



Engineering Better Patient Care

Embedded Engineering Design Process: Meeting Unmet Clinical Needs

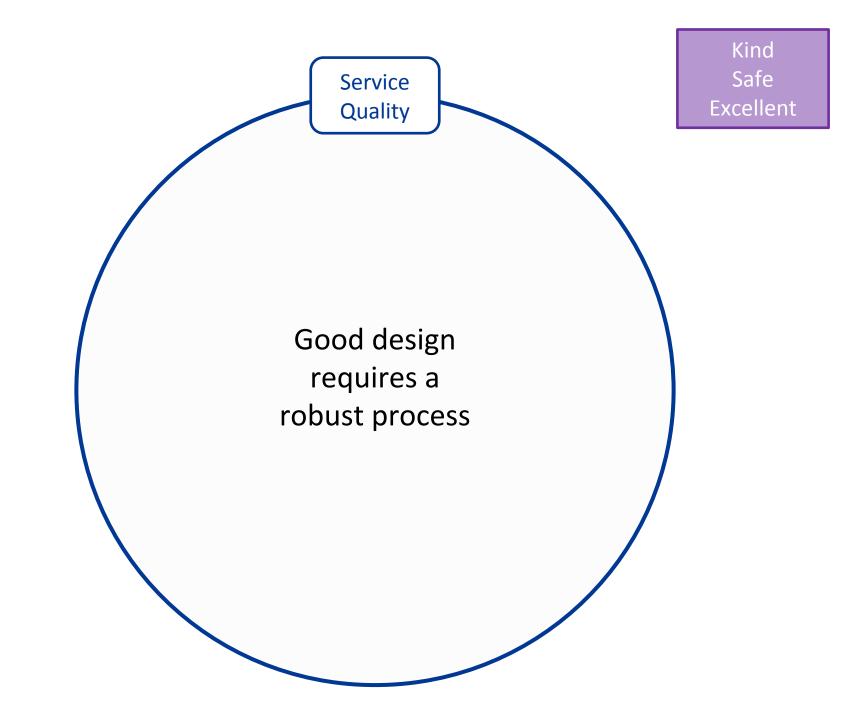


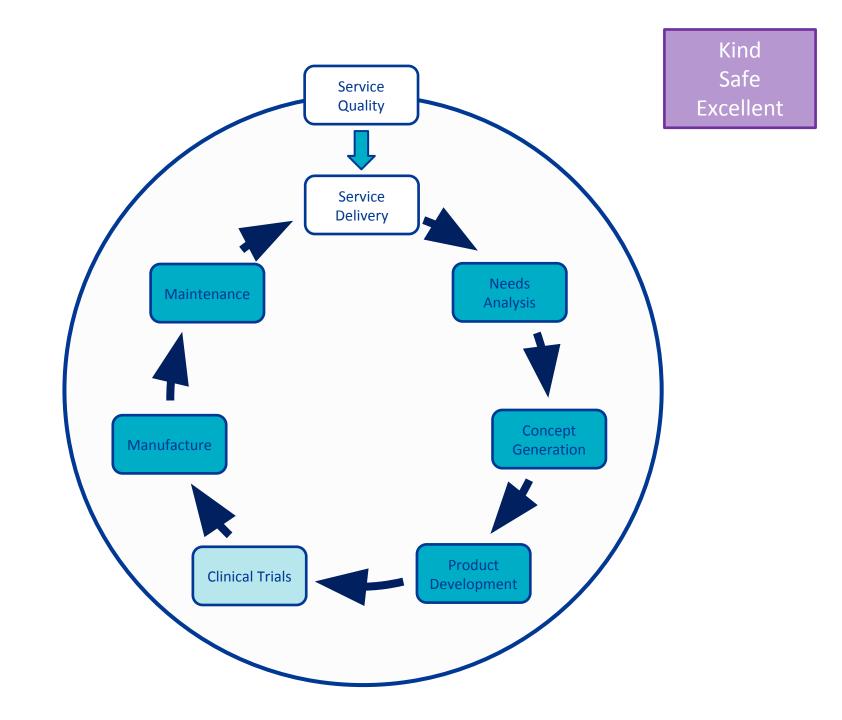




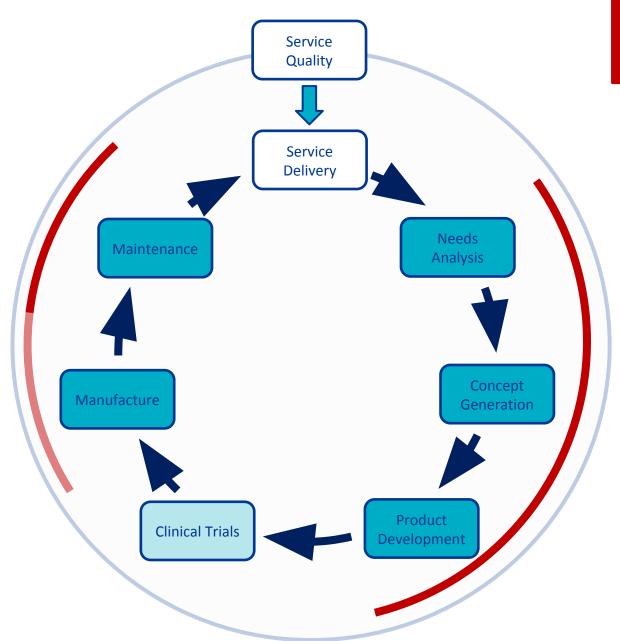
What is Design?

- The engineer, and more generally the designer, is concerned with how things ought to be - how they ought to be in order to attain goals, and to function - Herbert Simon
- All people are designers. All that we do, almost all the time, is design, for design is basic to all human activity.
 The planning and patterning of any act toward a desired, foreseeable end constitutes the design process. (modified)
 Victor Papanek
- Design is less about how things look and more about how we look at things – based on Design Council
- The business of better





ISO 13485 Quality Management



Standards

M H R A

European Medical Devices Directives

90/385/EEC (Active implantable) 93/42/EEC (General) 98/79/EC (In vitro)

Quality Management System

ISO 13485

C

Risk Management

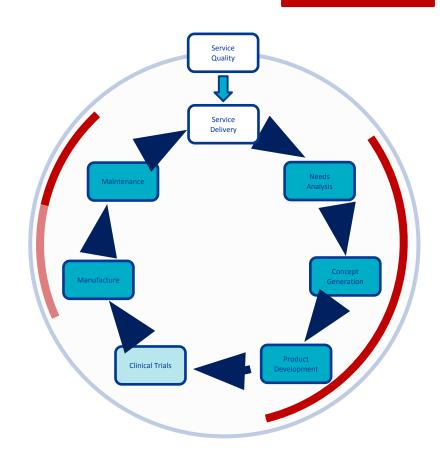
ISO 14971

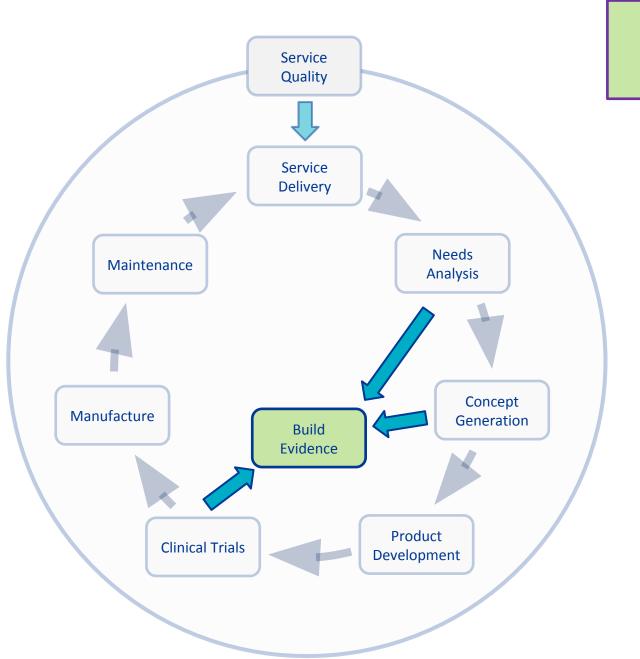
Human Factors

ISO 62366

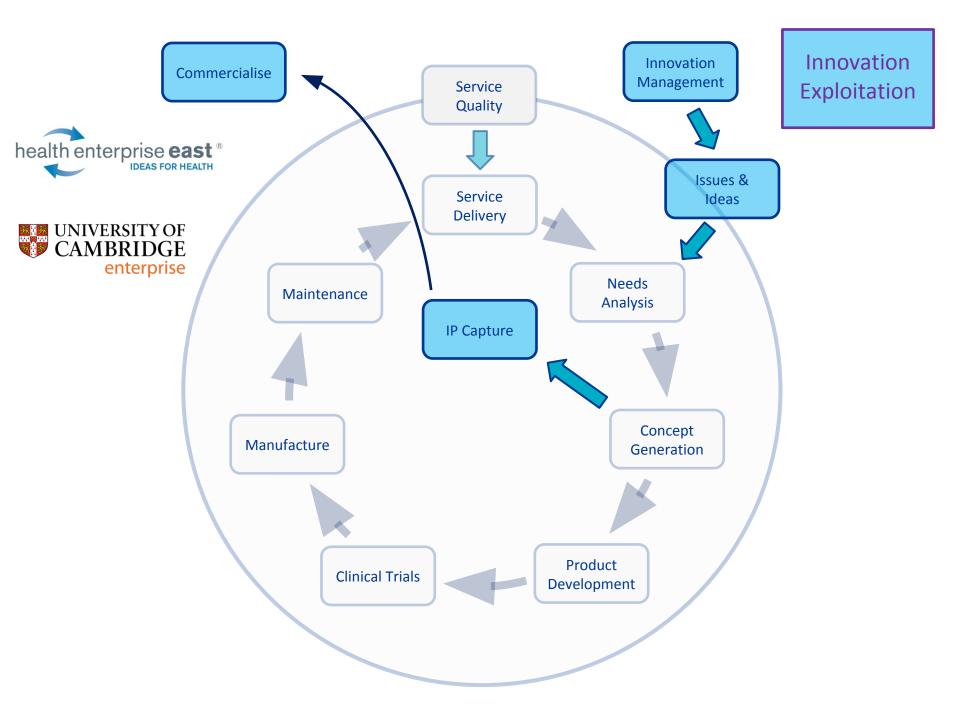
Other appropriate standards

Many 100's

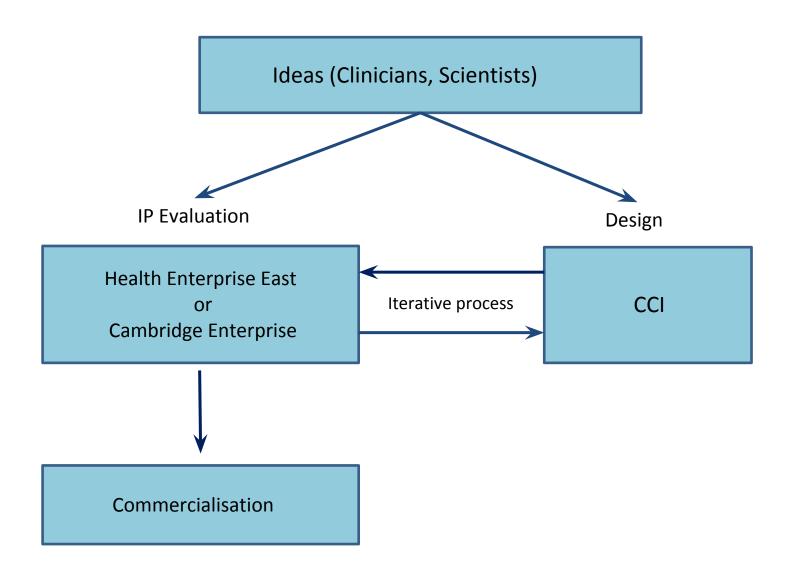




Clinical Case



IP Capture & Commercialisation

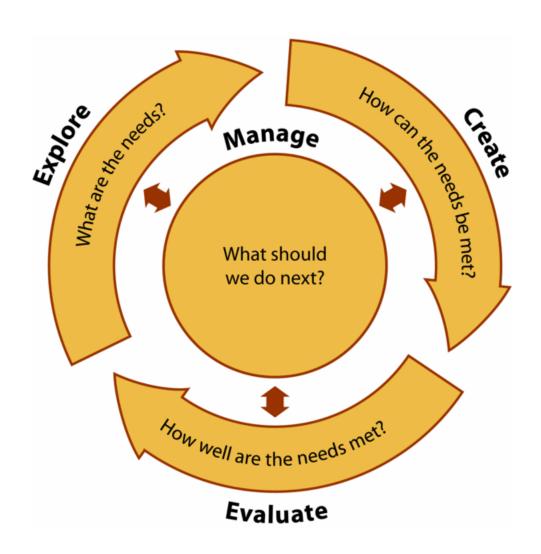


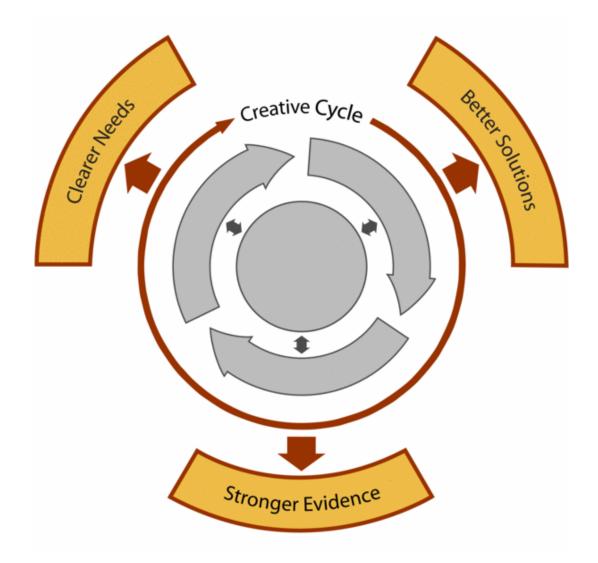
Service Quality

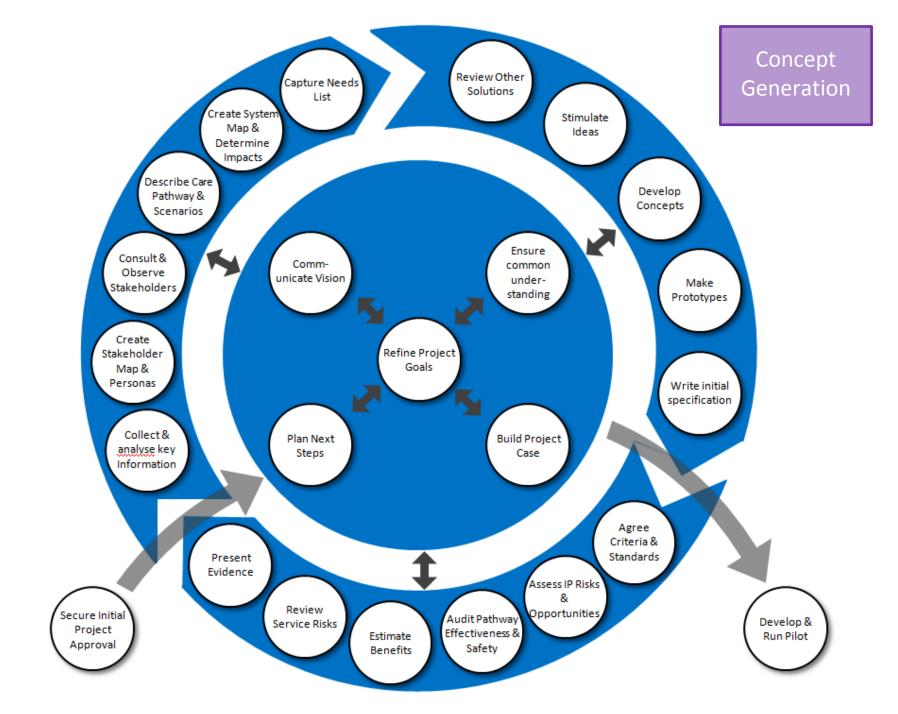
Good design is about asking the right questions

- What are the **needs**?
- How can they be met?
- How well are they met?

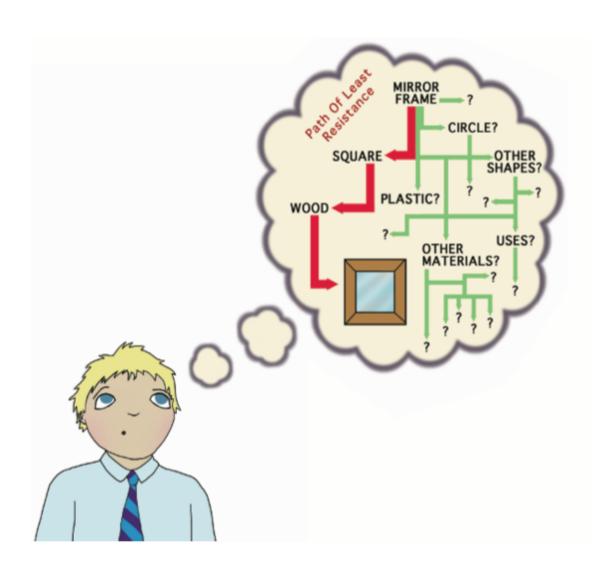
Explore Create Evaluate







Fixation – the path of least resistance



Today's un-met need



Getting from A to B

Assumptions

- Single pole
- Vertical pole
- Mounted on bed corner
- Must be clamped
- Must use device clamps

Patient Controlled Analgesia Pump

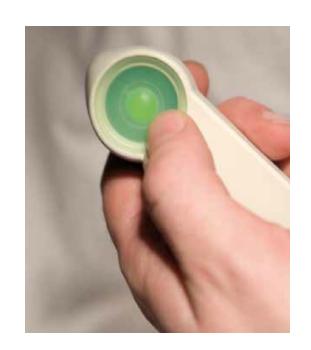


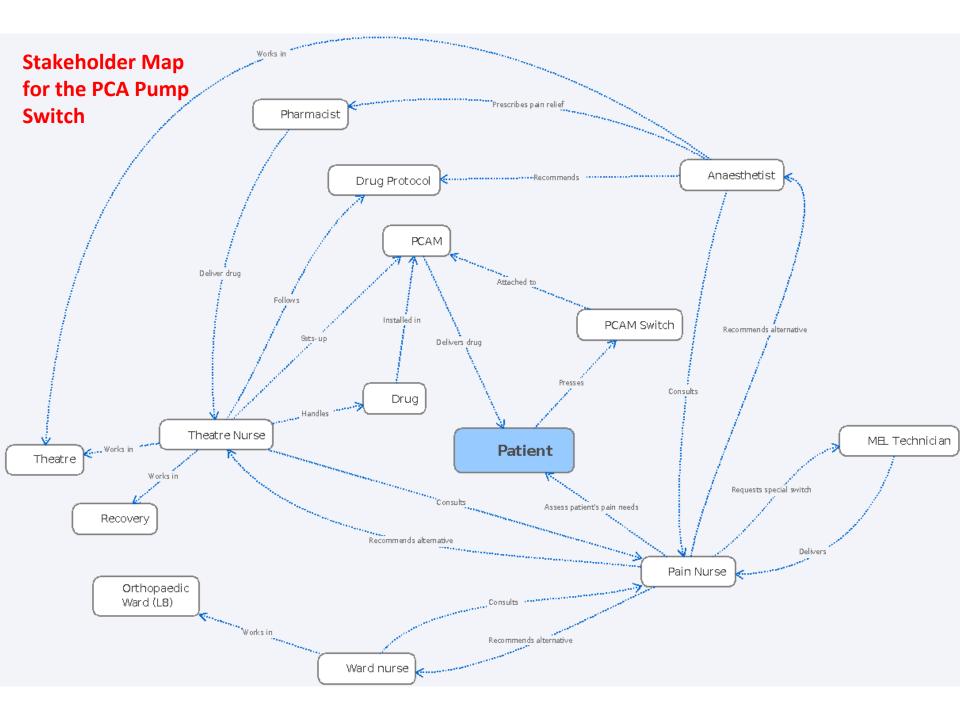


The Problem

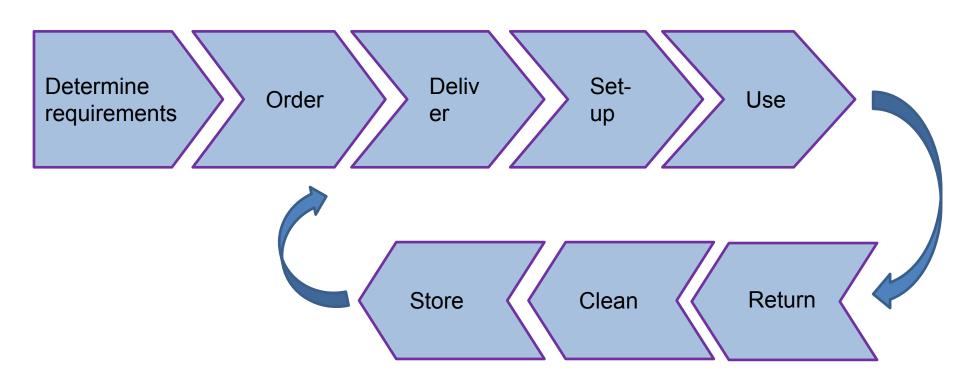
- Estimated 20% of patients can' t press the button
- Potential reduction to 1% with the right switch

Source: Addenbrookes NHS Trust (Pain Team)





A Switch Service



Detail Matters

Requirement			Stakeholder(s)	Measure
Requirement Stakeho Store			MAKEHUMET (3)	ricasuit
The device should be able to be stored on a shelf in the Medical Equipment Library		Medical Equipment Library Technician	A height x B width x C length	
Cleaning				
The system should be cleanable to trust infection control standards on a daily basis typically using a wipe			Infection control, HTA or Nurse	All areas that may cause a risk are accessible to standard wipe
The system should have no absorbent surfaces		Infection control, HTA or Nurse	No absorption of cleaning or bodily fluids	
The system should be suitable for end of us			Medical Equipment Library	It should be possible to disassemble for cleaning without damaging the components.
Transport MEL to recovery	. (1			All components must be suit
MEL to ward Recovery to ward (bed)	Storage		=	.,
Ward to MEL Locating in hospital	Cleaning		• Stakeholders	• Measures
The equipment should allo	Transport	amage	Varied	RFID mountable using cable
Install It should be possible to ra	Locating		MEL Technician	Assembly in less than 1 minute without reference to a manual and no prior experience of the system
It should be possible to w	•		MEL Technician	Someone who has never used the system before can work out if components are missing without reference to a manual
It should be possible to in	 Installing 		Nurse	Installation in less than 1 minute without reference to a manual and no prior experience of the system
It should be possible to in	• Training	eir body	Nurse & patient	The switch must be locatable at any point within the bed area up to a height of 50 cm
The switch should not into The switch mount must be	Training		Nurse & patient	The switch 'arm' must support multiple orientations that are at least 30 cm apart from another orientation to achieve the same location Resist a force of between 5-10 N from any direction
It should be possible to ch	 Adjustment 		Nurse	A HCP who is not trained should be able to spot common incorrect installation issues
	Adjustificiti			
Training It should be possible to tra	• Use		Nurse & patient	Training in less than 3 minute without reference to a manual and no prior experience of the system. 90% of patients should be able to correctly remember these instructions without further training.
It should be possible for the	 Emergency 		Nurse & patient	A clear practise mode that is clear which mode it is in
It should be possible to tra It should be possible to tra	Linergency		Nurse	It should be possible to train staff familiar with PCA within 10 minutes
	removal		Nurse and visitor	Training in less than 1 minute without reference to a manual and no prior experience of the system. 90% of visitors should be able to correctly remember these instructions without further training.
Adjust	. D t			
It should be possible to ch	• Return		Nurse	Installation in less than 1 minute without reference to a manual and no prior experience of the system
It should be possible accu	. N./a:taa		Nurse	One person can locate to within an accuracy of 1 cm within less than 1 minute
The patient should be awa	 Maintenance 		Palient	90% of patients remember that adjustment is possible
Use	• Tosting			
A patient should be able to	Testing	d	Patient	The patient can activate the switch on 95% of attempts within 5 seconds and know they have been successful 95% of the time
Emergency Removal				
It must be possible to rem			Any HCP	It should be possible to remove/relocate the system with 5 seconds
Return				
The system must work within the existing equipment return system			HCP/MEL technician	The system must comply with the return protocol and system
Maintain				

The PCA Switch







The business of better

