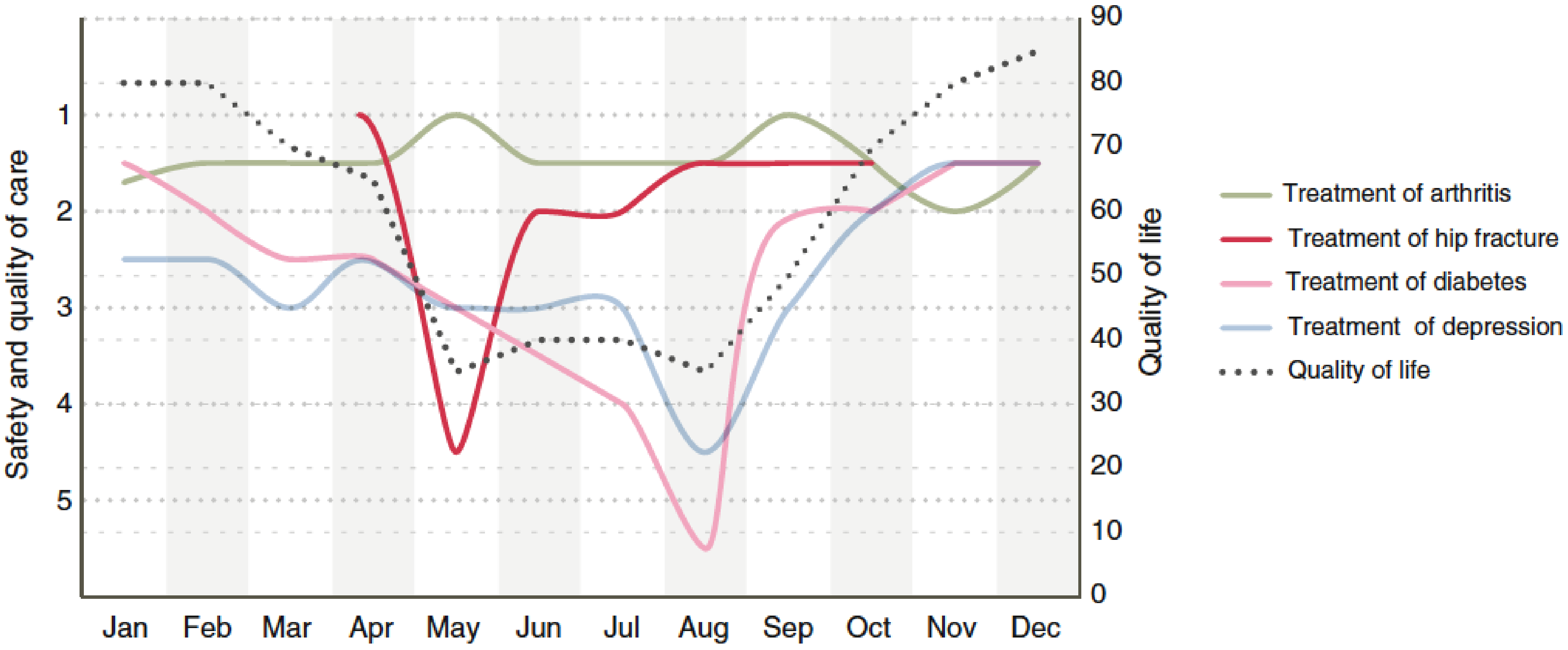
Resonance & Emergence



(Vincent & Amalberti, 2016)

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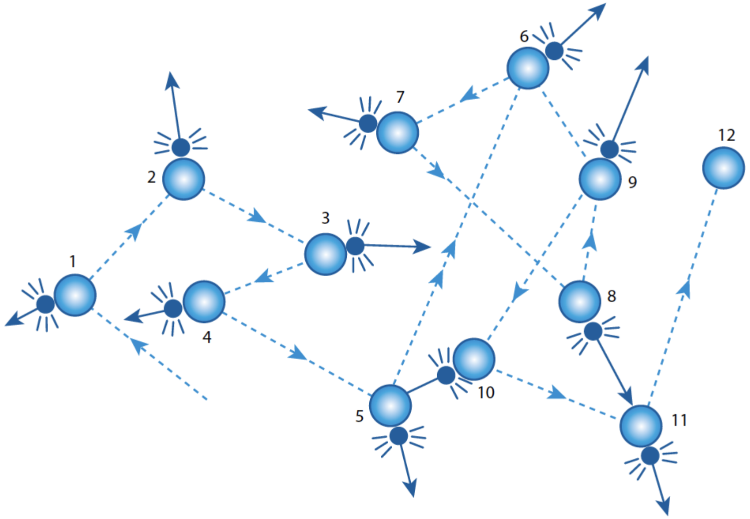
Complexity Thinking

- "Complexity thinking marks a changing perspective on causality, moving from sequential models to systemic models, which is a change from linear thinking to non-linear thinking."



Complexity thinking (non-linear) methods

Quote: (Adriaensen, Decré, & Pintelon, 2019)

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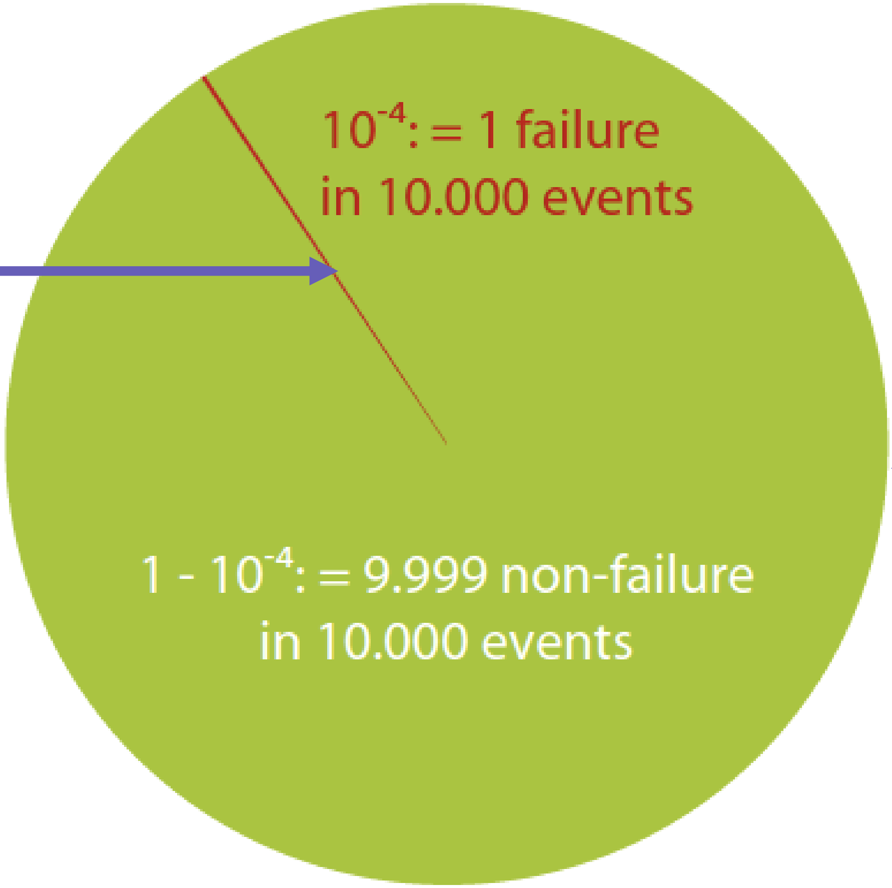
Imbalance of things that go wrong versus things that go right

Learning from incidents
Classic safety managment

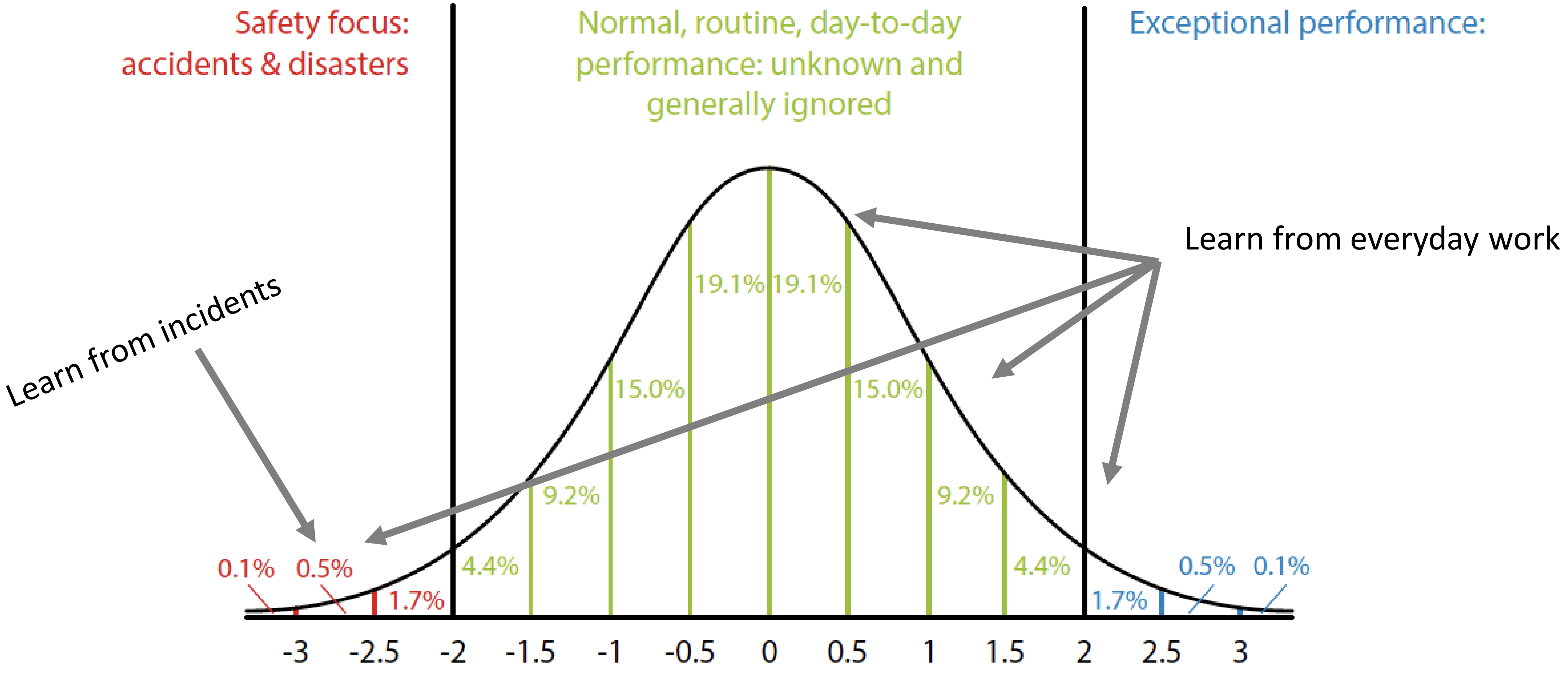


Learning from full performance variability

After: (Eurocontrol, 2013)

Bron: Eurocontrol. (2013). *From Safety-I to Safety-II: A White Paper, adapted from Hollnagel.*

Safety-I vs Safety-II



After: (Eurocontrol, 2013)

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Resilience Engineering

Resilience definitions:

- “a system’s capability to sustain, restore, and even improve its functionality under turbulent circumstances” (Ruth et al., 2019)
- “the ability of the system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required performance under expected and unexpected conditions” (Robson, 2013)

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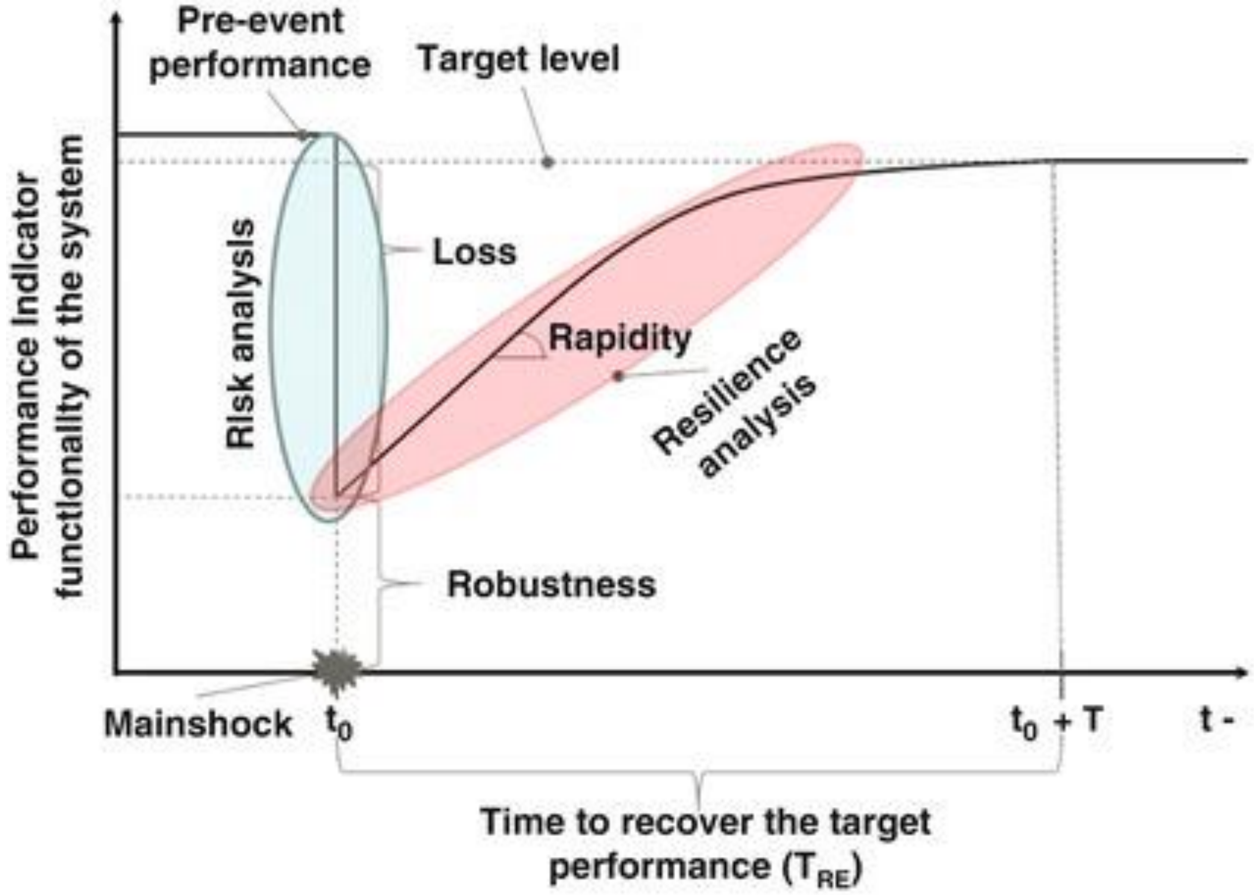
Resilience Analysis



(Cimellaro, 2016)

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Resilience Engineering

(Sources: Het Laatste Nieuws, De Standaard)

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Example of a Safety-II Risk Assessment Method

Functional Resonance Analysis Method (FRAM)

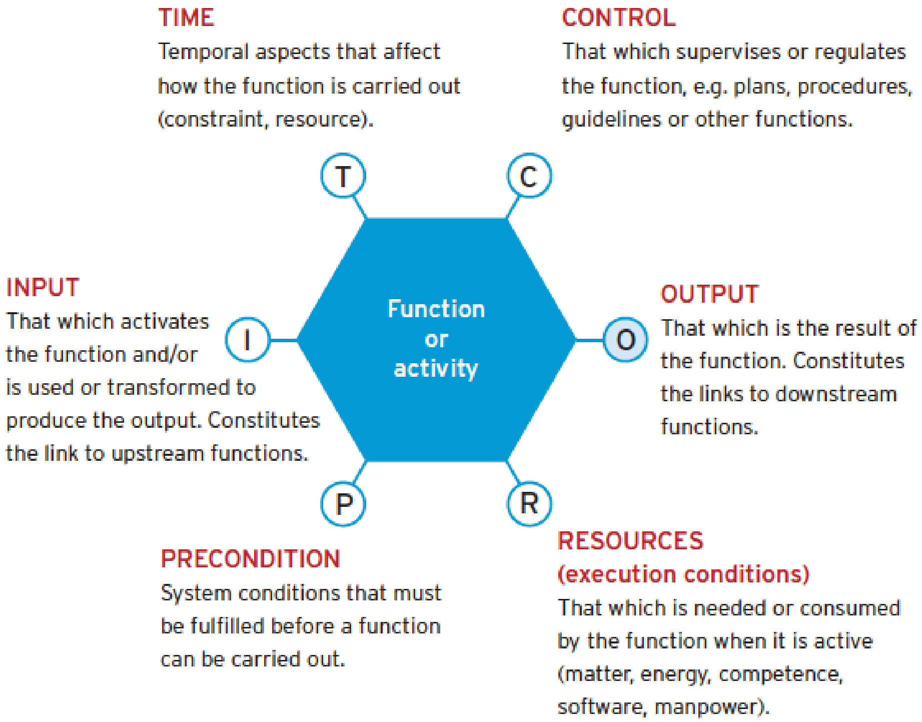
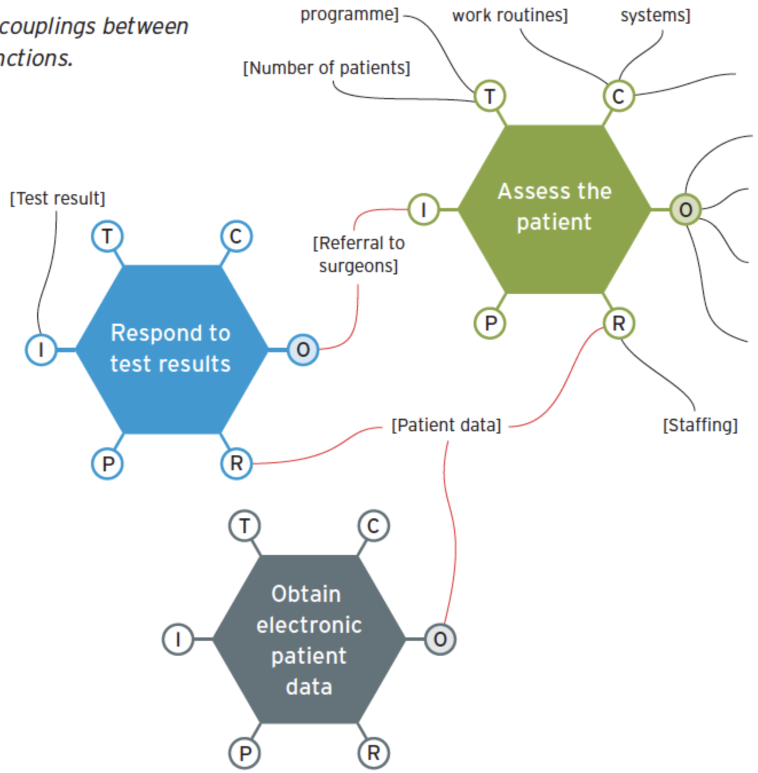


Figure 11: Illustration *of couplings between functions.*



(Hollnagel et al., 2014)

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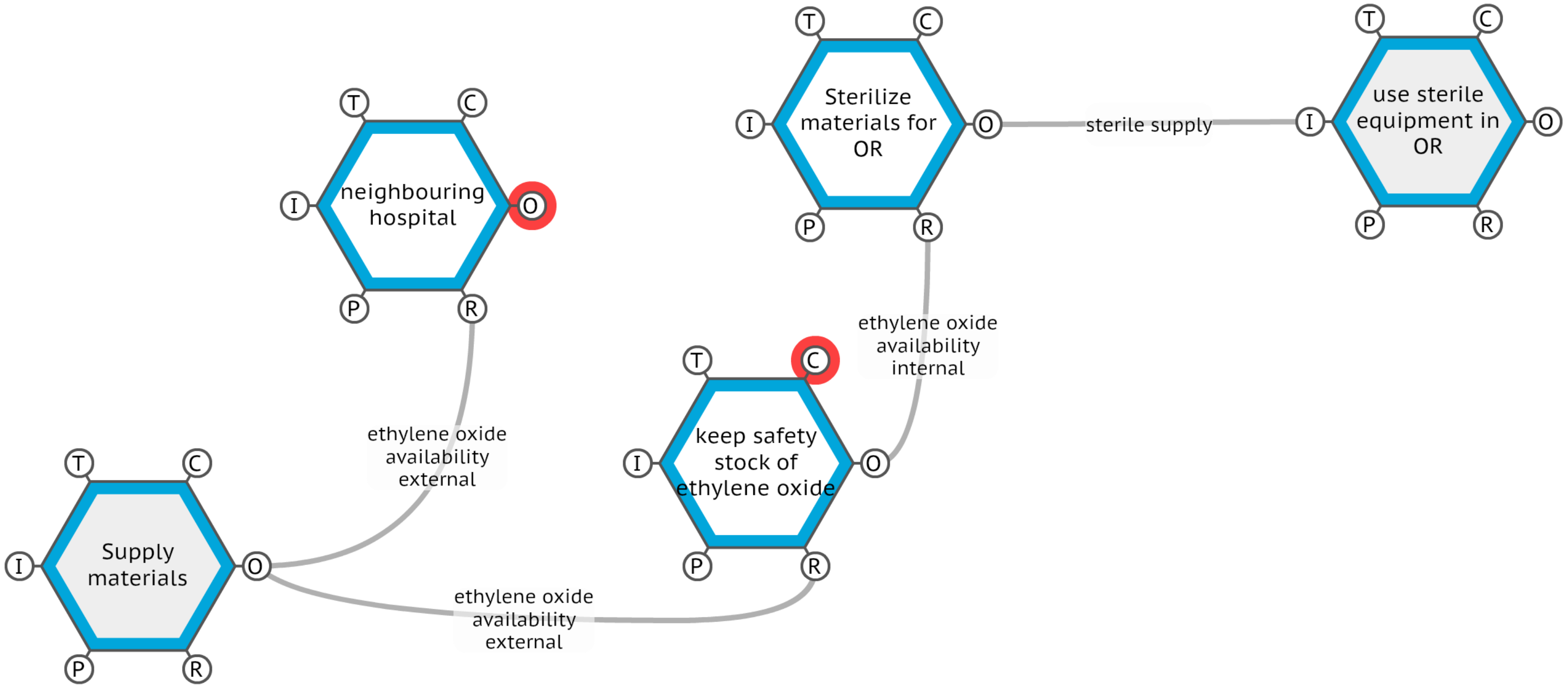
Example of a Safety-II Risk Assessment Method

Functional Resonance Analysis Method (FRAM)



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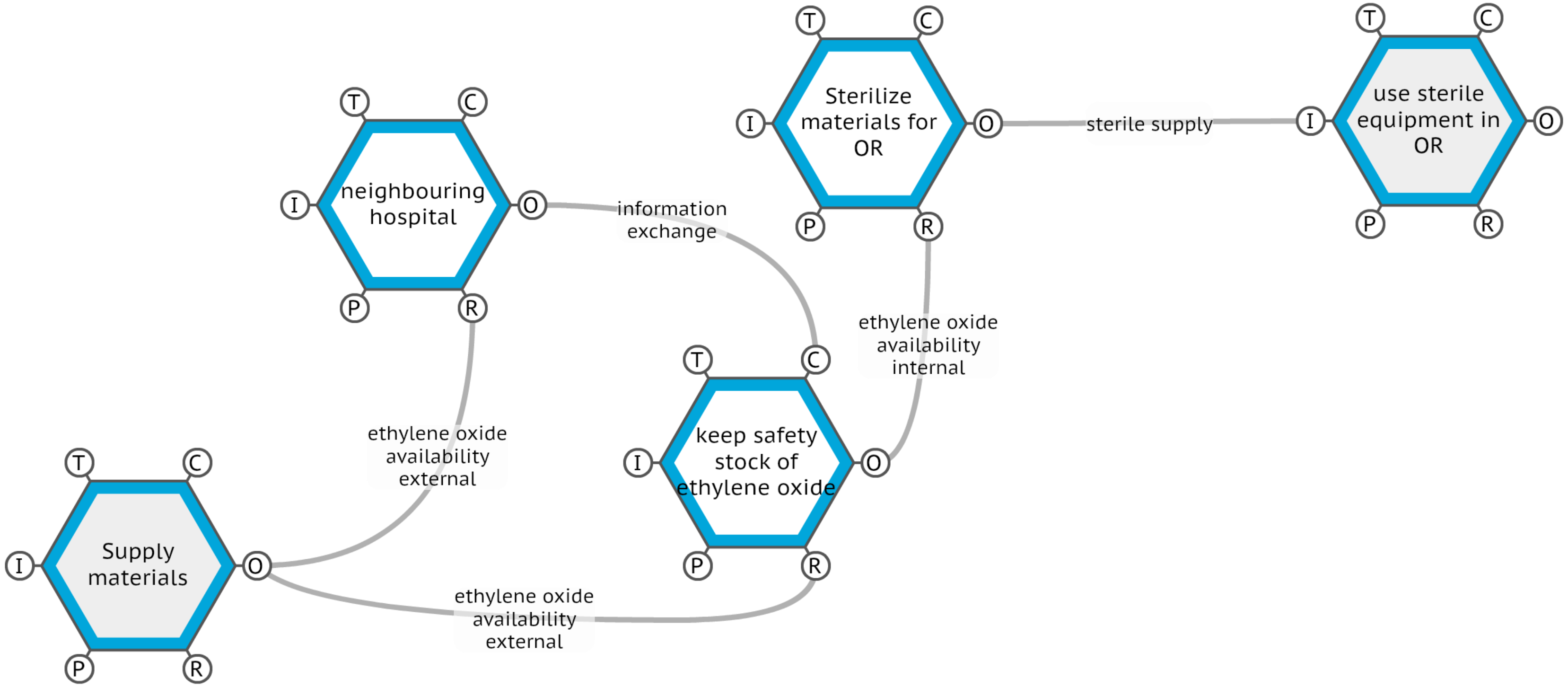
Functional Resonance Analysis Method (FRAM)



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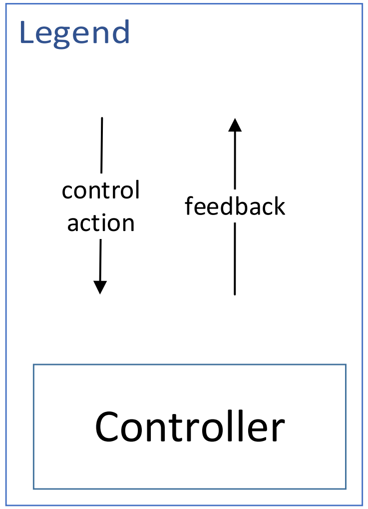
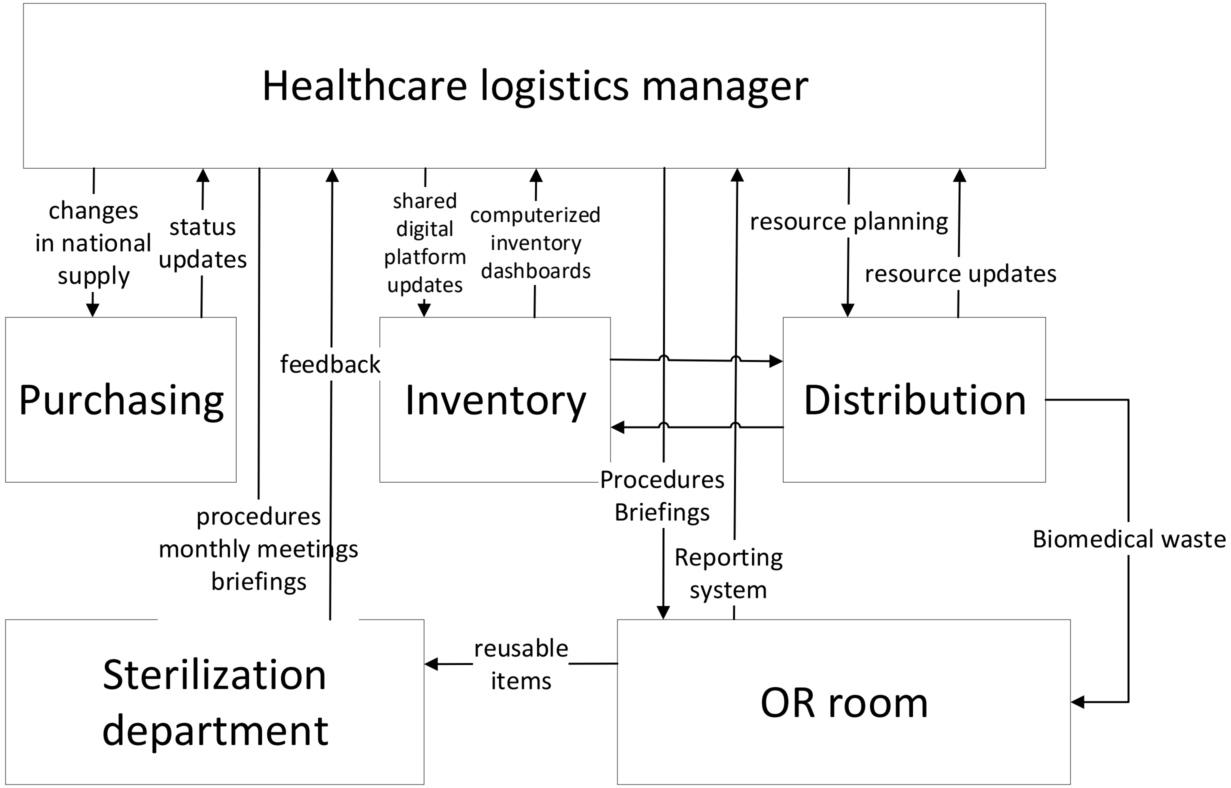
Systems Theoretic Analysis Method and Processes (STAMP)





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The End

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