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Engineering better care

a systems approach to health and care design and continuous improvement

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Foreword

The UK's health and social care system is, appropriately, one of our most treasured national assets. However, the sheer size and complexity of the system, as well as the pressures it faces from an ageing population and finite resources, mean that making improvements to health and care can be a significant challenge. Successful transformation must take into account the needs of all patients, carers, healthcare professionals and other staff. It requires consistent consideration of every element of the system, the way each element interacts, and the implications of these interactions for the system as a whole – that is, it requires a 'systems' approach.

Clinical leaders are increasingly exploring and recognising successes by using a range of evidence based approaches to work on design and improvement, including systems techniques. This work is leading to improved pathways, processes and patient experience. However, such approaches are not yet consistently defined or applied throughout health and care design and improvement.

Engineering is a sector where systems thinking is routinely applied to understand, design, deliver, and sustain systems ranging from the development of worldwide telecommunications networks to the latest Boeing 787 Dreamliner. As a pioneer of minimally invasive surgery, I personally have always been an advocate of an interdisciplinary approach between engineering and healthcare sectors and this project has provided an excellent opportunity for mutual learning. It has led to the development of a rigorous yet workable framework for the application of systems thinking in the unique context of health and care.

I fully endorse the recommendation that healthcare leaders and transformation teams consider the questions and tools laid out here to support a more consistent application of a systems approach to health and care design and improvement. With this work we hope to deliver benefits for patients, carers, and staff, and showcase the value in cross-sectoral working.

Rt Hon Professor Lord Darzi of Denham
OM PC KBE HonFREng FRS FMedSci
August 2017

Executive summary

The challenges facing the health and social care system are considerable – with competing pressures from an ageing population, increasing numbers of patients with multiple morbidities, new technologies, and the need for increasing efficiencies. The complexity of the system, along with the multiple pressures it faces, mean that efforts to improve it often achieve only limited benefits and can have unforeseen consequences. Over the past two decades, there have been numerous calls to implement a more holistic systems approach to transform health and care to address the needs of a changing patient population. However, there has been no clear definition of what this might mean in practice.

Engineers routinely use a systems approach to address challenging problems in complex projects. This allows them to work through the implications of each change or decision they make for the project as a whole. They consider the layout of the system, defining all the elements and interconnections, to ensure that the whole system performs as required. One example is the successful delivery of the London 2012 Olympic and Paralympic Games. Physical infrastructure and practical organisation were brought together, with innovative physical engineering, modelling and simulation of people flows, early testing of venues, and extensive risk management. A systems approach, combined with tried and tested engineering methods and tools, delivered real success on a massive scale.

"Systems that work do not just happen – they have to be planned, designed and built" [1]

This report was co-produced with engineers, clinicians, and healthcare leaders, to explore how an engineering approach could be applied in health and social care to develop systems that meet the needs of patients, carers and NHS staff. It presents a new framework to support ongoing work in service design and improvement in health and care.

All health and care improvement initiatives involve people, processes, technologies, the physical environment and systems that, in turn, are part of other systems. For example, the care pathway of an elderly frail patient must meet the needs of the patient, their immediate carer and wider family. Care must also coordinate across community support, a GP practice and hospital teams, and manage the patient's medication, their physical journey to and around healthcare facilities, home care technologies and associated health and care data. Such complexity means that health and care will benefit from using an approach that considers each relevant element of the system and, critically, the nature and performance of the interfaces between them.

Comparing current health and care improvement processes with engineering systems approaches, we found that:

- There is the potential for health and care improvement to benefit from the rigour of the engineering approach to systems, particularly with respect to:
  - systems being centred on people – an effective systems approach is centred on people, their needs, their capabilities and ultimately their role in understanding, designing, delivering and maintaining success
  - iteration before implementation – the behaviour of complex systems is not easily understood and improvement is most often the result of successive iterations targeted at maximising the chance of success prior to implementation
  - design as an exploratory process – improvement results from a creative process that seeks not only to explore the real need, but also to evaluate a range of possible solutions in order to select the best option
  - risk management as a proactive process – the identification of possible opportunities for and threats to a system before they arise is more likely to lead to the delivery of robust and adaptable systems.
- While islands of excellence exist in the use of a systems approach in healthcare, the common sense thinking presented here is still far from being common in practice.
- A systems approach can be defined and applied in a health and care context as a series of questions that integrate people, systems, design and risk perspectives in an ordered and well executed manner. It is only when all four are robustly understood and considered that a systems approach will have the greatest success.

These findings from this collaborative project have been integrated into a framework that can support the work of transformation teams and individuals. These tools can help facilitate the methodical application of a systems approach to improvement, dealing with complexity and improving performance. This approach can be applied to systems across all scales in the healthcare system, from service level improvement, through to organisational, cross-organisational, or cross-sector level change.

In summary, we found that more widespread application of a rigorous systems approach to health and care improvement, has the potential to have a transformative effect on health and care, with benefits for patients, service users, and providers.

We encourage transformation teams to test out the framework, and invite more partners to join us in the next phase, trialling and implementing this approach and augmenting what we have proposed.

1 *Creating systems that work: Principles of engineering systems for the 21st century*, Royal Academy of Engineering, 2007.

Introduction

The challenges and pressures facing the health and social care system are considerable and the complexity of the system makes improvement challenging. In recent years there have been numerous calls for the use of a 'systems' approach in efforts to transform health and care.[2,3,4] However, there has been a lack of a clear definition of what this might mean in a health context.

The work undertaken through this project aimed to define and describe the engineering systems approach and explore, in partnership with healthcare leaders, whether such an approach could be applied in health and care. While healthcare professionals know intuitively that there is a need to involve stakeholders in decisions and think across pathways, and many people working to improve health and care are aware of and use systems techniques, lessons could be learned from the different perspectives of the engineering sector and the analysis and rigour applied in engineering systems. Our project findings are based on an extended conversation within a unique forum of experts, led by the Royal Academy of Engineering, in collaboration with the Royal College of Physicians and the Academy of Medical Sciences. We brought together systems engineers, health and care professionals, quality improvement experts, and patient representatives (see *About the project*, page 87 for details) to define a systems approach for health and care, and develop a new and integrated approach to service design and improvement.

This preliminary report outlines the findings from this work, providing a clear definition of a systems approach, setting out a framework and tools for its implementation in health and care, and presenting case studies exemplifying the importance of such an approach for health and care improvement. It is aimed at

Engineers use a systems approach to address challenging problems in complex projects such as the Channel Tunnel stimulating conversations with funders, healthcare provider leaders, teams and individuals delivering quality improvement and service design. Its ideas and tools can be used for improvement by everyone in health and care roles in all professions, clinical and non-clinical, from the smallest local teams to the largest national organisations. This way of thinking is particularly powerful when dealing with complex changes across multiple organisations. Table 1 signposts sections of the report that may be particularly helpful for different readers.

Following our initial exploration, we invite more partners to join us in the next phase to test the contents of this report in the field and to build evidence for and augment what we have proposed. We are continuing discussions with project partners, workshop participants, funders and government on how to best test, and subsequently embed, our ideas into current drives to improve quality and transform health and care. We will seek to publish case studies of this work as it is tested and developed.

Table 1: Report sections that may be particularly helpful to different readers

Audience	Key sections	Content of key sections
Clinicians and other healthcare professionals	Section 1 Annexes 1 and 2	Worked case studies exemplifying the importance of a systems approach
Healthcare transformation and improvement professionals	Sections 3, 4 and 5 Annexes 1, 2, 3 and 4	Detailed description of an engineering systems approach and its application in a healthcare context
Executive leads, research and improvement funders	Sections 1, 2 and 5	Top level description of the systems approach and the value of its application in healthcare
Engineers and systems leaders	Sections 1, 2 and 5 Annexes 1 and 2	Description of the potential for application of systems approaches in a healthcare context

2 *Building a better delivery system: A new engineering/health care partnership,* National Academy of Engineering and Institute of Medicine, 2005.

3 *Learning from Bristol, The Bristol Royal Infirmary Inquiry*, Report of the Public Inquiry, 2001.

4 *Design for patient safety, A system-wide design-led approach to tackling patient safety in the NHS,* Department of Health and Design Council, 2003.

Section 1
Healthcare as a ‘system of systems’

What does Esther need?

The Esther model is guided by questions such as 'What does Esther need?' and 'What is important to her when she is not well?' to drive continuous improvement

See case study 1, page 52, and Annex 1: *Applications of the approach*

All improvement initiatives involve people, processes, technologies and systems that, in turn, are part of other systems. This complexity means that all parts of the health and care system stand to benefit from using an approach which considers each relevant element of the overall system and joins them up efficiently. As an example, consider the case of Mrs G:

After a fall Mrs G, a frail 80-year-old who lives alone, calls an ambulance and paramedics transfer her to hospital. She tells them she has diabetes, pulmonary disease, heart failure and kidney problems. The A&E staff are not sufficiently confident to send her home because they cannot establish the cause of her falls, access her GP record of treatment or enable extra support or assessment in her home for the next morning.

Mrs G is therefore admitted and it takes days for the hospital to investigate the reasons for her fall. After lying in bed for this time she loses all confidence to move unaided. Transfer to an intermediate care facility is advised and four days later she is moved, still not confident to get out of bed alone. Mrs G is worried she will end up in a nursing home and so are her family who live far away.

For Mrs G the 'system' does not meet her needs. This is because of inadequate planning, a lack of system-wide design and poor implementation, resulting in a disjointed service. The alternative, the result of taking a systems approach founded on an understanding of people, systems, design and risk, could be so different:

After a fall Mrs G, a frail 80-year-old who lives alone, calls a number given to her by her community support group. A community nurse attends, checks Mrs G's blood sugar level as she seems confused, and makes her something to eat. The nurse checks the care plan with the community-based team and rings Mrs G's daughter to update her on the situation.

Next day a speciality frailty nurse calls at Mrs G's home to reassess her abilities, as this was her second fall in two weeks. The nurse arranges extra short term care and discusses with Mrs G the possibility of moving into assisted living. The nurse arranges for her to visit a nearby facility with her daughter, updates her care plan and shares it with the GP and multi-professional team at the hospital. Mrs G is happy with the outcome and her family are reassured that plans are in place to deal with any future problems.

In the revised scenario, Mrs G lives in an area where frailty has been identified as a priority issue. Putting system-wide strategies and partnerships in place to improve the quality of care, based on the known needs of local people and using available teams, means Mrs G's care works smoothly across the interfaces between different systems of care. Healthcare is indeed a system of systems and optimising how it works saves money. In this scenario ambulance waiting times are reduced, hospital costs are avoided and patient flow improves because more people have the expertise and authority to contribute to Mrs G's care. She is safer because her care plan is seen by more health and care professionals and she has a better patient experience.

The participants of the programme leading to this report recommend that the situation described in the revised scenario would most effectively be achieved using a systems approach to design and improvement.

Improving safety

A solution was co-designed with patients, GPs, pharmacies the pharmaceutical industry and engineers to reduce the risk of death from methotrexate overdose

See case study 2, page 53, and Annex 1: *Applications of the approach*

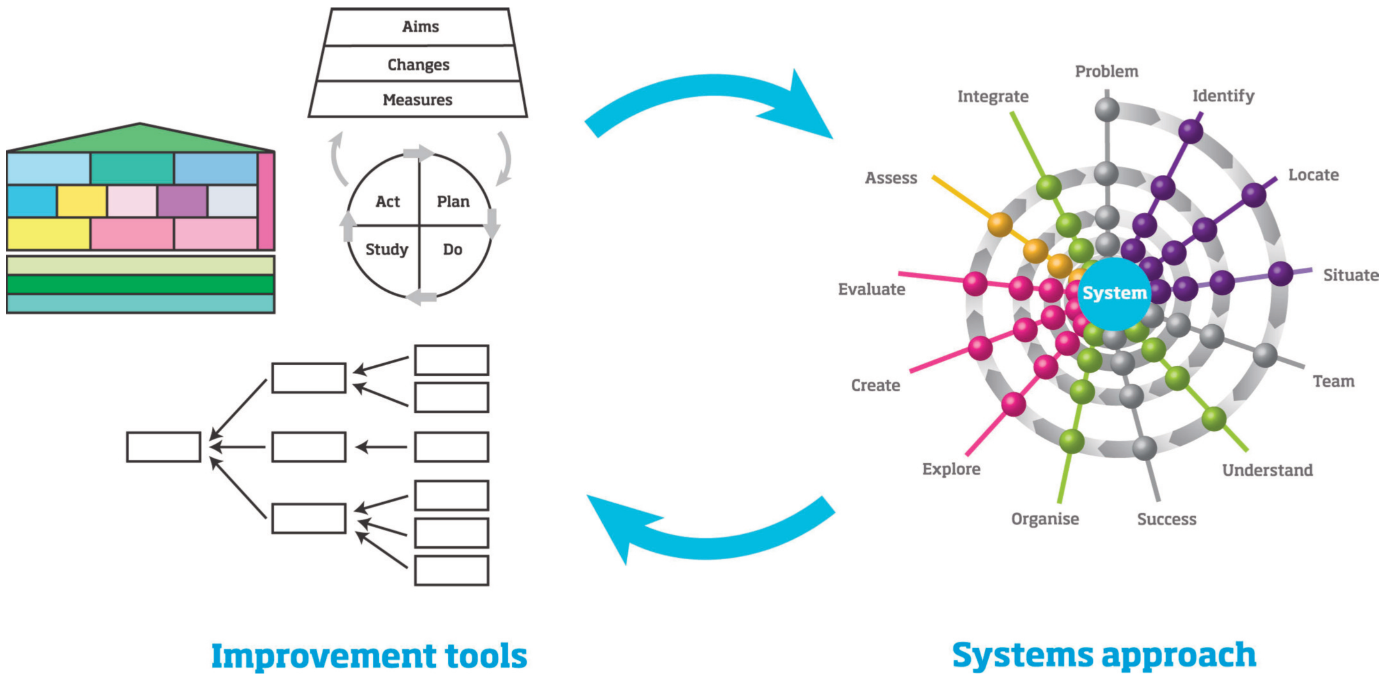
Section 2
Approaches to improvement

Improvement teams in health and care already have a range of theories of change and improvement approaches available: the *NHS change model, IHI model for improvement, leading large scale change, human factors in healthcare, lean in healthcare, experience-based co-design, root cause analysis,* to name a few.

While a number of these approaches already include tools, such as Failure Modes and Effect Analysis (FMEA) and mapping techniques, that may be found in engineering methods the systems approach proposed in this report has the potential to add further value to the improvement agenda in two distinct forms. The provision of new tools and ways of thinking can supplement existing approaches; and the adoption of a systems approach as a method in its own right can guide a design from a set of complex needs through to validated, effective operational systems (Figure 1).

Figure 1: A systems approach to health and care improvement

Improvement tools, such as the IHI model for improvement, the NHS house of quality and driver diagrams can complement the activities of a systems approach that in turn can add new tools and ways of thinking to existing improvement approaches.



New ways of thinking include designing for ease of access. As we live longer, we are more commonly living with cognitive and/or physical conditions that restrict our access to services. Consider the arthritis sufferer struggling with a child-proof cap, or the dementia sufferer regarded as a 'Did Not Attend' because she forgot her appointment. *Inclusive design*, the design of mainstream products and/or services that are accessible to and usable by people with the widest range of abilities within the widest range of situations, is embedded within the systems approach. It uses a suite of tools to help answer two important questions: what proportion of our service users can easily access the service we offer; and how do we systematically design for maximum user accessibility? While other approaches proceed with the user in mind – for example, *human-centered design* immerses the patient or service user in the design process – none systematically ensure that we design with the whole population in mind, both as patients and providers.

There are other key areas in which new ways of thinking, derived from a systems approach, can supplement existing methods. This includes, measuring and designing system interfaces to alleviate service integration issues and using *systems safety assessment* to proactively design risk out of systems and avoid incidents rather than merely reactively preventing a recurrence. In such cases, existing improvement approaches may be enhanced by using techniques from a systems approach.

The systems approach is also a method in its own right that applies tools to answer a series of questions (Section 5: *A framework for action*, page 33) in an iterative and systematic way in order to guide a design from a set of complex needs through to validated, effective operational systems. During this process, experienced improvers can use their own tools, frameworks and experiences of change to supplement those drawn from the systems community. Whether it is in enhancing existing approaches through additional tools and techniques, or encouraging improvements to be guided by a series of critical questions, a systems approach can greatly enhance the capability and potency of professionals delivering change.

There are a number of approaches from the health and care improvement and engineering communities that have the potential to help teams understand *people*, deliver *systems*, facilitate *design* and manage *risk* (Annex 4: *Compilation of approaches*, page 79). Most excel with one of these perspectives while some attempt to support a more holistic integrated systems approach. Table 2 maps their strengths in delivering a systems approach.

The approaches range from health and care improvement methods and tools to design-led safety management and human factors methods. It is evident from Table 2 that engineering approaches provide more complete coverage of a systems approach, particularly in terms of *design* and *risk*, than current healthcare approaches. Further details of all the methods and tools are given in Annex 4: *Compilation of approaches*, page 79. The interplay between a systems approach and current improvement approaches is explored in more detail in Section 5: *A framework for action*, page 33.

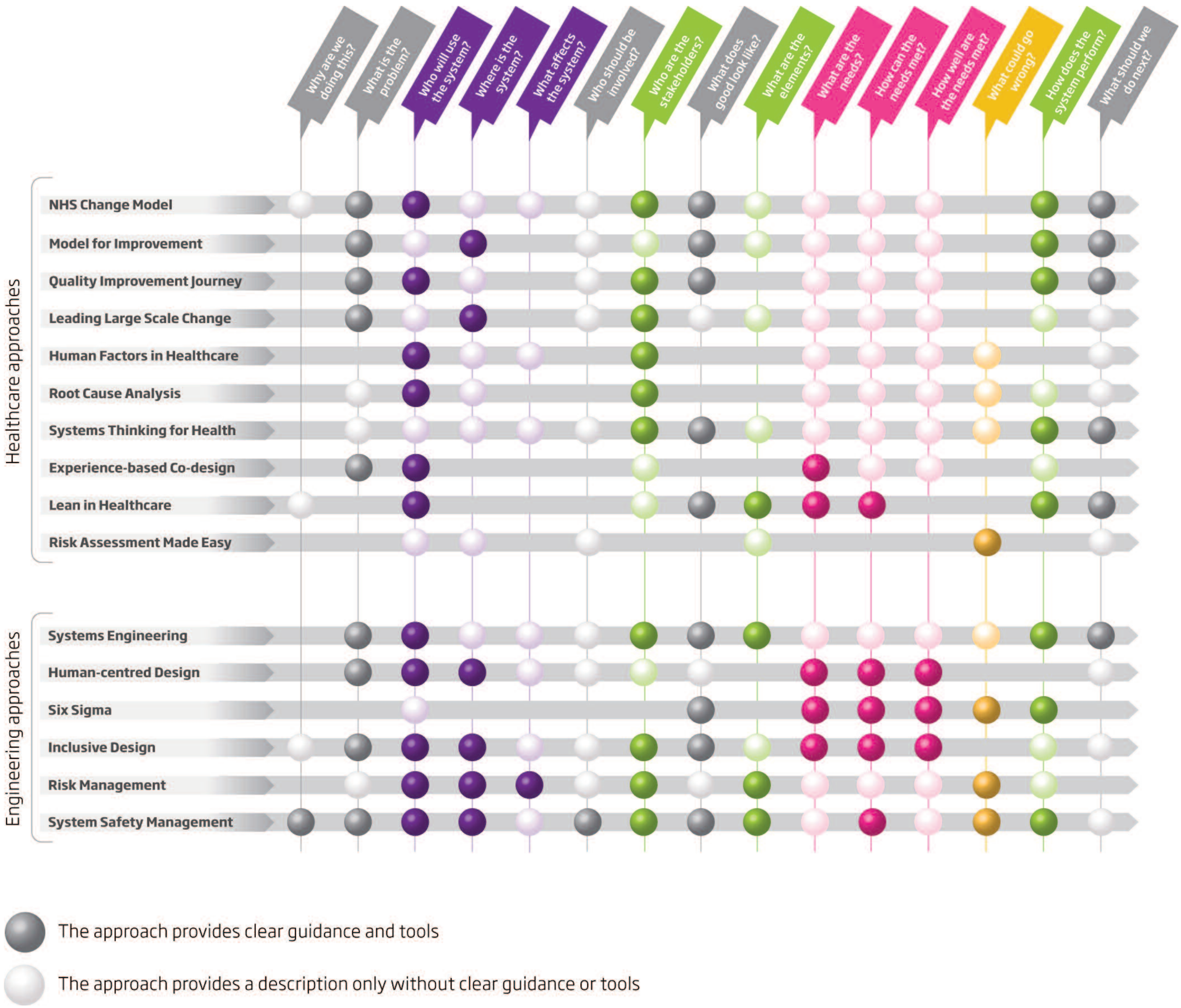
Large scale change

Michigan hospitals reduced the rate of catheter-related bloodstream infections to a median of zero infections per 1000 catheter days by proactively controlling risk

See case study 3, page 54

Table 2: Comparison of methods

A map of healthcare and engineering improvement approaches showing the working group's assessment of their relative strengths in delivering a systems approach as described in the following sections and Annex 3: *Elements of a systems approach.*

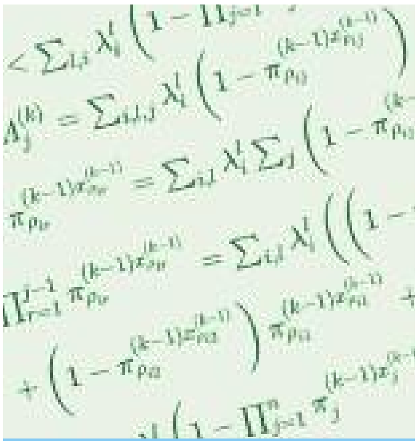


To a certain extent, this report describes what might be thought as common sense. However, common sense is not always as common as might be imagined. What is new is the development of a framework and language suited to health and care processes.

We explored the elements that make up a systems approach and asked health and care professionals who are active in delivering change to identify which of these elements are missing or not strong enough in current health and care practice.

We can summarise our shared learning as:

1. **Systems are centred on people** – an effective systems approach is centred on people, their needs, their capabilities and ultimately their role in understanding, designing, delivering and maintaining success.
2. **Iteration before implementation** – the behaviour of complex systems is not easily understood and improvement is most often the result of successive iterations targeted at maximising the chance of success prior to implementation.
3. **Design is an exploratory process** – improvement results from a creative process that seeks not only to explore the real need, but also to evaluate a range of possible solutions in order to select the best option.
4. **Risk management is a proactive process** – the identification of possible opportunities for and threats to a system before they arise is more likely to lead to the delivery of robust and adaptable systems.
5. **Thinking changes practice, process helps** – individual perspectives give rise to changes in thinking that can immediately permeate current practice; a new process is an opportunity to deploy new thinking.
6. **Common sense is not common** – there is an increasing number of islands of excellence when it comes to using a systems approach; however, the common sense thinking presented here is still far from being common in practice.



Predicting outcomes

Modelling and simulation informed the required patient-flows and resourcing levels in a London trauma centre, reducing waiting times and improving care

See case study 8, page 59

Section 3
Defining a systems approach

Empowering patients

Clinical support services in imaging, physiotherapy, occupational therapy, dietetics and speech and language therapy are coordinated through inpatient schedules

See case study 11, page 62

A true systems approach is one that consistently delivers a high-quality service and is most likely to be the result of a team successfully integrating *people, systems, design* and *risk* perspectives in an ordered and well executed manner.

A system (or system of systems) is a set of elements: people, processes, information, organisations and services, as well as software, hardware and other systems that, when combined, have qualities that are not present in any of the elements themselves.

A system is delineated by its spatial and temporal boundaries, surrounded and influenced by its environment, described by its structure and purpose, and expressed in its functioning. In other words, the whole is very likely to be greater than the sum of the parts.

For example, the human body is a system of systems where each has its own purpose and function. When combined, the systems produce for the body qualities not present in any of the individual elements. Conversely, if any individual system is compromised or a part of the body is damaged, the overall function may be significantly or terminally impaired (Figure 2).

Figure 2: A system of systems – different perspectives on the human body

The human body is a system of systems, comprising amongst others the circulatory, digestive, nervous, integumentary, muscular, skeletal and respiratory systems. Each has its own purpose and function and yet when combined, they produce for the body qualities not present in any of the individual elements.

A systems approach uses a range of techniques to determine requirements for the system, organise its structure, create and evaluate alternative designs, produce quantitative analyses and predictions where appropriate, assess possible threats to and opportunities for people and other systems, integrate all the individual elements and deliver a system that is shown to be fit for its intended purpose. A true systems approach does not deliver solely technical solutions; rather it ensures the appropriate alignment of technology, processes, interactions and policy to deliver innovative responses to today's most complex and pressing challenges.

A systems approach can be applied to the design and improvement of systems across many areas of health and care. This is illustrated by the inclusion of references to case-studies throughout the report.

A systems approach can be applied to the design and improvement of systems at all extremes of scale, with service level improvement taking place within a wider context that may subsequently require changes at the organisation level and cross-organisational level. Within the delivery of health and care, many systems are distinct and can be operated independently, yet are also connected to or integrated with other systems, either in layers or as part of a network. The strength of a systems approach is its ability to overcome the complexity associated with such systems of systems and deliver solutions at all levels of scale regardless of the form of the system. Its value has been recognised in health and care and increasingly referred to in national policies and used in improvement methods.

A systems approach aims to determine the system design and implementation that delivers the best service. It has the potential to drive greater efficiency and a better understanding of threats and opportunities present when shaping the delivery of health and care services. A systems approach brings together four key and complementary perspectives (Figure 3):

- **People:** understanding of interactions among people, at the personal, group and organisational levels, and other elements of a system in order to improve overall system performance (identify, locate, situate)
- **Systems:** addressing complex and uncertain real world problems, involving highly interconnected technical and social elements that typically produce emergent properties and behaviour (understand, organise, integrate)
- **Design:** focusing on improvement by identifying the right problem to solve, creating a range of possible solutions and refining the best of these to deliver appropriate outcomes (explore, create, evaluate)
- **Risk:** managing risk, based on the timely identification of threats and opportunities in the system, assessment of their associated risks and management of necessary change (examine, assess, improve).

A holistic approach

Seeing a visit to the Emirates stadium as one part of a wider 'system of systems' helps create a successful match day experience for Arsenal fans

See case study 6, page 57

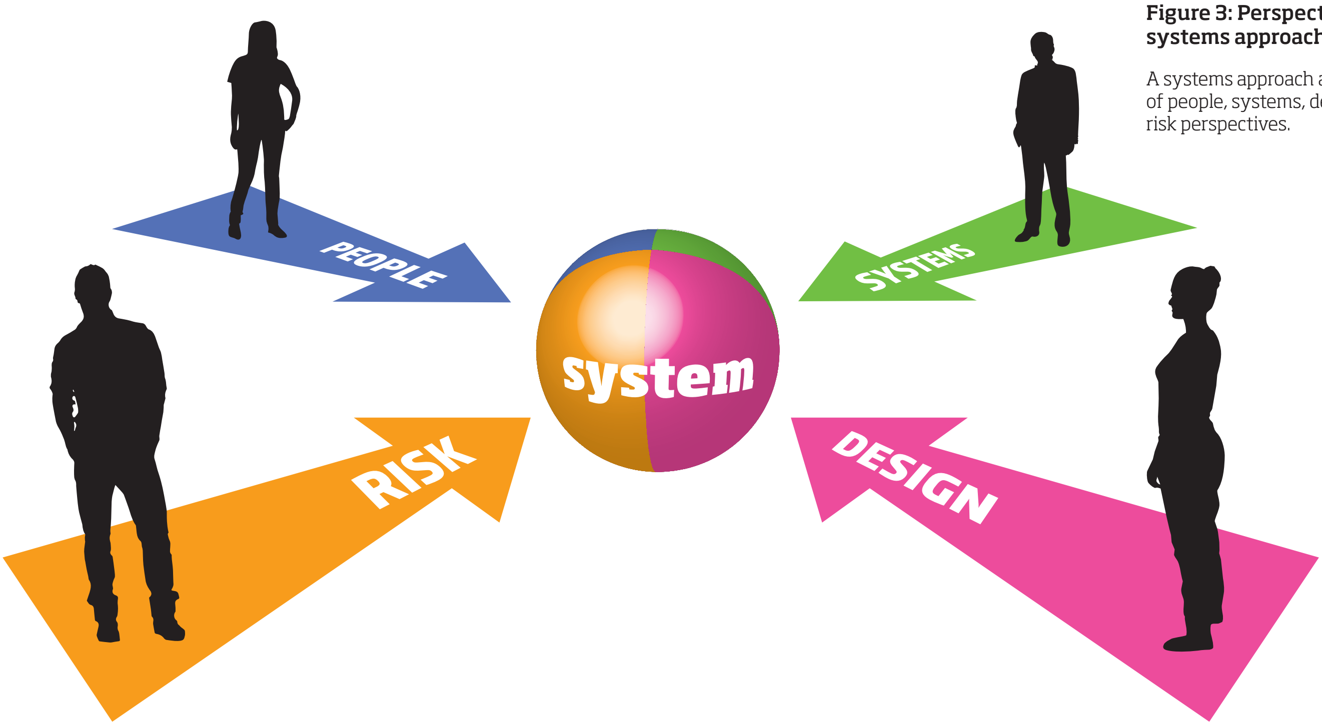


Figure 3: Perspectives of a systems approach

A systems approach as the sum of people, systems, design and risk perspectives.

All these perspectives are inextricably linked and uniquely contribute to a systems approach. It is only when all four are robustly understood (Annex 3: *Elements of a systems approach*, page 65). that a systems approach will have the greatest success. Their scope, purpose and operation can be summarised through the answers to a number of high-level questions (Table 3) that were developed and agreed during the project workshops (*About the project*, page 87). These are listed according to their particular perspective and with reference to a number of case studies (Annex 2: *Case studies*, page 51) that highlight their application in practice.

The challenge is to convert these questions into a useful, versatile and systematic process that repeatedly delivers results. Each of the four perspectives of *people, systems, design* and *risk* can be seen as individual components within an improvement process and there is merit in emphasising their particular individual characteristics when striving for improvement.

Strategies for implementing a systems approach range from the adoption of individual *people, systems, design* and *risk* perspectives within existing improvement processes, to the design of new processes that provide an appropriate framework for combining all the perspectives.

Table 3: Key questions that summarise an effective systems approach

People:

Who will use the system? – leads to an understanding of the diversity of people involved and their needs and capabilities (identify).

Where is the system? – leads to an understanding of the physical, organisational and cultural context of the system (locate).

What affects the system? – leads to an understanding of the political and policy landscape within which the system is situated (situate).

Systems:

Who are the stakeholders? – leads to a common view of the stakeholders and their individual interests, needs, values and perspectives (understand).

What are the elements? – leads to an agreed system boundary, architecture and details of the interfaces between all the system elements (organise).

How does the system perform? – leads to a complete, operational system that is proven to meet the stakeholder requirements (integrate).

Design:

What are the needs? – leads to a common understanding of the needs for a system, taking account of the full range of stakeholders (explore).

How can the needs be met? – leads to a range of possible solutions that would help meet the needs identified by the explore phase (create).

How well are the needs met? – leads to an evaluation of possible concepts that could meet the needs identified by the explore phase (evaluate).

Risk:

What is going on? – leads to an understanding of the system architecture and details of the interfaces between the elements (examine).

What could go wrong? – leads to a systematic assessment of the likelihood and potential impact of threats and opportunities in the system (assess).

How can we make it better? – leads to a range of possible solutions that would help mitigate the threats or exploit the opportunities (improve).

Improvement initiatives involve people and systems that, in turn, are inevitably part of other systems. Consequently, they would all stand to benefit from using a systems approach that delivers coordinated improvement to all the systems.

All improvement initiatives should start with the question:

- **why are we doing this?** – leads to a documented rationale for improving an existing system or developing a new one (trigger).

The trigger

The trigger defines the entry point for any subsequent improvement process and may be the result of:

- **strategic development:** where risk reduction and improvement is part of an ongoing strategic initiative
- **an incident:** where an event has resulted in actual or potential harm to patients or clinicians
- **local concerns:** where the potential for incidents has been identified through general observation or evidenced by data trends
- **routine service review:** where a team or individual wishes to check the integrity of their service
- **service improvement:** where national, regional or local changes are planned to an existing service or system
- **new service:** where a new service is to be introduced into practice or an existing one decommissioned
- **technology introduction:** where new equipment or technology is to be introduced to an existing service
- **building or estate changes:** where estates or buildings are being built, refurbished or maintained
- **staff changes:** where new staff are to be introduced to an existing service or exiting staff levels are changed
- **external directive:** where specific strategic changes or checks are requested
- **national initiatives:** where teams are encouraged to propose and deliver service improvements .

A clear understanding of the trigger helps to identify the initial scope of the improvement and ensures that an appropriate team is assembled to initiate any subsequent improvement process. Whether the trigger relates to people, systems, design or risk, a systems approach will consider all of these perspectives in a seamless and integrated way. This leads onto a final ongoing challenge:

- **what should we do next?** – leads to the ongoing development and execution of a plan of action to deliver the system in a timely manner (plan).

System failure

How limited understanding of whole system performance and emergent behaviours led to the collapse of a computerised command and control system

See case study 5, page 56

Section 4
A framework for thinking

Right first time

Patient and staff personas were created to increase the team's understanding of people's potential behaviour in the yet-to-be-built St. Aubyn centre

See case study 4, page 55

A true systems approach is one that consistently delivers a high-quality service and this is most likely to be the result from a team successfully integrating *people, systems, design* and *risk* in an ordered and well-executed manner.

As with a juggler (Figure 4), dropping any particular ball would compromise the integrity of their performance, in the same way that ignoring any particular perspective might compromise the performance of a system.

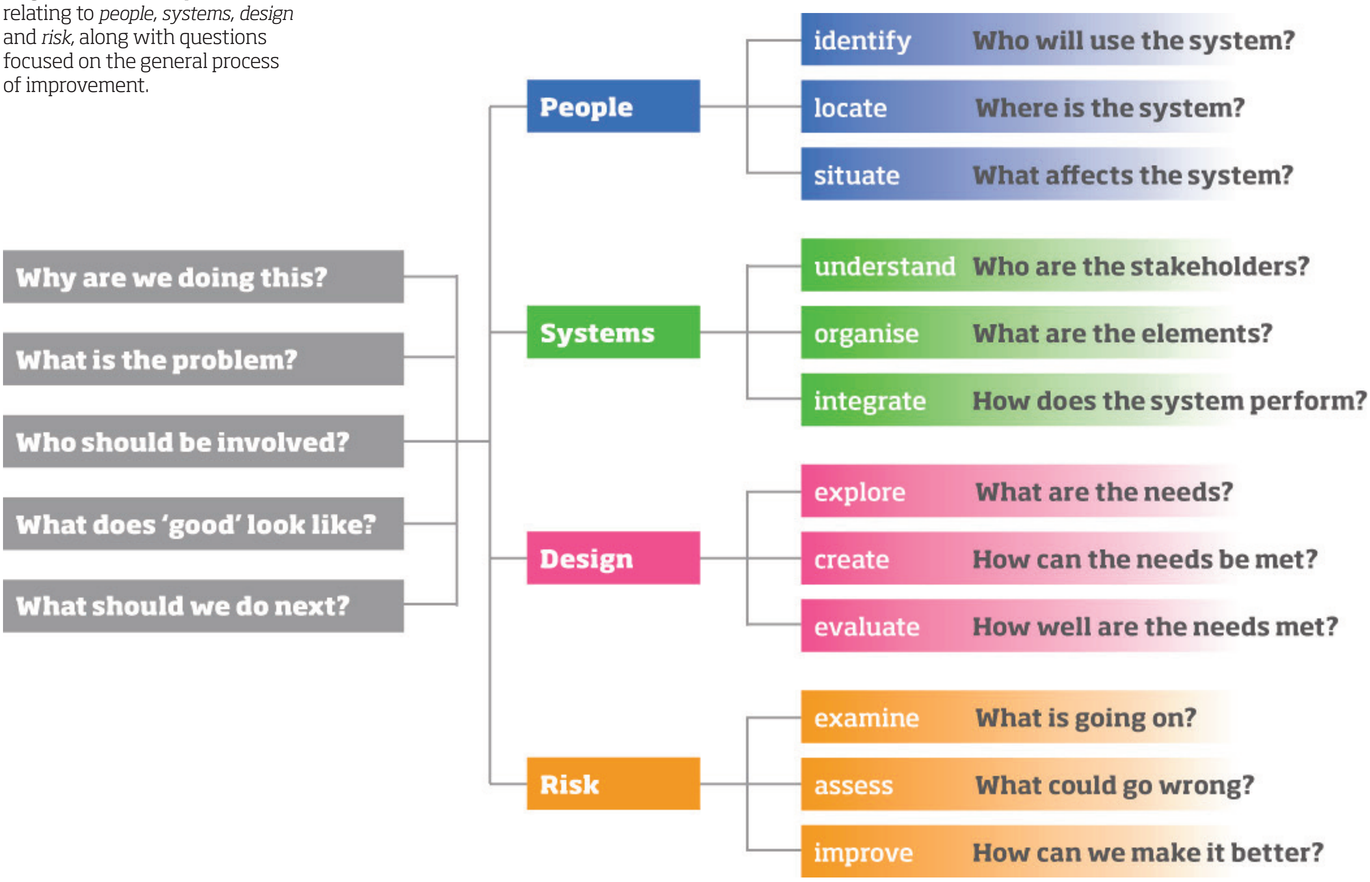
Adopting one or more of the four perspectives (Annex 3: *Elements of a systems approach*, page 65) into current practice can be done by simply asking ourselves the appropriate guiding questions (Figure 5). There should be an emphasis on integrating *people, systems, design* and *risk* thinking within current improvement processes, assisted by a number of existing tools (Section 2: *Approaches to improvement*, page 17).

Figure 4: A combined approach – keeping all the perspectives in play

When juggling, the performance is only complete if all the balls remain in the air. Similarly, a systems approach is only complete if all the perspectives are kept in mind during the design or improvement of the system.

Figure 5: An integrated approach – a framework for thinking

A systems approach can be thought of as a set of activities targeted to answer questions relating to *people, systems, design* and *risk*, along with questions focused on the general process of improvement.



Section 5
A framework for action

The systems approach can also be considered as a method in its own right that applies tools to answer the key questions in an iterative and systematic way to guide a design from a set of complex needs through to validated and effective operational systems.

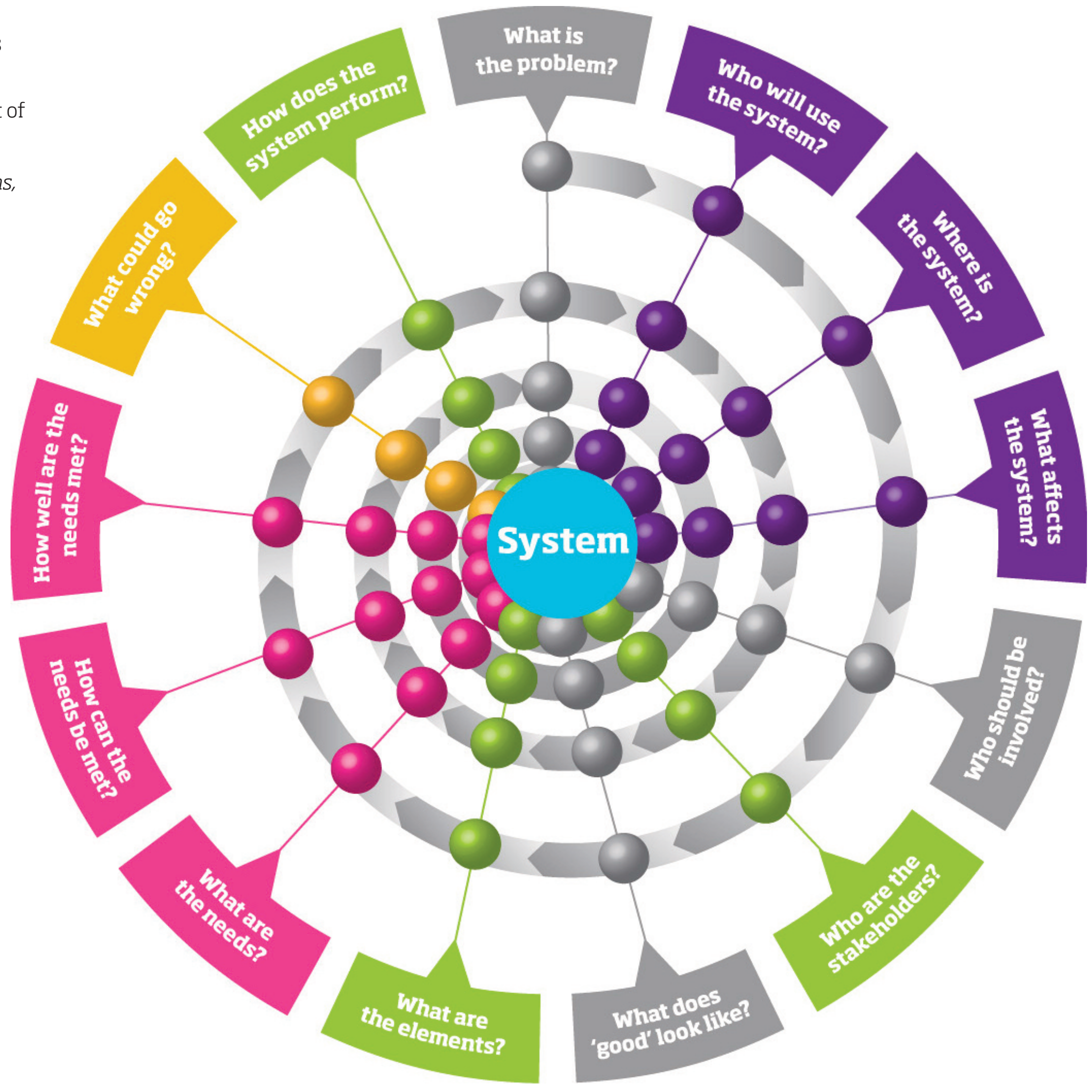
In this context, the questions have been rationalised where the four perspectives overlap and improvement programme questions, relating to the *problem, team* and *success*, have been added:

- **What is the problem?** – leads to a common and clearly articulated view of a better system based on an understanding of the current system (problem).
- **Who should be involved?** – leads to a common and clearly articulated understanding of who should deliver the improved system (team).
- **What does 'good' look like?** – leads to a common and clearly articulated understanding of success and how it would be measured (success).

Reordering then provides a natural sequence for all the questions (Figure 6):

Figure 6: A systems approach as an ordered series of questions

A systems approach can be thought of as an ordered and iterative set of activities targeted to answer questions relating to *people, systems, design* and *risk,* and the general process of improvement.



The spiral model shows the natural order of the steps. It also highlights that a systems approach is not a simple linear process, but an iterative process of continuous improvement. It suggests that the first question to be asked concerns the problem to be addressed by the system. This would be followed by questions based on people to understand the background and context to the new system. The questions on systems, design and risk are then interwoven to provide an opportunity to specify, design and evaluate the system and its constituent elements, with a question on what a good outcome would look like early in this sequence.

The idea would be that in the first 'pass' of the questions, preliminary answers would be provided. Further 'passes' would offer an opportunity to provide more detailed answers or again to 'skip' and use the previous answer for that iteration. This process affords the opportunity to progressively increase knowledge of the problem, reduce uncertainty regarding the solution, and manage the implementation risk to an acceptable level. Ultimately, the answers would form a description of the improved system.

It is expected that the methods used to answer the questions would increase in complexity as each question is revisited, until further effort brings limited benefit to other questions in the cycle. For example, initial answers might be based on estimates or knowledge of previous solutions, while later answers could be determined by extensive investigation, advanced modelling and simulation, or evaluation of prototypes.

The spiral model allows the questions to be overlaid on an existing improvement process, at sufficient intervals and to the level of precision required, while ensuring that they are asked in an appropriate order. A number of existing approaches already exist that may assist in answering the questions (Section 2: *Approaches to improvement*, page 17 and Annex 4: *Compilation of approaches*, page 79). The spiral model is also adaptable to all levels of scale, from the service level, through the organisation level to the cross-organisational level, and is sufficiently versatile to apply across all areas of health and care.

This approach is common to all improvement processes where the focus on moving a system from its current performance to a future, measurably better state. Such processes typically include a number of key phases to ensure success (Figure 7):

- **Understand** – leading to a description of the current system (now), a common understanding of the problem, a consensus view of what the future system might look like (better) and a clearly articulated case for changing the system.
- **Design** – leading to a clear description of the future system, based on the iterative design of the system architecture with its elements and interfaces, the evaluation through successive prototyping of its likely behaviour, and a plan for its delivery.
- **Deliver** – leading to the successful deployment of the new system with the levels of measurement necessary to evidence its success, and acceptance that it achieves appropriate value for its stakeholders.
- **Sustain** – leading to the continued operational success of the new system along with consideration of further improvement potential or wider deployment.

End of life care

Services needed by terminally ill patients and their carers are coordinated across Airedale General Hospital by a 24/7 telehealth and phone line service

See case study 10, page 61

Design Bugs Out

A collaborative programme to identify opportunities to help combat infections by making hospital furniture and equipment easier and quicker to clean

See case study 7, page 58

The purpose of the phased approach is to progressively increase the clarity of definition of the revised system while reducing the operational risk. Each of these phases can be inspired by the adoption of the individual *people, systems, design* and *risk* perspectives. Alternatively, the spiral model, which may be thought of as progressing through time and spanning all phases, can be adopted and adapted to complement the generic improvement approach (Figure 8).

The early iterations of the spiral would focus on increasing understanding of the problem and, if a case for change is agreed, later iterations would provide more focus on the design and delivery of the system and its sustainability. The model also lends itself to the development of systems of systems, where early iterations of the spiral would focus on architecting the overall system, leading to parallel iterations to develop and deliver individual systems, and further iterations to ensure their integration and subsequent evaluation of the overall system.

The ultimate success of the systems approach would depend on keeping all of the relevant questions in mind on each iteration. In practice, a degree of concurrency across the phases is required. The *understand* phase requires adequate consideration of the *design, delivery* and *sustain* phases to create a clear view of the future system, while the *sustain* phase depends on consideration of sustainability issues throughout the previous phases. Such concurrency, or involvement of key stakeholders throughout the improvement process, is essential if new performance targets are to be realised in a safe, timely and cost-effective manner.

The sequence of questions in the spiral model not only provides an excellent starting point for delivering a successful improvement process, but also assists in addressing a number of other factors that should be considered when designing systems:

Behaviour – when integrating people, processes, technology and the built environment, it is hard to predict all the behaviours that will subsequently emerge. It is important to design for intended behaviours and outcomes, observe the resultant system behaviours, identify unintended consequences and predict possible variations over time (*problem, identify, locate, organise, evaluate, assess, integrate*).

Measurement – systems behave in a variety of predictable and less predictable ways in response to internal and external data and events. It is important to understand the need for measurement of a system's performance, implement the means to facilitate such measurement and determine the way in which the resulting data will be used (*success, organise, explore, create, evaluate, integrate*).

Communication – dysfunctional teams are unlikely to deliver good systems; functional teams are more likely to do so. It is important that the team talks to one another, develops clear plans and instructions, ensures there is a common understanding of the system and engages with all the stakeholders, particularly the users, in the delivery of the system (*identify, locate, understand, organise, integrate, plan, team*).

Learning – the ability of individuals and organisations to learn enhances their chances of delivering and sustaining effective systems. It is important to develop a culture of continued learning for all stakeholders, build capacity within organisations to deliver effective systems and share stories of success to inspire future systems-based change (*identify, locate, situate, team*).

Interfaces – systems are only as good as their interfaces. Between every element of a system there are interfaces to other elements or systems. It is important to organise the elements of a system, define and maintain the necessary interfaces between them, and define and manage the interfaces between the system and its environment (*problem, identify, locate, organise, success, integrate*).

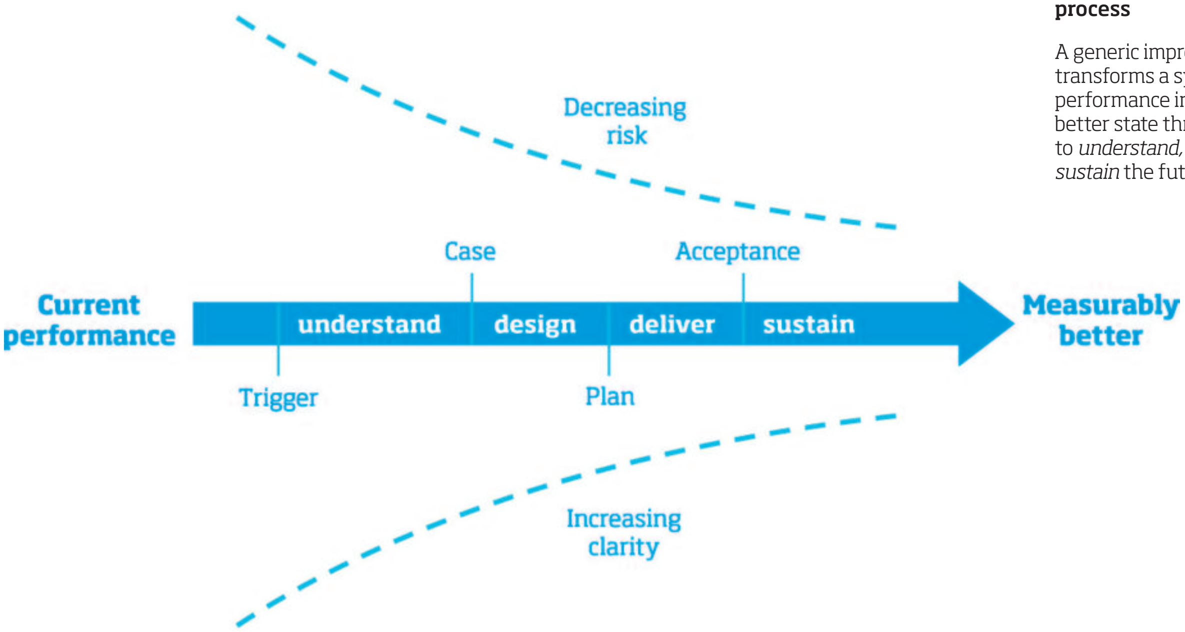


Figure 7: A generic improvement process

A generic improvement process transforms a system's current performance into a measurably better state through phases intended to *understand, design, deliver* and *sustain* the future system.

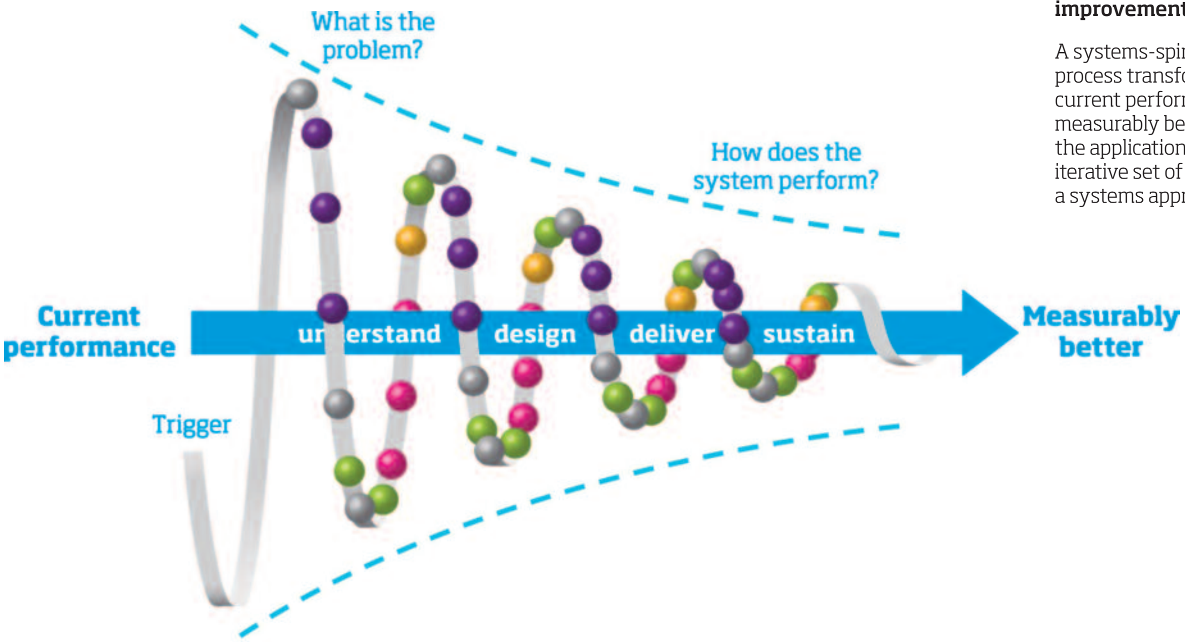


Figure 8: A systems-spiral improvement process

A systems-spiral improvement process transforms a system's current performance into a measurably better state through the application of an ordered and iterative set of activities based on a systems approach.

Sustainability and care

Lighting levels in a new neonatal intensive care unit provide a calm environment for parents and staff leading to better care and lower energy consumption

See case study 13, page 64

A true systems approach then combines consideration of *people, systems, design* and *risk* in an ordered and well-executed manner to ensure that improvement is driven by clear and agreed goals, is systematic, holistic and inclusive, is supported by trustworthy evidence and is sustainable.

The adoption of a systems approach to design and improvement will transform health and care. Transformation teams and individuals charged with improving care are encouraged to ask the questions posed in this preliminary report as a first step towards changing the way they think and act.

Further assistance may be sought from members of the working group and project team listed in *About the project*, page 87, or by reference to reading material and tools listed in the Bibliography.

Annex 1
Applications of the approach

The studies that follow explore retrospectively how the questions from the spiral model of the systems approach could have been applied (Section 5: *A framework for action*) to the development and deployment of:

- **The Esther Model of care for elderly persons with complex care needs** – a multi-organisational collaboration between acute, primary and social care providers was created by Jönköping County Council to develop a model for the improvement of patient-centred care in the community, based on a fictitious patient known as Esther (see also Case study 1: *Esther Model*).

- **Safer care for patients using oral methotrexate for the treatment of rheumatoid arthritis** – local and national stakeholders, led by the National Patient Safety Agency (NPSA), were engaged in making the design of methotrexate tablets and their prescription, delivery and monitoring safer for patients (see also Case study 2: *Oral methotrexate*).

The Esther Model, health and care integration in Jönköping, Sweden

The answers that follow represent those that may have been formulated by the end of the programme, accepting that there was some iteration between the *people, systems* and *design* elements of the work. They are nonetheless representative of the systems approach originally applied to the challenge of improving the care for elderly persons.

Why are we doing this?

Esther lived alone and one morning developed breathing difficulties. After contacting her daughter, who did not know what to do, Esther sought medical advice. She saw a total of 36 different people and had to retell her story at every point, while having problems breathing. A doctor finally admitted her to a hospital ward. This case inspired the head of the medical department of Höglandet Hospital in Nässjö to initiate an extensive series of interviews and workshops to identify redundancies and gaps in the medical and community care systems.[5]

What is the problem?

Elderly patients with complex care needs may receive services from multiple specialists, as well as primary care physicians. In addition, they may visit emergency departments, have frequent hospitalisations and post-hospital rehabilitations, and receive long-term care services at their home or in nursing facilities.[6] The central idea was that care should be guided by the following questions: What does Esther need? What does she want? What is important to her when she is not well? What does she need when she leaves the hospital? Which providers must cooperate to meet Esther's needs?

Who will use the system?

Elderly persons who have complex care needs that involve a variety of providers, along with carers and a number of health and care professionals.

Where is the system?

The Höglandet (Highland) region (population: 110,000) in Jönköping County, in the south of Sweden, where the county has 34 primary care centres and three acute hospitals, with a total health workforce of 9,500, serving a local population of 350,000 across 11 municipalities.

What affects the system?

Care coordination in Sweden is complicated by a legal structure that gives the country's 21 counties responsibility for funding and providing hospital and physician services while the 290 municipalities are responsible for funding and providing community care. Home health care (nursing services for sick patients) and home care (assistance with activities of daily living) are also provided by different professionals.

Who should be involved?

Patients and carers, and people involved in the supply, management and control of care for elderly people, such as physicians, nurses, social workers, other providers representing the Höglandet Hospital and physician practices in each of the six municipalities.

Who are the stakeholders?

Stakeholders are those that have an interest in the successful performance of the system and can be described by their role title, need(s) and purpose:

As a *patient* I need care in or close to my home **so that** I can stay at home. **I need** to experience care from multiple providers as if it were from the same provider **so that** they all know my medical history. **I need** to have care uniformly available throughout the region **so that** I feel free to travel, and **I need** to know who to turn to when problems arise **so that** I feel safe.

As a *carer* I need to understand Esther's needs **so that** I can help care for her, and **I need** to know who to call if Esther needs help **so that** I can be sure of talking to someone who knows her.

As a *neighbour* I need to have a contact number for emergencies **so that** I can quickly summon medical assistance.

As a *primary care physician* I need to provide the best care possible for Esther in the community **so that** her medical needs are met locally as far as is possible. **I need** access to Esther's full medical history **so that** I know what treatment may have been provided by the hospital and what level of social care is being provided.

As a *pharmacist* I need access to Esther's medical history **so that** I can check that her medications are safe to be taken together.

As a *hospital physician* I need access to Esther's medical history **so that** I can prescribe the most appropriate treatment, and **I need** to be sure that appropriate care is available **so that** I can safely discharge Esther from hospital.

As a *specialist* I need access to Esther's medical history **so that** I can provide appropriate specialist treatment as required.

As a *nurse* I need access to Esther's medical history **so that** I can care for her, and **I need** to know Esther **so that** I can do what is best for her.

As a *home healthcare worker* I need access to Esther's medical history **so that** I understand her care needs, and **I need** to know Esther **so that** I can do what is best for her.

As a *home care worker* I need to have a contact number for emergencies **so that** I can be sure of talking to someone who knows her, and **I need** to know Esther **so that** I can do what is best for her.

As a *hospital manager* I need to understand Esther's care needs **so that** I can ensure she receives the care she needs and coordinate her discharge from hospital. **I need** to ensure she remains in hospital only as long as is medically required **so that** I can manage my budget wisely.

As a *community care manager* I need to understand Esther's care needs **so that** I can coordinate her care, and **I need** to be consulted if she is to be discharged from hospital **so that** her immediate care needs can be met.

As a *service provider* I need to ensure that I meet Esther's care needs **so that** I can do what is best for her, and **I need** to know how well I am meeting her needs **so that** I can continuously improve the care I am able to provide.

As a *funder* I need to be confident that the money I provide for the care of elderly persons is spent wisely **so that** the benefit of good care is provided for all.

As an *administrator* I need to ensure good communication between care providers **so that** they understand Esther's medical and care needs and provide coordinated care for her.

What does good look like?

Success will be measured by Esther getting care in or close to home, experiencing care from multiple providers as if it were from the same provider, having care uniformly available throughout the region and knowing who to turn to when problems arise.[7]

What are the elements?

The elements of the system can be considered to be Esther and her family and neighbours, the people who provide all aspects of medical and home care to her, the geographical and transport systems around her home and points of care, the organisations that facilitate her care, and the bodies that fund her care.

What are the needs?

The analysis of interviews with over 60 patients and providers throughout the system identified six key needs for action:[8]

- The development of a flexible organisation with patient value in focus.
- The design of more efficient and improved prescription and medication routines.
- The creation of approaches to documentation and communication of information that can be adapted to the next link of the care chain.
- The provision of efficient IT-support through the whole care chain.
- The provision of a diagnosis system for community care.
- The development of a virtual competence centre for better transfer and improvement of competence through the care chain.

How can the needs be met?

Many of the problems experienced by Esther involved more than one organisation. It was important to bring together people from different levels in these organisations to develop and deliver solutions to support the needs identified. These included:

- A steering committee of the community care chiefs from municipalities, hospitals and primary care centres to address challenges across organisations.
- Four 'Esther cafés' in municipalities each year, which were cross-organisational, multiprofessional meetings for sharing and learning from the experiences of

specific patients who were hospitalised in the past year and have continued on to home care or other services.

- Interorganisational training workshops on palliative care, nutrition and fall prevention, among other topics.
- An annual 'strategy day' for nurses and other staff, physicians, managers, as well as 'Esthers' themselves to come together to team build and generate priorities and ideas for addressing problems in care.

In 2006 coaches were introduced to the model to promote the Esther Network vision and values and to support ongoing improvement.[9] The aim was to develop internal coaches to facilitate improvement across organisational boundaries, providing: customer focus, modelled by involvement of senior citizens in the training programme; a shared set of values; networking skills with a solution-focused approach; and systems thinking.

How well are the needs met?

The Esther model calls for continuous and coordinated improvement with a focus on providing what is best for Esther. The evidence points to a cultural shift in the way leaders and workers in the Jönköping County health and care systems now provide for Esther, facilitated by the solutions introduced in response to her needs – "the focus is on her now." [10] It is also evident that the changes have not only been sustained and further developed, but also have provided the inspiration for change in other health and care systems around the world.

What could go wrong?

Proactive risk assessment was not employed within this programme. However, the impact of the changes introduced were continuously monitored.

How does the system perform?

This innovation programme was not designed as a research project and involved many organisational and process changes that were introduced in different components of the model at different times. Therefore, it is important to be cautious in assessing the impact of the Esther model.[11] Positive changes are noted, but it is difficult to attribute them to the model in the absence of comparative information. With this in mind, program leaders cite the following outcomes:

- Admissions to the medical department of Höglandet Hospital declined from 9,300 in 1998 to 6,500 in 2013.
- Hospital readmissions within 30 days for patients age 65 and older dropped from 17.4% in 2012 to 15.9% in 2014.
- Hospital lengths of stay decreased between 2009 and 2014 for surgery (from 3.6 to 3.0 days) and rehabilitation (from 19.2 to 9.2 days).
- Surveys conducted in Jönköping in 2008 and 2011 showed that Esthers felt safe and were appreciative of the personal contacts.

What should we do next?

"Taking a system approach to meeting the needs of the frail elderly is unusual, difficult, and necessary." The Esther model depends on "the power of patients' stories", which were elicited and collected as part of the model to show how patients' lives are affected by their health challenges and their experiences in getting care.[12] The model creates mechanisms, including an annual retreat and development of action plans for each forthcoming year, to help members of different professions to continue to think together to solve problems and help to motivate the coaches. "The secret of Esther is the change in state of mind – stop thinking what is best for my organisation, but instead think what is best for Esther." [13]

5 *Sweden's Esther Model: Improving Care for Elderly Patients with Complex Needs,* The Commonwealth Fund, New York, 2016. www.commonwealthfund.org/publications/case-studies/2016/sep/sweden-esther-case-study

6 *Is Sweden's model of integrated care a beacon of light for the NHS?* NHS Voices, NHS Confederation, 2015. www.nhsconfed.org/blog/2015/01/is-sweden-s-model-of-integrated-care-a-beacon-of-light-for-the-nhs

7 Sweden's Esther Model (see footnote 5)

8 *Improving Patient Flow: The Esther Project in Sweden*, Institute for Healthcare Improvement, Boston. www.ihi.org/resources/Pages/ImprovementStories/ImprovingPatientFlowTheEstherProjectinSweden.aspx

9 *What Is Best for Esther? Building Improvement Coaching Capacity With and for Users in Health and Social Care–A Case Study*. Vackerberg et al., Qual Manag Health Care, 25(1):53-60, 2016.

10 Improving Patient Flow (see footnote 8)

11 *Sustained improvement? Findings from an independent case study of the Jönköping quality program.* Øvretveit and Staines, Qual Manag Health Care, 16(1):68-83, 2007. www.ncbi.nlm.nih.gov/pubmed/17235253/

12 Sweden's Esther Model (see footnote 5)

13 Is Sweden's model of integrated care a beacon of light (see footnote 6)

Oral methotrexate for the treatment of rheumatoid arthritis

The answers that follow represent those that may have been formulated by the end of the programme, accepting that there was some iteration between the *systems, design* and *risk* elements of the work. They are nonetheless representative of the systems approach originally applied to the challenge of improving the safety of patients using oral methotrexate for the treatment of rheumatoid arthritis.

Why are we doing this?

In 2000, a Cambridgeshire patient died as a direct result of failures in their care and treatment. The inquiry into their death highlighted the need to review the use of oral methotrexate for the treatment of rheumatoid arthritis in the UK.[14] In this particular case, the patient had been taking a weekly dose of methotrexate for rheumatoid arthritis. The strength of methotrexate had been altered in error by her GP to a daily dose of 10 mg from the previous weekly dose of 17.5 mg. This was dispensed by a community pharmacy. The patient inadvertently overdosed on methotrexate and their immune system became severely compromised. The patient was later admitted to hospital with symptoms of a severe sore throat, where they continued to receive treatment at this high daily dose until the mistake was identified on the fourth day following admission.

What is the problem?

Of the 13,000 medicines licensed for use in the UK at that time, oral methotrexate was one of only six that should have been taken weekly. Previously, 25 deaths and 26 cases of serious harm had been attributed to the incorrect use of methotrexate.[15] More than half of the 167 adverse events associated with patients taking methotrexate between 1993 and 2002 were the result of the drug being prescribed on a daily basis. Some cases were due to errors occurring during the transfer of information from hospitals to GPs, others were due to problems with information technology systems that failed to give clear information on the frequency of dosing.

Who will use the system?

People who are actively 'using' the system are those within the Shared Care Arrangement (Figure 9), such as patients with rheumatoid arthritis, their carers, GPs, pharmacists, phlebotomists and hospital doctors.

Where is the system?

The system is in the UK and spans from the home to general practice to the community pharmacy to the hospital, working under a shared care arrangement (Figure 9).

What affects the system?

There are three suppliers of methotrexate for the UK market. They provide 2.5 mg and 10 mg tablets that are similar in colour and size in 100 tablet bottles and 2.5 mg tablets in blister packs of 28 tablets.

Who should be involved?

People should be involved in the improvement programme if they are involved in the supply, management and control of methotrexate in the UK, such as:

- patients and carers
- community pharmacies
- GPs and hospital doctors
- drug manufacturers
- drug prescription and dispensing software vendors
- information providers and packaging designers.

Who are the stakeholders?

Stakeholders are those that have an interest in the successful performance of the system and can be described by their role title, need(s) and purpose:

As a *patient* I need sufficient methotrexate **so that** I have relief from the pain resulting from my rheumatoid arthritis, **I need** methotrexate in an easy-to-open pack **so that** I am able to open the pack and easily retrieve the correct dose and **I need** to be confident that I am taking the correct dose of methotrexate **so that** I do not suffer adverse effects from the drug.

As a *general practitioner* I need to ensure that the patient knows how to administer methotrexate **so that** there is no chance of the patient taking the wrong dose. **I need** to be sure that I prescribe the correct dose of methotrexate **so that** there is no chance of the patient taking the wrong dose, and **I need** to ensure that the patient's bloods are monitored **so that** the dose can be controlled.

As a *hospital doctor* I need to understand the particular challenges of oral methotrexate use **so that** I am able to recognise the needs and potential problems experienced by these patients.

As an *arthritis specialist* I need to identify patients who might benefit from the use of oral methotrexate **so that** their quality of life can be improved, and **I need** to determine the most appropriate dose of oral methotrexate for the patient **so that** their condition may be improved.

As a *drug manufacturer* I need to supply oral methotrexate in a form **so that** pharmacies can adjust the quality dispensed to meet individual patient needs, and **I need** to sell sufficient quantity of oral methotrexate **so that** the product line is commercially viable.

As a *pharmacist* I need to dispense methotrexate in a timely way **so that** the patient always has the medication they need, and **I need** to ensure that the patient understands the particular restrictions on the use of oral methotrexate **so that** they are kept safe.

As a *carer* I need to know that the patient understands the importance of taking the correct dose of methotrexate **so that** they remain safe, and **I need** to be sure that methotrexate is not confused with other medications **so that** they remain safe.

As a *phlebotomist* I need to collect blood samples from the patient **so that** methotrexate toxicity tests can be carried out in the hospital. **I need** to ensure that any change to the methotrexate dose is communicated to the patient and GP **so that** they are both informed of the new dose.

As a *pathologist* I need good blood samples **so that** I can test methotrexate levels in the patient's blood.

As a *software supplier* I need to deliver competitive prescribing and dispensing systems **so that** GPs/pharmacists use my software, and **I need** to ensure that my products enhance GP/pharmacist practices **so that** errors are reduced.

As an *information supplier* I need to ensure that information is trustworthy and accessible **so that** GPs/pharmacists use my services, and **I need** to ensure that my services enhance GP/pharmacist practices **so that** errors are reduced.

As a *packaging/labelling supplier* I need to provide clear identification **so that** the pharmacist and patient can unambiguously select the correct medication.

As a *practice receptionist* I need to ensure that repeat prescription forms are authorised **so that** patients receive their prescriptions in a timely manner.

As a *practice manager* I need to ensure that everyone is aware of our policies and practice relating to methotrexate **so that** patients receive safe care.

What does good look like?

Success will be measured by a significant reduction of deaths and serious injury to patients being treated with methotrexate for rheumatoid arthritis while maintaining the benefits of disease and symptom control.

What are the elements?

The management of patients taking methotrexate is organised using a Shared Care Arrangement, sharing responsibility for safe care between the general practice, the community pharmacy and the hospital. This forms the core of the system. In addition, computer software enabling the prescribing and dispensing of methotrexate is used, drug information leaflets and record books are provided, and the drug and packaging are required (Figure 9).

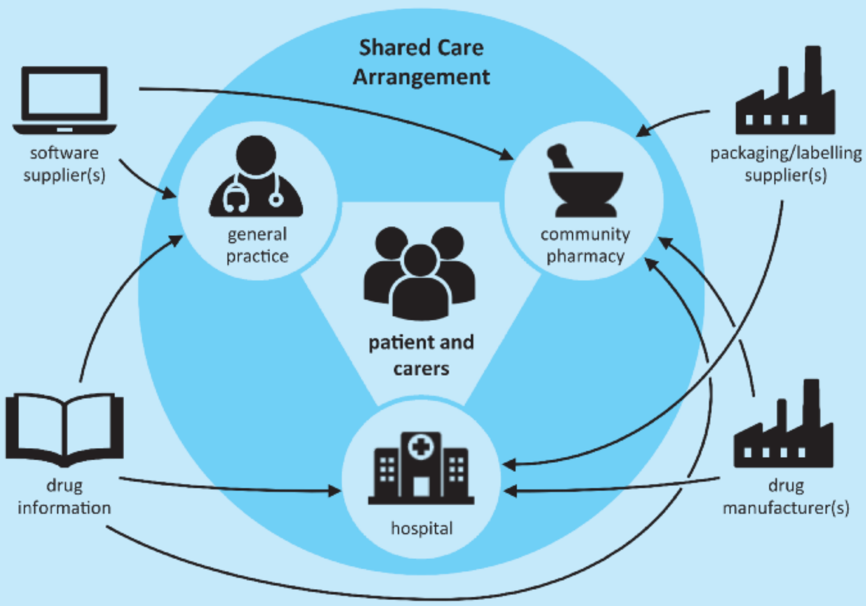


Figure 9: The methotrexate system

Methotrexate used for the treatment of patients with rheumatoid arthritis is administered and controlled in the UK using a shared care arrangement, involving GPs, community pharmacies and hospitals. Other organisations supply the drug, packaging and labelling, prescribing and dispensing software, and drug information.

What are the needs?

The needs for redesign of the system are dominated by the needs of the patient, where the priority is for an easy-to-follow medication management process, easy-to-understand information about methotrexate, easy-to-identify medication and easy-to-open packs. Other needs, derived from the stakeholders list, should also be considered in the context of meeting the fundamental patient needs.

How can the needs be met?

In response to the patient needs, a number of potential solutions were identified, each of which would prevent some opportunity for harm and collectively would prevent or reduce all harm based upon the causal and contributory data available at the time: [16,17]

1. Better information for the patient prior to treatment and use of patient-held records to include monitoring schedules and results.
2. Clear branding of methotrexate as a weekly medication with clear instructions to take methotrexate on Mondays.
3. Improved warnings and flags for GP prescribing and pharmacy dispensing software systems which were not easily over-ridden.
4. Reshaped tablets from manufacturers to ensure that 2.5 mg round tablets are easily distinguishable from 'new' 10 mg torpedo shaped tablets.
5. Repackaged tablets using novel designs and in reduced quantities so that the patient receives the original manufacturers pack.

How well are the needs met?

A new information leaflet for patients, emphasising the weekly dose for methotrexate, was drafted and trialled. This led to the provision of a methotrexate treatment guide incorporating a pre-treatment leaflet, designed to provide patients with guidance on low dose methotrexate, and a blood monitoring and dosage record booklet.[18]

The changes proposed for the shape of the methotrexate tablets were delivered, but this did not address potential confusion with other medications and, in particular, folic acid which is often prescribed along with methotrexate.

Software vendors provided enhancements to their existing GP prescribing software to ensure methotrexate was clearly labelled as 'High Alert', 'Alert' or 'Toxic' in the drug list, to generate an additional alert message when selecting methotrexate highlighting the need for weekly doses and to provide dosing options that clearly articulated the number of tablets to be taken.[19]

Novel packaging designs were not pursued at this stage. However, manufacturers began to provide tablets in 16 and 24 packs with improved design (for patients with reduced manual dexterity), labelling and safety information. The use of existing pharmacy labels continued.

What could go wrong?

A review of the risks associated with the original oral methotrexate system was undertaken prior to determining the design interventions described above. This identified the following high-risk scenarios:

i. Failure to identify changed prescription request arising from blood test results.

ii. GP prescribes methotrexate "as directed".

iii. Patient receives wrong dose due to confusion between different strengths of methotrexate tablets.

iv. Patient receives wrong dose due to confusion between folic acid and methotrexate tablets.

v. Patient experiences difficulties reading print on blister pack.

vi. Incorrect prescription of methotrexate is dispensed to the patient because of poor design of prescribing/dispensing software.

vii. Pharmacy picking error results in wrong medications being dispensed.

viii. Pharmacist only writes total dose of methotrexate, not number of tablets.

ix. Poor hospital drug chart review by hospital pharmacy.

x. Poor education of healthcare professionals regarding use of methotrexate.

Many of these issues were addressed by the design changes proposed and other patient safety initiatives. However, a number remained, including the potential for patients to be confused by the two strengths of methotrexate tablets and this led directly to the policy in many regions to prescribe only 2.5 mg tablets. There was also a danger that patients might be confused by the variation in dose that was the direct result of the review of regular blood tests designed to determine the optimal dose for each individual. It was important that changes in dose were communicated clearly to the patient and others in the shared care arrangement to ensure that all patient records were up to date.

How does the system perform?

Limited data was collected to enable direct comparison with previous error rates and subsequent patient harm resulting from use of oral methotrexate. Communications from the NPSA suggested that early compliance with new guidance[20] remained poor, likely contributing to ongoing errors in the use of methotrexate, resulting in patient harm.[21]

Eighteen months after the shape of the 10 mg methotrexate tablet was changed the Medical and Healthcare Products Regulatory Agency (MHRA) issued a Class 3 Medicines Recall.[22] Original round 10 mg tablets that had remained in circulation alongside the new torpedo shaped 10 mg tablets were recalled as their continued presence had given rise to confusion where patients had been told all round tablets were 2.5 mg.

Despite all the best efforts of the improvement team, methotrexate remains a potentially harmful drug that is ultimately administered by the patient. Deaths and serious harm continued at a lower level and in 2011 a patient, prescribed an increasing dose of methotrexate in order to identify the required level of medication, continued to increase the weekly dose beyond the mandated maximum and died. This was not an error that had been predicted and shows the importance of shared care arrangement team taking full responsibility for all aspects of the prescribing, dispensing and monitoring cycle when working with patients receiving oral methotrexate.

What should we do next?

The use of oral methotrexate as a treatment for rheumatoid arthritis relies on a number of systems working with the patient to ensure their safety. Further improvements in the use of this drug will need to follow a systems approach to ensure that key stakeholders work together to identify and implement changes that would minimise future loss of life.

14 *An inquiry into the death of a Cambridgeshire Patient in April 2000.* Cambridgeshire Health Authority, 2000.

15 *Patient briefing – Making sure you take oral methotrexate safely.* National Patient Safety Agency, London, 2006.

16 *Towards the safer use of oral methotrexate.* UK National Patient Safety Agency, London, 2004.

17 *Patient Safety Alert – Reducing the harm caused by oral methotrexate.* UK National Patient Safety Agency, London, 2004.

18 *Methotrexate treatment.* UK National Patient Safety Agency, London, 2006.

19 Towards the safer use of oral methotrexate – Appendix 2 (see footnote 16)

20 Patient safety Alert (see footnote 17)

21 *Patient Safety Alert – Improving compliance with oral methotrexate guidelines.* UK National 13 Safety Agency, London, 2006.

22 *Drug Alert, Class 3 Medicines Recall – Methotrexate 10mg Tablets.* UK Medical and Healthcare Products Regulatory Agency, London, 2004.

Annex 2
Case studies

The following case studies of change or transformation projects aim to put the guiding questions and perspectives described in Section 3: *Defining a systems approach* into context. Whilst not all the projects described will have explicitly used a systems approach, the case studies highlight how they have taken into account the people, systems, design and risk perspectives in their work.

The spread of examples from the healthcare and engineering sector were deliberately chosen, as were the mix of successes and failures. The range of case studies demonstrate that a systems approach is adaptable to all levels of scale, from service level through organisation to cross-organisation, and sufficiently versatile to apply across all areas of health and care. The case studies are representative of systems that are simple, complicated and complex and found at service, organisation and cross-organisation levels (Figure 10).

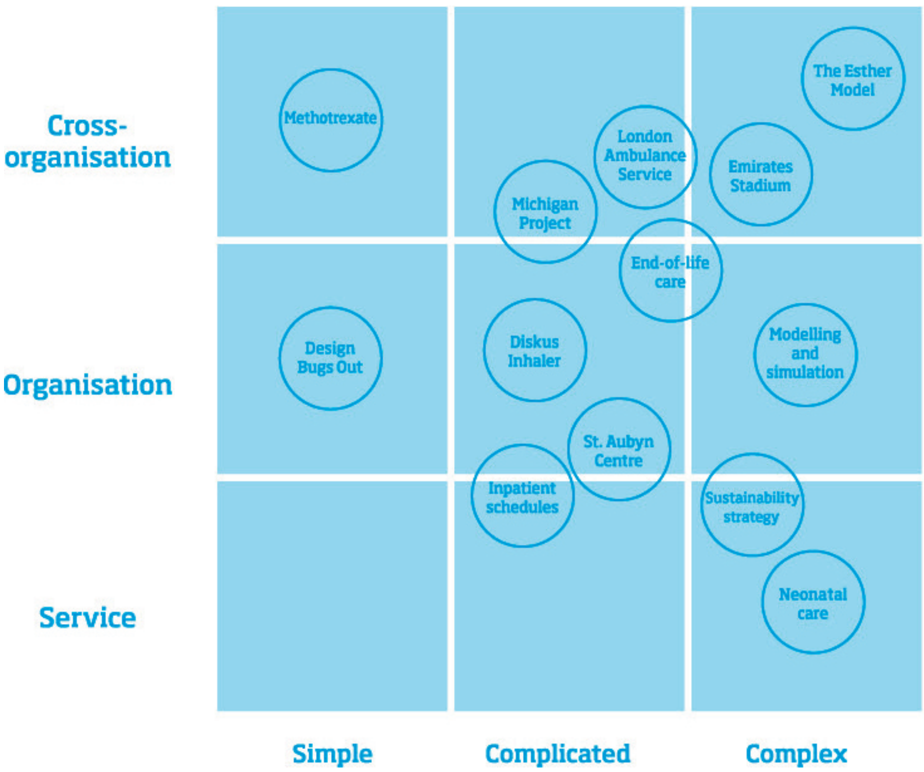


Figure 10: The range of case studies across scale and complexity

The case studies are representative of systems that are simple, complicated and complex and found at service, organisation and cross-organisation levels.

Case study 1

The Esther model, health and care integration in Jönköping, Sweden

A collaborative approach to systems design

Esther lived alone and one morning developed breathing difficulties. After contacting her daughter, who did not know what to do, Esther sought medical advice.

She was seen by a district nurse and told to visit her general practitioner, who said that she needed to go to hospital and called an ambulance. After being admitted to emergency care she retold her story to a variety of clinicians at the hospital during a five-and-a-half-hour wait. Esther saw a total of 36 different people and had to retell her story at every point, while having problems breathing. A doctor finally admitted her to a hospital ward.[23]

In the late 1990s, with Esther's experience in mind, the then head of the medical department of Höglandet Hospital in Nässjö, initiated an extensive series of interviews and workshops to identify redundancies and gaps in the medical and community care systems and develop an action plan for improvement.

'Esther' came to represent elderly persons who have complex care needs that involve a variety of providers.

The idea was that care should be guided by the following questions: What does Esther need? What does she want? What is important to her when she is not well? What does she need when she leaves the hospital? Which providers must cooperate to meet Esther's needs?

The now widely adopted Esther model uses continuous quality improvement, cross-organisational communication, problem-solving, and staff training to provide the best care for elderly patients with complex care needs.[24]

Further details of the application of a systems approach to this case study can be found in Annex 1: *Applications of the approach.*

Success factors

The success of the Esther model may be attributed to:

using the 'Esther' persona to exemplify the need for coordinated care

involving multiple stakeholders to develop an improvement action plan

delivering multi-provider care experienced as if it were from the same provider

significant improvements in care leading to better outcomes for patients

23 *Sweden's Esther Model: Improving Care for Elderly Patients with Complex Needs*, The Commonwealth Fund, New York, 2016. www.commonwealthfund.org/publications/case-studies/2016 sep/sweden-esther-case-study

24 *Is Sweden's model of integrated care a beacon of light for the NHS?* NHS Voices, NHS Confederation, 2015. www.nhsconfed.org/blog/2015/01/is-sweden-s-model-of-integrated-care-a-beacon-of-light-for-the-nhs

Case study 2

Oral methotrexate
A response to clinical problems

Following the death of a Cambridgeshire patient in April 2000 from a suspected overdose of methotrexate, an inquiry was established as the "incident appeared to have resulted from failings within all stages on the patient's care pathway."[18] This led to 28 recommendations, of local and national relevance, to reduce the risk of further incidents.

Methotrexate is a folic acid antagonist and is classified as an antimetabolite cytotoxic immunosuppressant agent. As well as being a therapy for cancers, it is widely used as a disease modifying drug for rheumatoid arthritis. Because of its toxicity, it is only given weekly and its use is carefully monitored through regular blood tests, often leading to changes in the weekly dose prescribed.

Following the inquiry, the National Patient Safety Agency took a systems approach, working with health professionals, patient groups, the pharmaceutical industry, and medical and pharmaceutical software suppliers, to identify risks associated with the delivery of methotrexate and to co-design safer solutions.[19]

Subsequent changes included better information for patients and patient-held records, improved warnings for GP prescribing and pharmacy dispensing, and the repackaging of the tablets to ensure that the two doses available were more easily distinguishable.

The changes made to the methotrexate supply system, requiring the cooperation of a variety of stakeholders, led directly to a measurable reduction in patient harm and an approach that focuses on enabling the patient to take the right dose at the right time.

Further details of the application of a systems approach to this case study can be found in Annex 1: *Applications of the approach.*

Success factors

The success of changes to the methotrexate supply system may be attributed to:

- People — **improvements to patient information, clinician knowledge and prescribing policy**
- Systems — **consideration of the wider prescribing, monitoring and medication supply system**
- Design — **improvements to GP protocols, prescribing software and medication packaging**
- Risk — **acknowledgement of the role of the patient in ensuring safe medication practice**

25 *Methotrexate toxicity: an Inquiry into the death of a Cambridgeshire patient in April 2000*, Cambridgeshire Health Authority, July 2000. www.blacktriangle.org/methotrexate-toxicity.pdf

26 *Towards the safer use of oral methotrexate*, National Patient Safety Agency, July 2004. www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=59985&type=full&servicetype=Attachment

Case study 3

Michigan intensive care unit project

Changing practice on a large distributed scale

Catheter-related bloodstream infections are costly and potentially lethal. In 2003, all Michigan hospitals with an intensive care unit (ICU) were invited to join the Keystone ICU project to evaluate the effect of a number of patient-safety interventions targeted at reducing the number of central venous catheter blood stream infections.[27]

One physician and one nurse were selected by each ICU as team leaders and underwent extensive training in the science of safety and in interventions that they introduced to their teams. A checklist was used to encourage compliance with observation of appropriate hand hygiene, removal of unnecessary catheters and use of full-barrier precautions during catheter insertion, chlorhexidine for skin preparation and subclavian vein placement as the preferred site. A central-line cart was also created.

Open reporting of infection rates was introduced. When the project began, the median rate of infections for the participant ICUs was 2.7 per 1,000 catheter-days. This decreased to zero after three months, a rate sustained throughout the 15 month project.

A subsequent project sought to understand how and why the interventions had worked and identified a number of social, technical and socio-technical approaches that together led to sustained change.[28] Many of these factors translate directly to a systems approach, reflecting elements of cultural change, a focus on local teams and regional systems, deployment of effective data and measurement systems and risk control through the use of checklists and design of elements, such as carts, supportive of good practice.

27 *An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU,* Pronovost et al., N Engl J Med, 355(26):2725-2732, 2006. www.nejm.org/doi/full/10.1056/NEJMoa061115#t=article

28 *Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program,* Dixon-Woods et al., Milbank Q, 89(2):167-205, 2011. onlinelibrary.wiley.com/doi/10.1111/j.1468-0009.2011.00625.x/abstract

Success factors

The success of the Michigan project may be attributed to:

reframing the problem as one where human action and behaviour could succeed

creating a networked community to facilitate and encourage knowledge sharing

developing a consistent approach to data collection and feedback of information

changing practice and culture by reframing risk across interrelated domains.

Case study 4

St. Aubyn Centre
Fixing problems before they happen

The St. Aubyn Centre,[29] opened in October 2012, is the only NHS Adolescent Acute and Intensive Care unit in the south of England.

It provides care for young people between the ages of 13 and 18 who are experiencing acute, complex and/or severe mental health, emotional and psychological problems.

During the design of the new centre, the management of the previous facility worked with the architects to co-develop ideas for the new physical and social environment. While still at the planning stage, risk assessments were undertaken to investigate a range of operational procedures that would take place in the centre, leading directly to a number of significant changes to the detail design.

A new no-smoking policy was also proposed for the facility in contrast to previous practice. This led to the creation of a number of patient and staff personas to assist the team with a further risk assessment, focused on the potential success of the new policy. The study not only increased the team's understanding of the likely behaviour of 'desperate' smokers, but also led to a plan to impose a staff smoking ban some months before the move and introduction of the new no-smoking policy for patients.

The new policy proved very successful, with the prior risk assessment giving the staff confidence to proceed with such a change. This proactive approach to safety assessment[30,31] has proved increasingly useful in delivering safe and effective healthcare services.

Success factors

The successful delivery of the St. Aubyn Centre may be attributed to:

understanding of possible patient and staff behaviours within a new environment

seeing the centre as a facility set in the context of wider care services

consideration of the impact of the physical layout of the new centre

systematic risk assessment of the potential impact of the new policy

29 *St Aubyn Centre*, North Essex Partnership University NHS Foundation Trust, 2016. www.nepstaubyncentre.nhs.uk/

30 *System Safety Assessment toolkit*, University of Cambridge, 2016. www.ssatoolkit.com/toolkit/index.html

31 *Safer Clinical Systems: A new proactive approach to building safe healthcare systems*, University of Warwick, 2014. patientsafety.health.org.uk/sites/default/files/resources/hf_safer_clinical_systems_reference_guide_final_1.pdf

Case study 5

London Ambulance Service
Software redesign leading to emergent failures

The London Ambulance Service first considered introducing a computerised command and control system in the early 1980s.

This was in line not only with many other ambulance services, but also with police and fire services. In the autumn of 1990, following the abandonment of the previous attempt to computerise the system, work began on the drafting of requirements for a new state-of-the-art system.

The concept behind the design was to create, as far as possible, a totally automated system whereby the majority of calls to the service would result in an automatic allocation of the most suitable ambulance. Only in the most complex cases would a human 'allocator' need to identify and allocate the best resource.

The full requirements specification was an ambitious document and its intended functionality was greater than for any existing system. Given the previous difficulties, allegedly caused by the supplier's inability to understand the complexity of the service, it was interesting that the new system was intended to go considerably further.

The new system failed in October 1992 leading to some interesting headlines.[31] The lesson learned was that the particular geographical, social and political environment in which London Ambulance Service operated, and the cultural climate within the service itself, required a more measured and participative approach from management and staff.[32] Several attempts later, a new system went live in March 2012 and has subsequently met its operational expectations.

Factors contributing to early failure

The early failure of the new command and control systems may be attributed to:

poor understanding of paramedic behaviour and culture of requirements creep

limited understanding of whole system performance and emergent behaviours

poor design of ambulance location reporting systems

inadequate preparation for and risk assessment of system rollout

32 *Ambulance chief quits after patients die in computer failure*, Independent, 29 October 1992. www.independent.co.uk/news/ambulance-chief-quits-after-patients-die-in-computer-failure-1560111.html

33 *Report of the Inquiry into the London Ambulance Service*, South West Thames Regional Health Authority, 1993. www0.cs.ucl.ac.uk/staff/A.Finkelstein/las/lascase0.9.pdf

Case study 6

Arsenal's Emirates Stadium
A football match as a system of systems

The match-day experience begins months before with fans purchasing tickets for the North London derby. These are selected not only for their view, but also for their proximity to the most convenient post-match route from the stadium, as defined by the local police in line with its crowd management policy.

The police presence around Highbury operates to a well-rehearsed plan accompanied by the usual assortment of temporary food and memorabilia vendors. Programmes and scarves, bespoke for the day, sell quickly along the directed route.

On the stadium plaza spectators are guided through colour-coded quadrants to lettered turnstiles where their membership card, pre-allocated a ticket, is read by a laser scanner ensuring that they enter the correct zone. Inside, fans can immediately access food and drink counters that provide quick service, as well as an extensive number of toilets. The whole system is simple to ensure the efficient handling of the large crowds that will converge on such events.[34]

Ultimately, the fans' experience is likely to be dominated by the final score. However, it will also be influenced by the carefully choreographed system of systems, comprising both the physical architecture of the new stadium[35] and its surroundings, and the numerous organisations and businesses that provide for a safe, fun day out.

All these stakeholders will take much satisfaction from successfully serving a typical 60,432 person match day crowd.

Success factors

The continued success of match days at the Emirates Stadium may be attributed to:

- People: **understanding the match day fan behaviour and role of stewards and policing**
- Systems: **seeing the stadium as one part of the wider transport, retail and policing system**
- Design: **careful design of major access routes to and from the stadium plaza**
- Risk: **active consideration of match day crowd safety within and around the stadium**

34 *Creating systems that work*, Royal Academy of Engineering, 2007. www.raeng.org.uk/publications/reports/rae-systems-report/

35 *Emirates Stadium, United Kingdom*. designbuild-network.com, 2016. www.designbuild-network.com/projects/ashburton/

Case study 7

Design Bugs Out, the Design Council

A design-led approach to a complex problem

The Design Bugs Out programme was launched in 2008 with the Department of Health and the NHS Purchasing and Supply Agency (now NHS Supply Chain). It brought designers and manufacturers together with clinical specialists, patients and frontline staff to help combat infections by making hospital furniture and equipment easier and quicker to clean.[36]

A wide-ranging review of the clinical environment, by a team including designers, ergonomists, researchers, patients, nurses, domestics and other staff, identified 51 design opportunities. These were shortlisted to 10 opportunities: five 'quick wins' that were developed by the Helen Hamlyn Centre (Royal College of Art) and five that were advertised via a national design competition.

The project led to the development of four pieces of furniture and equipment specifically designed to eliminate dirt traps, make cleaning easier and reduce the incidence of Healthcare Associated Infections. Designers and manufacturers worked in conjunction with NHS users to create product prototypes for evaluation in eight showcase hospitals.

Manufacturers Bristol Maid and designers Kinneir Dufort teamed up to create a radically new bedside cabinet with wipe-clean polymers instead of wood and metal, to make it easier to clean and help stop bacteria spreading.[37] Clean lines and ample storage make the cabinet attractive not only to patients, but also to staff who now spend less time cleaning, releasing more time for patients.

Success factors

The success of the new products may be attributed to:

- **People**: **involving patients and staff with the design and manufacturing teams**
- **Systems**: **seeing the equipment use as part of a wider infection control system**
- **Design**: **designing equipment with features less likely to trap dirt and germs**
- **Risk**: **understanding the sources of risk for hospital associated infections**

36 *Design Bugs Out*, Design Council, 2008. www.designcouncil.org.uk/resources/case-study/design-bugs-out

37 *The easy-clean hospital bedside cabinet, Bristol Maid.* www.designcouncil.org.uk/resources/case-study/bristol-maid

Case study 8

Modelling and simulation saves lives

Predicting outcomes in London hospitals

Healthcare systems are typically characterised by complexity, variability, uncertainty and use of scarce resources.

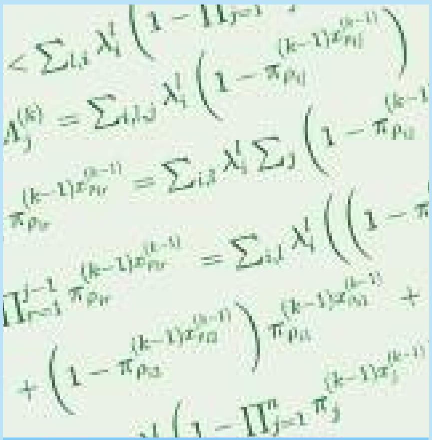
The modelling of such systems requires the development of mathematical and simulation models that are able to account for these conditions, along with complex and large-scale patient pathways, at both operational and strategic levels.

Hospitals have traditionally measured demand by the length of waiting lists or numbers of referrals, but this does not provide health professionals with specific information about patients' treatment needs and resource requirements. However, the application of mathematical models has recently enabled the modelling of real life scenarios, such as complex and unpredictable patient flows. Managers are now able to change their processes on screen before they do it for real, avoiding unnecessary risk to patients.[38]

Models were used in the design of a major new trauma centre at St George's Hospital in London. The models informed the required patient-flows and resourcing levels for the centre and were used to create service level agreements with commissioners. This enabled patient waiting time to be reduced and better levels of patient care to be delivered, leading to an observed increase in survival rates.

Models were similarly utilised by a new hyper-acute stroke unit covering the South London area.

The outcomes were again lifesaving, significantly lowering risk-adjusted mortality for stroke patients, as verified by data comparing mortality rates pre and post the introduction of the new unit.



Success factors

The successful application of the models may be attributed to:

- **People** – **working with stakeholders to derive realistic system models**
- **Systems** – **taking a system-wide view of patient flow and resource needs**
- **Design** – **creating virtual design alternatives to explore process options**
- **Risk** – **evaluating new process risks utilising simulation models**

38 *Mathematics and Healthcare: Saving Lives and Reducing Costs*, 2013. impact.ref.ac.uk/CaseStudies/CaseStudy.aspx?Id=3387

Case study 9

The GlaxoSmithKline 'Diskus' inhaler

Reducing the risk in new product innovation

The Diskus dry powder inhaler (DPI) was launched in the mid-1990s at a time when the use of pressurised metered dose inhalers (MDI) was being criticised owing to the difficulties of repeatability with some users and the use of environmentally unfriendly chlorofluorocarbon propellants.[39] Inhalers are typically used for asthma and chronic obstructive pulmonary disease.

An inhaler is one part of a drug delivery system that involves many stakeholders, all focused on providing the right drug in the right formulation to the right patient at the right time. To meet this need, the Diskus delivered individual factory-metered dry powder doses to the patient via multiple reservoirs without the need for any propellant.[40]

This design dramatically reduced the risk of dose variation. Indeed, the rationale for the presentation of drug as individually, factory-metered unit doses was specifically chosen to ensure a high degree of dose consistency throughout the life of the device. This avoided some of the challenges of multi-dose reservoir devices where the drug is stored in bulk in the device and a dose is retrieved when required.

Careful consideration was given to different use scenarios of the device, accounting for different users, storage regimes and methods of use. As a result, the device has been shown to be easier to use than competitor devices, leading to better outcomes for users. This systems approach to device development enabled the Diskus to satisfy the regulatory authorities, sell over one billion devices and, most importantly, fulfil its original clinical purpose.

Success factors

The successful launch of the inhaler may be attributed to:

understanding of user behaviour and the impact of regulatory policy

consideration of the inhaler as a component of the pharmaceutical supply chain

innovative design of the device to miniaturise the drug delivery system

active risk assessment of the device through manufacture, supply and use

39 *The Diskus™: a review of its position among dry powder inhaler devices*, International Journal of Clinical Practice, 61(6):1022–1036, 2007. www.ncbi.nlm.nih.gov/pmc/articles/PMC1974824/

40 *The GlaxoSmithKline Diskus, Beach Branding and Packaging Design*, 2012. beachpackagingdesign.com/boxvox/technical-packaging-the-diskusaccuhaler

Case study 10

24/7 medical support in end-of-life care in Airedale

Coordinated care at end of life

A 24/7 telehealth and phone line service, Gold Line, was set up at Airedale General Hospital for senior nurses to take calls from patients thought to be within their last 12 months of life and their relatives.

The service, which runs across Airedale, Wharfedale and Craven, Bradford City and Bradford District,[41] was designed with input from healthcare professionals, patients, carers and Clinical Commissioning Group (CCG) representatives, with funding from the Health Foundation. The service design was provoked by using a fictitious 'Day in the Life' diary of a patient approaching the end of their life. This aimed to evoke an emotional response from those involved and takes into account the support needed by the people delivering the service.

The project was built within the Digital Care Hub infrastructure system already in place at Airedale. It used the same telemedicine service to hold key information, including future care wishes of these patients, in a template within the electronic records. This can be accessed by Gold Line and community staff, as well as GPs and district nurses. Several projects are serviced from the same Digital Care Hub meaning that costs are shared and they work in synergy with each other.

The project has provided high quality, coordinated care for a large number of people facing the last year of their lives and their carers. It has been recognised with several awards and staff are in talks with the CCG to expand the service model to the top 3-5% of people with the most complex care needs.[42]

Success factors

The success of the new telecare system may be attributed to:

- **People** – **understanding the needs of the patients, carers and senior nurses providing care**
- **Systems** – **developing a realisable and shared purpose between all stakeholders**
- **Design** – **using personal dairies and PDSA cycles to motivate change**
- **Risk** – **utilising existing digital infrastructure to ensure integration with other services**

41 *Bringing healthcare home final report*, Airedale NHS Foundation Trust, 2016 www.health.org.uk/sites/health/files/Final%20End%20of%20implementation%20Report%20Jan%202016.pdf

42 *Gold Line service local evaluation, Year End Report April 2014 – March 2015*, 2015 www.health.org.uk/sites/health/files/Appendix%202%20%28a%29%20Gold%20Line%20Service%20Local%20Evaluation.pdf

Case study 11

Daily inpatient schedules in Queen Elizabeth Hospital Birmingham

Local improvement through empowerment

By mapping the system, Queen Elizabeth Hospital Birmingham found that very little of the inpatient clinical event scheduling was visible to inpatients and ward staff.

MyDay@QEHB,[43] a Health Foundation project, was designed with the aim of empowering patients and helping ward staff manage resources by generating a daily schedule of clinical interventions. It mines referrals and booked appointments from the trust's existing clinical portal systems.

Since each ward has its own ways of working, there was a risk of resistance to change from local teams. However, by understanding each local context and taking account of differences in working practice by using storytelling, patient and staff feedback were used as powerful tools for alleviating staff fears.

The project took the time to understand the people and context. Key clinical support services, including inpatient imaging, physiotherapy, occupational therapy, dietetics, and speech and language therapy, did not schedule inpatient appointments at all, and porter bookings were not coordinated. The project enabled all of these services to change the way that they worked before MyDay@QEHB could be deployed.

MyDay@QEHB has reduced patient anxiety and allowed staff to better manage resources. There was an increase in the number of patients discharged before midday. Between 2012 and 2015, the percentage of patients who said they had a good understanding of the timing of ward events rose from 54% to 86%. Porter delays were also reduced in the wards using MyDay@QEHB compared to those that did not.

Success factors

The success of the introduction of inpatient scheduling may be attributed to:

- **People:** **communicating the needs of clinical support services with stakeholders**
- **Systems:** **integrating the existing clinical systems with the new scheduling system**
- **Design:** **using experience-based co-design to engage with patients, carers and staff**
- **Risk:** **mitigating the risk of teams being resistant to change**

43 *Shared purpose final report, Project: MyDay@QEHB – a personalised schedule of care events for inpatients*, University Hospitals Birmingham NHS Foundation Trust, 2015 www.health.org.uk/sites/health/files/MyDay%20Final%20report%20template%20-%20Shared%20Purpose%20-%20Dec%2015%20Final.pdf

Case study 12

Barts Sustainability Strategy [44]

Achieving energy efficiency and improved patient experience

Barts Health is the UK's largest NHS Trust, serving a population of 2.5million people within five hospitals and over 5.7million square feet of built estate. In the 2000s they were facing challenges to improve the energy efficiency of the estate, to decrease CO_2 emissions and reduce costs, while maintaining estates that were fit-for-purpose for patients and staff.

The estates and facility management team procured an energy performance contract that included the introduction of a combined heat and power plant, lighting improvements and mechanisms to address maintenance backlog. These were able to reduce CO_2 emissions at the same time as improving the environment for patients and staff and supporting healthcare delivery.

The team introduced very low energy LED lamps that adjusted to levels of natural light. These reduced energy use and provided more consistent lighting to enable staff to better monitor patients.

The LEDs had a 10 year life, dramatically reducing the need for re-lamping and the accompanying disruption for both patients and staff that can compromise infection control.

The team also increased the use of computer-aided facilities management systems. This directly led to improvements in the management of required maintenance and allowed better monitoring and enhanced control of the internal environment in response to changing external weather, lighting levels, and other occupational needs.

Success factors

The success of this sustainability strategy may be attributed to:

integrating the needs of staff, patients, and facilities management teams

accounting for technology, the external environment and human behaviour

developing a flexible technology strategy, building on current systems

considering both the short and long term impact of changes made

44 www.skanska-sustainability-case-studies.com/index.php/latest-case-studies/item/128-barts-and-the-london-hospitals-uk?limitstart=0

Case study 13

The Dyson Centre for Neonatal Care at Royal United Hospitals Bath

A sustainable and calming neonatal intensive care unit

Royal United Hospitals Bath opened a new neonatal intensive care unit in 2011 to provide care for up to 500 premature and seriously ill babies every year. The new unit had to allow healthcare to be delivered effectively to babies, provide a calm environment for parents and staff, and reduce energy consumption when compared to the old unit.[45]

Architects and design engineers carried out extensive consultations with hospital staff and parent groups that emphasised the importance of creating an environmentally sustainable family centred care facility. Special attention was given to lighting levels as they are a crucial element in creating a therapeutic and calming environment for sick babies. A small self-contained wireless device was also developed for mounting on the baby's nappy to measure breathing, restlessness and sleep patterns, allowing the impact of changes in the unit to be monitored.

The design team created peaceful and practical internal spaces with the clinical rooms grouped around a central staff base to enhance visibility. A research study, supported by the Sir James Dyson Foundation, showed that, in the research groups, 90% of the babies went home from the new unit breastfeeding, compared with 64% in the old centre, and babies achieved 20% more sleep in the new unit. Parents also visited their children more often and spent more time in direct contact with them.

In addition, during the day, the nurses typically spent nearly twice as much time in clinical rooms looking after the babies. The novel unit design also resulted in energy consumption dropping from £80 to £50 per 100 cubic metres.

Success factors

The success of this new neonatal unit may be attributed to:

- **People** consulting extensively with staff and parents
- **Systems** integrating the building design along with technological solutions
- **Design** designing novel technology to meet the needs of specific users
- **Risk** identifying the need for early identification of detrimental impacts

45 *Inside Bath's new neonatal unit,* Tooley and Marden, Health Service Journal 2013. www.hsj.co.uk/home/innovation-and-efficiency/inside-baths-new-neonatal-unit/5064365.article

Annex 3
Elements of a systems approach

This annex describes the essence of the *people, systems, design* and *risk* perspectives on the delivery of systems (Section 3: *Defining a systems approach*, page 23), along with an introduction to systems engineering, an established systems approach commonly used by engineers in the development of technical and socio-technical systems.

A true systems approach is one that consistently delivers a high-quality service and is most likely to be the result of a team successfully integrating *people, systems, design* and *risk* perspectives in an ordered and well executed manner. It is only when all four perspectives are robustly understood that a systems approach will have the greatest success. Further reading may be found in the Bibliography, page 85.

Figure 11: A people perspective – identify, locate and situate

The people perspective can be thought of as the iterative sum of the identify, locate and situate phases.

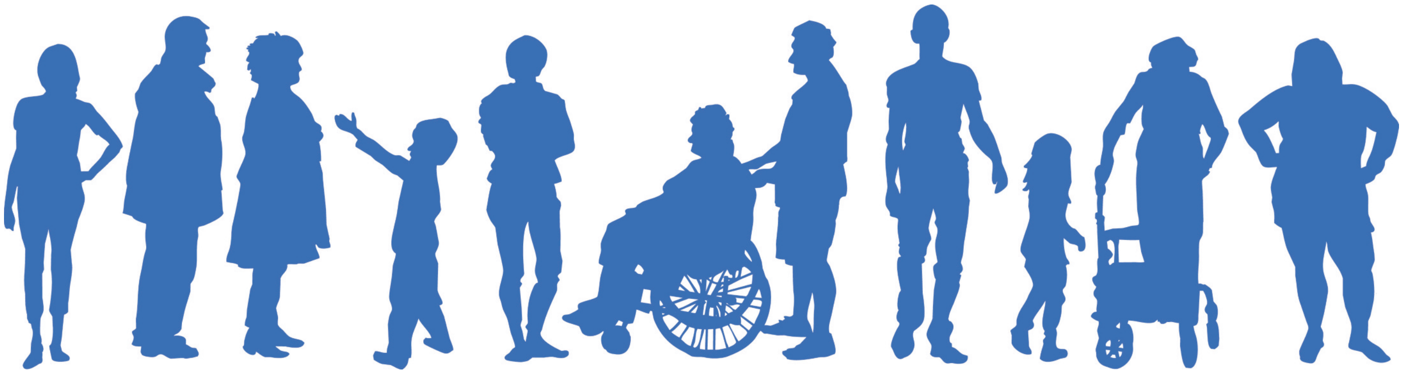
A *people* perspective uses knowledge of stakeholders' abilities, experience, competence and culture to enable the design of systems that are fit for their intended purpose.

The contribution of treatments, equipment, systems, processes and protocols are undeniably critical to health and care provision; however, it is people who ultimately affect the quality of that delivery. An appropriate awareness of people applies not only to the recipients of care, but also to the providers of care. It is important to acknowledge the diversity of the population and that health and care services should be accessible to, and usable by, as many people as reasonably possible, regardless of age or health condition (Figure 12). Equally, a chief executive and other senior people can have a significant impact on an organisation, through their actions and behaviour, creating a culture that values the importance of the quality of relationships between employees and, most critically, the people in their care.

People are diverse in their size and capability, whether they are members of the public, patients or providers of care. Systems should be designed to be accessible to, and usable by, as many people as reasonably possible.

The success and effectiveness of a system are dependent on consideration of the people within the system, its context or place and the policy defining its operation. This can be represented as a series of iterative **identify**, **locate** and **situate** cycles where it is crucial to pay attention to provider/patient relationships as well as the relationships between health professionals, and how these can be enhanced by providing appropriate technologies, systems and policies to deliver a quality of care judged by the degree of warmth and reassurance shown to both colleagues and the people receiving care.

Figure 12: Population diversity – a need for inclusive systems



Identify

The *identify* phase asks the question 'Who will use the system?' and leads to an understanding of the full range of people involved and their needs and capabilities. It is likely to include a variety of activities to develop this understanding, for example:

- identify all the people who will use the system
- co-create the system with system users
- ensure accessibility for all systems users
- maintain communication between all system users.

Locate

The *locate* phase asks the question 'Where is the system?' and leads to an understanding of the context within which the system is situated, including reference to organisation and culture, as well as the demographics and needs of the local population. It is likely to include a variety of activities to develop this understanding, for example:

- capture needs of the local population
- identify related or adjacent systems of care
- define structures that will contribute to success
- establish culture to maximise quality of care.

Situate

The *situate* phase asks the question 'What affects the system?' and leads to an understanding of the wider context within which the system is situated, including reference to policy opportunities and constraints, and the political landscape. It is likely to include a variety of activities to develop this understanding, for example:

- understand the political landscape
- identify opportunities for improvement
- encourage a systems approach to care
- identify policies that put patients first.

People are at the heart of an effective systems approach,[46] permeate all stages of the development and delivery of a system, and are rightfully central to the systems, design and risk perspectives.

A people perspective serves to involve patients, practitioners and the public to ensure that the systems created are truly fit for their intended purpose and reflect a deep understanding of how knowledge, competence and culture enables people, individually and corporately, to deliver and receive health and care within a complex socio-technical environment.[47]

46 *New care models: empowering patients and communities, a call to action for a directory of support.* NHS England, Redditch, UK, 2005. www.england.nhs.uk/wp-content/uploads/2015/12/vanguards-support-directory.pdf

47 *Implementing human factors in healthcare, 'taking further steps'.* Clinical Human Factors Group, 2013. chfg.org/best-practice/how-to-guide-to-human-factors-volume-2/

Figure 13: A systems perspective – understand, organise and integrate

The systems perspective can be thought of as the iterative sum of the understand, organise and integrate phases.

A *systems* perspective ensures the design and improvement of safe and efficient systems that satisfy their required purpose in the context of a wider system.

A system is a set of elements: people, processes, information, organisations and services, as well as software, hardware and other systems that, when combined, have qualities that are not present in any of the elements themselves. A systems perspective takes a holistic approach to understanding this complexity that enables the delivery of intended outcomes based on the way in which a system's constituent parts relate to each other and to the wider system (Figure 14).

The design of a system can be considered to be made up of a series of iterative **understand**, **organise** and **integrate** cycles that enable a team to progress from identifying the stakeholders and their needs through to organising a system of elements and interfaces that are subsequently designed, integrated, validated and delivered to satisfy those needs.

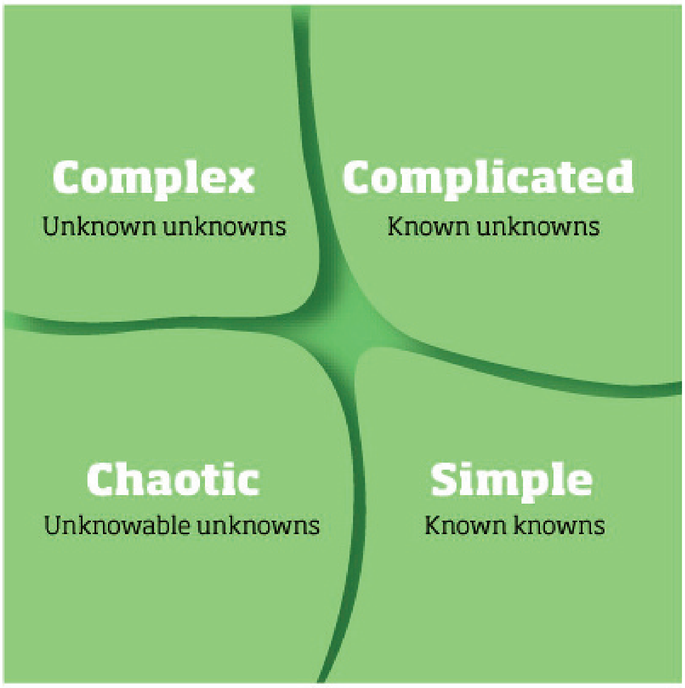


Figure 14: Complicated vs complex – a map of systems behaviour

Health and care outcomes are often dependent on systems working together. The inherent nature of these systems and the way in which they are connected determines the predictability of their combined behaviour.

Understand

The *understand* phase asks the question 'Who are the stakeholders?' and leads to a common and accepted understanding of the range of stakeholders and their individual interests, needs, values and perspectives. It is likely to include a variety of activities that can help to build this understanding, for example:

- identify system stakeholders
- capture stakeholder needs
- define stakeholder priorities
- draft system business case(s).

Organise

The *organise* phase asks the question 'What are the elements?' and leads to an agreed system boundary and architecture comprising a description of existing systems, requirements for new systems and details of the interfaces between them. It is likely to include a variety of activities that can help to deliver this architecture, for example:

- agree functional and information requirements
- define system boundary and external interfaces
- define system architecture and internal interfaces
- agree system integration and evaluation plan.

Integrate

The *integrate* phase asks the question 'How does the system perform?' and leads to a complete, operational system that is proven to meet the stakeholder requirements and be fit for its intended purpose. It is likely to include a variety of activities that can help to deliver an integrated system, for example:

- combine system elements
- verify system performance
- validate system performance
- monitor system performance in use.

The world is made up of a set of highly interconnected technical and social elements that produce emergent behaviour and challenges for communication and control. Some systems are simple, others are chaotic[48] (Figure 14). Some are complicated with many elements, but operate in patterned ways, others are complex with features whose interactions are continually changing.

It is the co-production of health outcomes with the patient, often across a number of systems rather than with any individual health and care system, that can add significant complexity and uncertainty, leading to behaviours not expected when focus is limited to individual systems.

As a result, the solution to a challenge may actually involve changing another system and not the one where the problem or symptom is appearing, relying on collaboration and an integrated holistic view of the systems.[49]

48 The Cynefin framework is a decision framework showing that different situations require different processes to successfully navigate them – The new dynamics of strategy sense-making in a complex world. Kurtz and Snowden 2003, *IBM Systems Journal*, 42(3):462-483, 2003.

49 *Creating systems that work: Principles of engineering systems for the 21st century*, Royal Academy of Engineering, 2007.

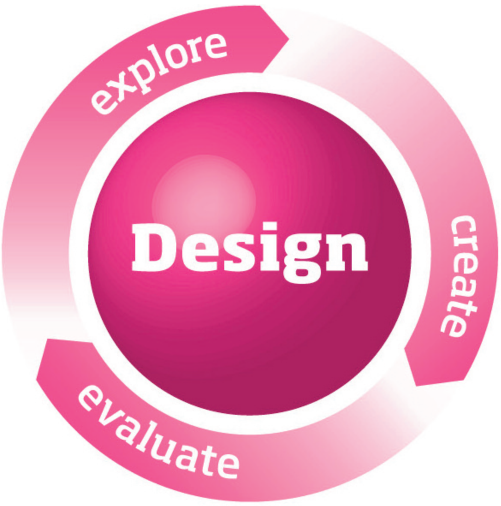


Figure 15: A design perspective – explore, create and evaluate

The design perspective can be thought of as the iterative sum of the explore, create and evaluate phases.

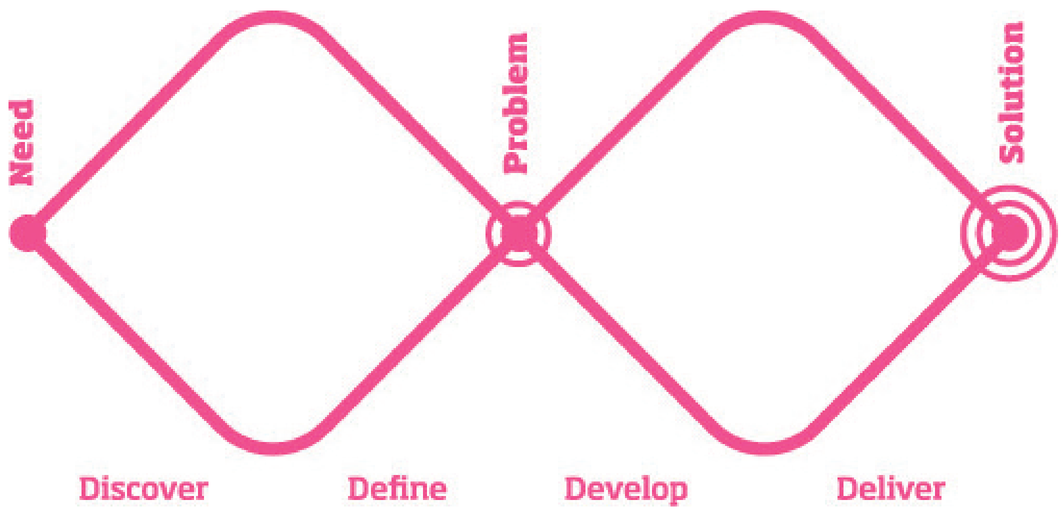
A *design* perspective ensures that systems are delivered using a range of perspectives, creative approaches and evaluation strategies in order to meet stakeholder needs.

It has been argued that many problems addressed by designers are 'wicked problems', defined as a class of problems that are ill-formulated, where the information is contradictory, where there are many stakeholders with conflicting values, and where the behaviours in the system are confusing. In response, the Design Council's 'double diamond'[50] comprises an initial *analytical* phase, which determines all of the elements of the problem and specifies the requirements for a successful solution, and a *synthesis* phase, which generates a range of possible conceptual solutions and an implementation plan (Figure 16).

In practice, design is iterative in nature, comprising multiple **explore**, **create** and **evaluate** cycles that enable a team to progress from understanding the need through to developing the solution. Design can be seen as a risk reduction exercise, set to maximise the chances of delivering the right solution to the right problem reflecting the right need.

Figure 16: The 'double diamond' – defining the problem before the solution

Good design focuses on discovering the real need before defining the problem and delivering the solution. Good design also explores a range of problems and solutions before selecting the most likely to fulfil the need.



Explore

The *explore* phase asks the question 'What are the needs?' and leads to a common and accepted understanding of the likely needs for a system, taking account of the full range of stakeholders. It is likely to include a variety of activities that can help to build this understanding and draw the findings together, for example:

- observe users to reveal what they really need
- generate personas to represent key users
- describe typical user journeys through the system
- specify performance requirements.

Create

The *create* phase asks the question 'How can the needs be met?' and leads to a range of possible system solutions that would help meet the needs and criteria identified by the explore phase. It is likely to include many of the activities commonly thought of as conceptual design, for example:

- generate a wide range of solution ideas
- develop solutions that could satisfy the needs
- make prototypes to demonstrate the solutions
- select the best solution(s) for development.

Evaluate

The *evaluate* phase asks the question 'How well are the needs met?' and leads to an evaluation, both virtually and in practice, of possible system concepts that could meet the needs and criteria identified by the explore phase. It is likely to include activities to provide evidence that the needs are actually met, for example:

- test system with experts
- test system with users
- evaluate how well the needs are met
- present evidence from the evaluation.

The design process is typical of those used to address wicked problems,[51] where it is not only highly creative, but also very likely to be highly iterative in order to deal with the intrinsic uncertainty in understanding the real needs and finding an appropriate solution.

This is evidenced by the Institute for Healthcare Improvement's iterative model for improvement (Aim, Feedback, Changes, Plan, Do, Study, Act) often encountered in health and care, where the planning stage is particularly influential in ensuring the delivery of safe systems into practice.

50 *Eleven lessons managing design in eleven global companies.* Design Council, London, UK, 2007. www.designcouncil.org.uk/resources/report/11-lessons-managing-design-global-brands

51 Dilemmas in a general theory of planning. Rittel and Webber. Policy Sciences, 4(2):155-169, 1973. www.researchgate.net/publication/225230512_Dilemmas_In_a_General_Theory_of_Planning

Figure 17: A risk perspective – examine, assess and improve

The risk perspective can be thought of as the iterative sum of the examine, assess and improve phases.

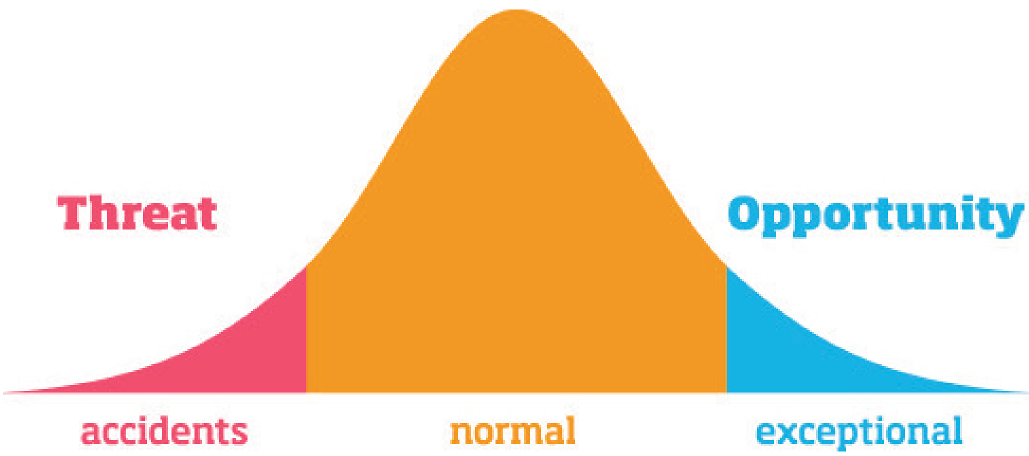
A *risk* perspective ensures that system threats and opportunities are identified and their consequent risks are managed in accordance with stakeholder expectations.

Engineering risk and safety management methods, such as *Failure Mode and Effects Analysis, Hazards and Operability Analysis* and *Fault Tree Analysis*, are used to identify potential threats and opportunities within a system and to manage their likelihood and/or impact on people, property, progress or profit. The role of risk management is to identify, assess and control the level of known risk, accepting the inherent threat or opportunity that may be present within the system, in particular with complex medical interventions and in the distributed system of social care (Figure 18).

It is useful to consider the process of risk management to be made up of a series of iterative **examine**, **assess** and **improve** cycles that enable a team to progress from understanding what is known about the system through to developing interventions to manage the risk presented by the system. Active risk management is appropriate at all stages of a product or service lifecycle, from early conception, through use to disposal.

Figure 18: Safer systems – avoiding error and encouraging good practice

Risk can be represented as a distribution of possible outcomes, where most reflect normal behaviour. Exceptional outcomes provide opportunities for improvement, while accidents represent threats to be avoided.



Examine

The *examine* phase asks the question 'What is going on?' and leads to a common and accepted understanding of needs, which takes account of the range of stakeholders. It is likely to include a variety of activities that can help to build this understanding, for example:

- outline goals of the assessment
- describe and understand the system
- identify critical risk stakeholders
- agree acceptable system risk levels.

Assess

The *assess* phase asks the question 'What could go wrong?' and leads to a systematic assessment of the likelihood and potential impact of risk within a system, which takes account of the nature of the threat or opportunity. It is likely to include a variety of activities that enable this assessment, for example:

- identify threats or opportunities within the system
- identify current safeguards with the system
- evaluate resultant risk and its detectability
- specify mitigation or exploitation needs.

Improve

The *improve* phase asks the question 'How can we make it better?' and leads to a specific plan for managing the likelihood and potential impact of risk within a system, which takes account of the acceptability of such risk. It is likely to include a variety of activities that enable this implementation, for example:

- propose actions to manage the risk within the system
- examine effectiveness of the planned actions
- implement key actions within the system
- review assessment in a timely manner.

Risk can be referenced to a system's ability to deliver high-quality, cost-effective care, where quality is defined as the combination of clinical and cost effectiveness, patient safety and patient experience.[52] Risk management is commonly used as a clinical tool for the prospective analysis of an individual patient's risk, with or without a particular intervention.

However, it may also be used to evaluate the risk in sustaining or not achieving the desired outcomes for a population of patients, the efficiency of a care process or the finances of a care provider.[53]

Different stakeholders may have different risk priorities within the same system and risk tolerance levels will vary with time and be dependent upon the context of each specific care delivery system or process.

Risk may also be attributed to uncertainty in performance where mitigation will likely focus on the identification of the sources of such variation and their reduction.

52 From Safety-I to Safety-II: A White Paper. Hollnagel, Wears and Braithwaite, The Resilient Health Care Net, 2015. resilienthealthcare.net/onewebmedia/WhitePaperFinal.pdf

53 *Design for patient safety: a system-wide, design-led approach to tackling patient safety in the NHS.* Department of Health and Design Council, London, UK, 2003. webarchive.nationalarchives.gov.uk/20120104123857/http://www.designcouncil.org.uk/Documents/Documents/Publications/Health/Design%20for%20Patient%20Safety_Design_Council.pdf

Engineering systems

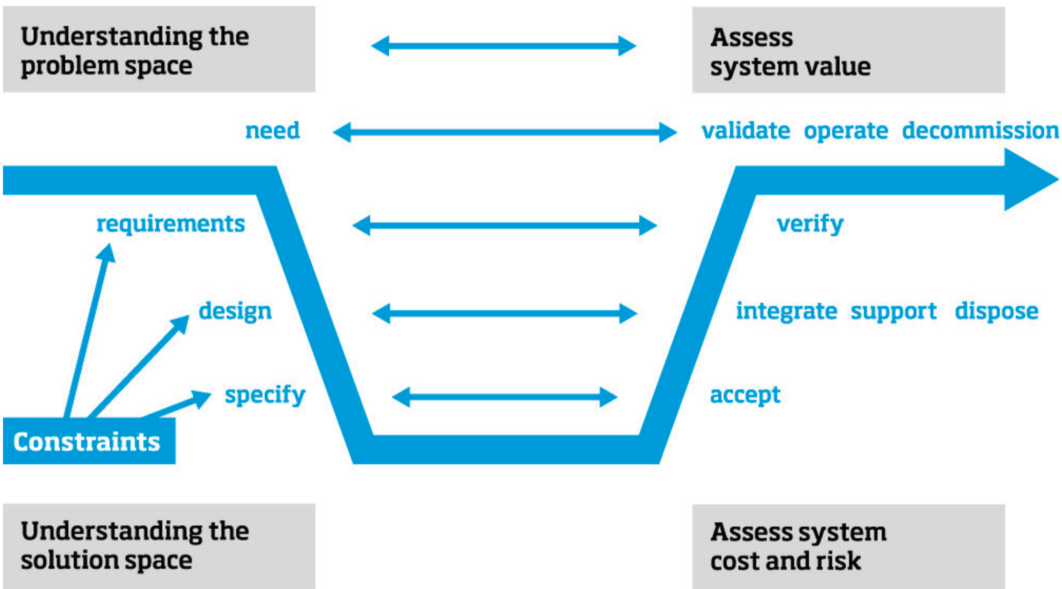
The engineered world is full of systems. From the simple water heater to the fully integrated international airport, from ancient irrigation systems to modern communication networks, all systems share one key feature: their elements together produce results not obtainable by the same elements alone. These elements, or parts, can include people, processes, information, organisations and services, as well as software, hardware and other systems.

"Systems that work do not just happen – they have to be planned, designed and built"[54]

The layout of the system, defining all the elements and their interconnections, needs to be carefully considered to ensure that each element on its own and in combination with others performs as required. In response to this challenge and the ever increasing complexity of modern systems, a new discipline of systems engineering has evolved as an interdisciplinary approach to enable the realisation of successful systems.

Figure 19: The systems engineering V-Model

The systems engineering V-Model (INCOSE UK Z-Guides[55]) provides a succinct description of an engineering systems approach. It not only makes specific reference to systems, design and risk thinking activities, but also provides implicit reference to the need for and value of people-centric activities.



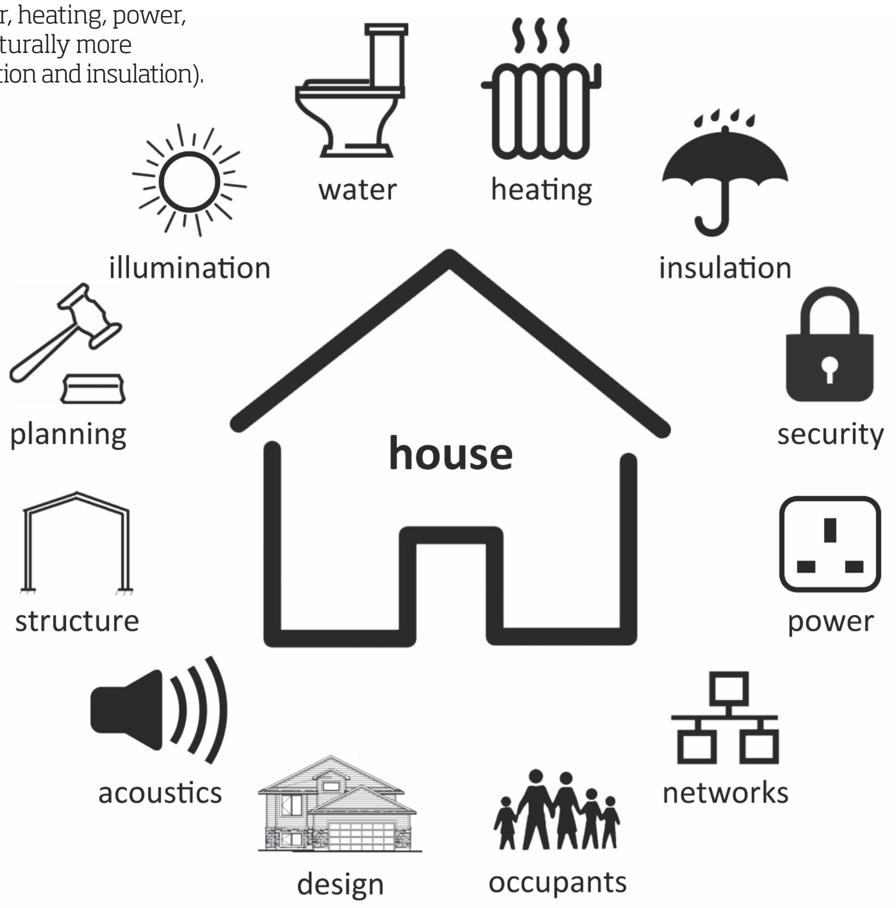
Systems engineering focuses on defining stakeholder needs and required functionality early in the development cycle, documenting requirements, then proceeding with design synthesis and system validation while considering the complete problem. It integrates all the necessary disciplines and specialty groups into a team responsible for using a structured development process that proceeds from needs to requirements to concepts, and from design to production to operation, addressing all the stakeholders' business and technical needs (Figure 19).

A successful system delivery process brings together technical specialists and system architects to ensure a holistic system perspective is maintained throughout; not only in terms of the overall layout of the system and its elements, but also with regard to the whole system lifecycle. Some will provide a focus on individual elements and their role in the system, others will take a holistic view of the system and its performance. Both will play a part in defining the boundary of the system, its requirements, the partitioning of its elements and interfaces, its integration and evaluation, and ultimately its release into service. Typically, different and yet coherent perspectives of the system are developed and held by different teams and stakeholders.

Consider a house that is made up of a number of systems that co-exist to ensure that a house becomes a home (Figure 20). Some are discrete yet interconnected (water, heating, power, security and networks) while others are naturally more holistic (design, structure, planning, illumination and insulation).

Figure 20: A typical house system

A typical house relies on a number of interrelated systems to provide a safe, functional environment for its occupants. The layout and exterior design rely on a sound structure and deliver should appropriate thermal and acoustic behaviour. Water, heating, power, security and networking all add to the home experience.



54 *Creating systems that work: Principles of engineering systems for the 21st century*, Royal Academy of Engineering, 2007.

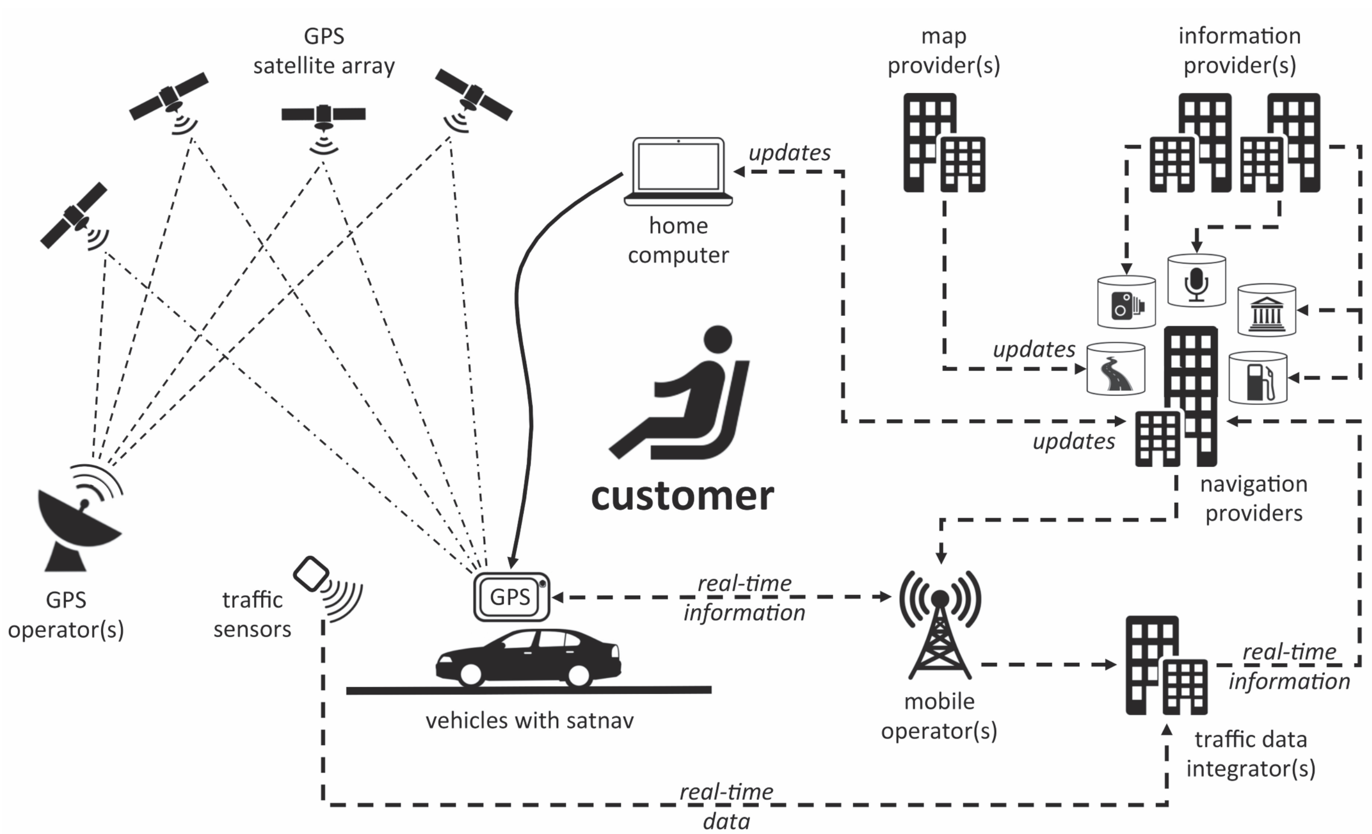
55 *INCOSE (International Council on Systems Engineering) UK Z-Guide 1: What is Systems Engineering*, INCOSE UK, 2009.

Figure 21: A satellite navigation system

Satellite navigation systems extend far beyond the 'satnav' found in many cars. They rely on the GPS operators for positional information via an array of satellites, navigation service providers for up-to-date maps, traffic data integrators for current traffic information and mobile operators for real-time communication.

The delivery of any particular system requires expert knowledge of that system and how it will interface to the whole. The heating specialist cannot develop an appropriate solution without knowledge of the design, structure and insulation, nor can they deliver the solution without detail of the power and water systems. Each specialist will have a different perspective on the house, yet architects, and subsequently builders, act as system integrators, delivering homes with emergent properties greater than the sum of the individual parts. For example, the energy rating of a house depends on a combination of design, structure, insulation and heating, while its desirability may depend on these and many more factors.

A good house design is critically dependent not only on its architectural properties but also on engineers systematically evaluating its performance. Structural engineers model the resilience of the house under all expected loads, insulation specialists model its thermal properties and heating engineers size their systems based on these results and the likely behaviour of its occupants. Utility providers model the water, waste and power requirements, particularly where multiple houses are being built. Local authorities model the impact of new homes on the environment and on local services such as schools, hospitals, highways and waste collection. Governments model the demand for new homes based on expected patterns of migration. As a result, the house may be seen as an element in an extended system of systems.



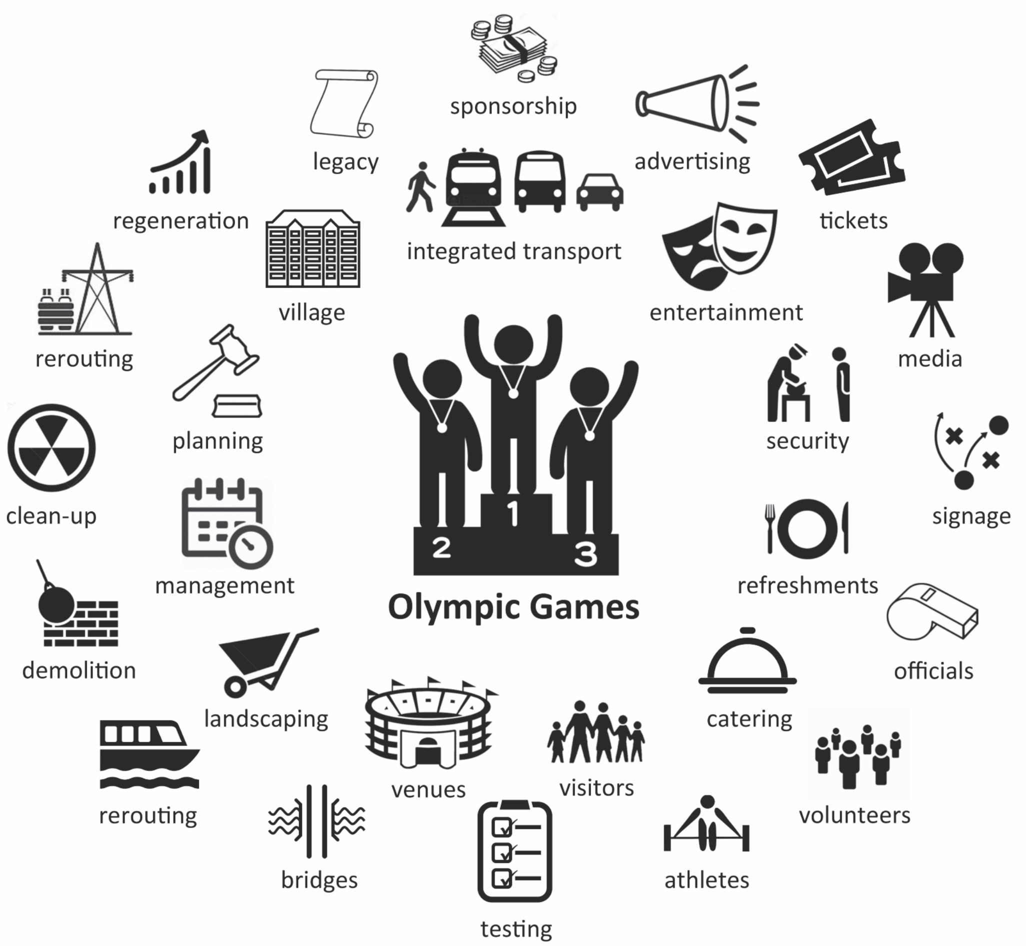


Figure 22: Engineering the Olympics and delivering a system of systems

The 2012 Olympic and Paralympic Games provided an opportunity for London to deliver the best Games ever, but to do so required the delivery of not only the Games' distributed physical infrastructure (challenges on the left), but also the systems required to organise the single largest peacetime event in the world (on the right).

Engineered systems often rely for their operation on a number of independent, but interrelated systems. For example, a satellite navigation system depends on the action and operation of a number of service providers (Figure 21). The degradation of any one of these systems or the interfaces between them will have an adverse impact on the navigation experience and possibly the safety of the vehicle occupants.

Further systems, such as rocket launch vehicles, mapping technologies and voice recording studios, are also required to enable the successful deployment of a navigation system. Inevitably, the focus of individual development teams for these systems would have been different, particularly since GPS satellite arrays and mobile telecommunication systems were not initially designed with commercial navigation systems in mind. However, the architects of 'satnav' systems would have had a holistic vision for their system of systems and robust descriptions of the interfaces relevant to the individual elements and to the whole.

Systems are designed at many levels of scale from the micro to the macro, where they often involve complex interactions between people, physical infrastructure and technology. This is exemplified by the London 2012 Olympic and Paralympic Games: 205 competing nations, 17,000 athletes and officials, 26 different sports, covered by 22,000 journalists and over 10 million tickets to be sold. An Act of Parliament established the Olympic Delivery Authority (ODA) with a budget of £8 billion to deliver the infrastructure, venues, athletes' village and transport, all to time and budget, in a sustainable manner and to leave a lasting legacy.[56]

56 *Engineering the Olympics: The 2011 Lloyd's Register Educational Trust Lecture*, Royal Academy of Engineering, 2001.

The ODA commissioned a delivery partner to manage the construction of the Olympic Park in East London and to manage the complex logistics on the site. Both were similarly incentivised to ensure an alignment of objectives between the two teams to deliver a programme over six phases: Plan, Demolish, Build, Test, Games and Legacy. Their common purpose was to deliver the best Games ever and a lasting legacy for London. A number of interrelated elements were developed relating not only to the physical infrastructure required, but also to the practical organisation of the Games (Figure 22).

The success of the Games and its legacy was critically dependent on early decisions relating to the Olympic Park, a challenging site that needed significant redevelopment. Both the immediate and future needs were realised through the provision of temporary or reconfigurable sports venues, removable bridges alongside permanent structures and landscaping for the longer term. Innovative engineering delivered world-class, cost-effective buildings. Modelling and simulation of people flows informed provision of signage, refreshments, security, helpers, transport and information for visitors. Testing of new venues identified problems early, leading to better provision for athletes, officials and visitors. The opening ceremony saw the choreographed actions of thousands of volunteers, athletes and officials broadcast live to more than 900 million people worldwide. Extensive planning and risk management by the engineering-led team made the complex merely complicated. A systems approach, combined with tried and tested engineering methods and tools, delivered real success on a massive scale.

Systems engineering enables the co-development of the individual components of a system through the rigorous definition of the whole and individual system requirements, careful design and integration of the parts, and sustained evaluation and improvement of the system performance. Further information on this topic can be obtained from the INCOSE UK Chapter.

Annex 4
Compilation of approaches

This annex describes a number of approaches from the health and care improvement and engineering communities that have the potential to help teams understand *people*, deliver *systems*, facilitate *design* and manage *risk* (Section 2: *Approaches to improvement*, page 17). Most excel with one of these perspectives while some attempt to support a more holistic integrated systems approach.

The approaches range from health and care improvement methods, such as the NHS change model, IHI model for improvement, leading large-scale change, human factors in healthcare, lean in healthcare, experience-based co-design and root cause analysis, to design-led safety management tools and human factors methods. Wherever possible references are provided for further information.

Change Model

The NHS Change Model is an organising framework for sustainable change and transformation that delivers potential benefits for patients and the public. It was developed with senior leaders, clinicians, commissioners, providers and improvement activists to support health and care to adopt a shared approach to leading change and transformation.

As a way of thinking, the model is relevant to numerous change programmes and provides an approach that can be tailored to fit individual situations. It is a way of making sense at every level of the 'how and why' of delivering improvement, to consistently make a bigger difference.

The model has eight components that lead to a better understanding of how to create an environment and programme(s) that can make change happen:

- Our shared purpose
- Leadership by all
- Spread and adoption
- Improvement tools
- Project and performance management
- Measurement
- Influencing factors
- Motivate and mobilise

www.england.nhs.uk/ourwork/qual-clin-lead/sustainableimprovement/change-model/

Model for improvement

The model for improvement was developed by Associates in Process Improvement as a tool for accelerating improvement and has been adopted by the Institute of Healthcare Improvement as its primary framework for improvement in healthcare. The model has two parts: three fundamental questions, which can be addressed in any order; and the Plan-Do-Study-Act cycle to test changes in real work settings in order to determine if the change is an improvement.

Use of the model is widespread within the NHS due to its simplicity and ability to bring about rapid testing of ideas. Some criticism of its effectiveness has been raised, suggesting that it is poorly applied and often pursued through time-limited, small-scale projects, led by professionals who may lack the expertise, power or resources to instigate the changes required.

The model for improvement ensures that teams know the *purpose* behind what they are trying to accomplish, understand what *success* will look like and identify those changes that will result in improvement. It also guides them through the process of establishing appropriate measures, *creating* changes, *evaluating* changes, *implementing* changes and spreading changes.

www.ihi.org/resources/Pages/HowtoImprove/default.aspx

futurehospital.rcpjournal.org/content/3/3/191.long

Quality improvement journey – NHS Scotland

The improvement journey is a structured approach that supports individuals and teams to test, implement and spread sustainable improvement across a system. The journey consists of seven stages, from identification of the need through to the successful delivery of change and its spread.

Each stage provides a particular focus:

- discover – identifying the problem to fix
- explore – further investigating the aim and defining success
- design – reviewing all the ideas for improving the system and establishing the priorities for improvement
- refine – identifying what has been learned from evaluating the change
- introduce – making the change happen
- spread – communicating success
- close – capturing lessons learned for the future.

Each stage consists of a series of questions for quality improvers to consider as they carry out an improvement project. These link to suggested tools and resources that will help to further explore and analyse the wider aspects of improvements being made. The journey pays particular attention to cultural aspects of change in the 'introduce' and 'spread' sections, as well as capturing learning for future projects in the 'close' section.

www.qihub.scot.nhs.uk/media/340181/2012–06–15_measurement_improvement_journey_process.pdf

Leading large-scale change

The guide to leading large-scale change (LSC) was developed by managers and clinicians within the NHS and is based on experience and literature around large scale change. The guide includes change management tools such as: key planning questions, driver diagrams, structure / process / pattern thinking, 30/60/90 day cycles, and stakeholder analysis.

LSC is defined as the emergent process of moving a large collection of individuals, groups, and organisations towards a vision of a fundamentally new future state, by means of: high-leverage key themes; a shift in power and a more distributed leadership; massive and active engagement of stakeholders; and mutually-reinforcing changes in multiple systems and processes. This leads to such deep changes in attitudes, beliefs and behaviours that sustainability becomes largely inherent.

Some of the key principles described in LSC may be summarised as:

- moving towards a new vision that is better and fundamentally different from the status quo
- identifying and communicating key themes that people can relate to and will make a big difference
- framing the issues in ways that engage and mobilise the imagination, energy and will of a large number of diverse stakeholders
- continually refreshing the story and attracting new supporters
- transforming mind-sets, leading to inherently sustainable change.

www.slideshare.net/NHSIQ/leading-large-scale-change-part-1

www.slideshare.net/NHSIQ/leading-large-scale-change-part-2

Human factors in healthcare

Human factors is the science of understanding human performance within a given system. Translated into a healthcare context, human factors has been defined as enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture, organisation on human behaviour and abilities, and application of that knowledge in clinical settings.

Designing healthcare facilities, equipment and the delivery of care around an understanding of human behaviour is vital to reduce the potential for human error. This also helps healthcare staff to act as a barrier against harm. Human factors is a broad discipline that studies the relationship between human behaviour, system design and safety.

Many healthcare organisations have carried out work on implementing human factors and the 'how to' guide aims to:

- broaden understanding among healthcare teams of the potential ways in which human factors methods can be applied to improve patient safety
- share practical experience of applying human factors in healthcare, using case studies from different care settings
- signpost healthcare teams to further information and resources to support them to implement human factors in their own organisations.

chfg.org/best-practice/how-to-guide-to-human-factors-volume-2/

Root cause analysis

Root cause analysis (RCA) is a class of problem solving methods, including fishbone diagrams, Pareto charts and scatter diagrams, aimed at identifying the root causes of a problem or event. It is predicated on the belief that problems are best solved by attempting to address, correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms. By identifying measures at the root cause, it is more probable that problem will not occur again.

The principle behind RCA is to take a systems approach to identifying problems that increase the likelihood of errors while avoiding the trap of focusing on mistakes by individuals. Thus RCA identifies both active errors (errors occurring at the point of interface between humans and a complex system) and latent errors (the hidden problems within healthcare systems that contribute to adverse events).

The approach generally begins with the collection of prescribed data and reconstruction of the event through record review and participant interviews. Within healthcare, a multi-disciplinary team would analyse the sequence of events leading to the error, with the goals of identifying how the event occurred (through identification of active errors) and why it occurred (through systematic identification and analysis of latent errors). RCA is typically used as a reactive method of identifying event causes, revealing problems and solving them, where analysis is done *after* the event has occurred. Its ultimate impact is typically dependent on spending sufficient time, effort and resources on risk control following the analysis.

www.nrls.npsa.nhs.uk/rca/

qualitysafety.bmj.com/content/26/5/417

Systems thinking for health

Systems thinking has its origins in the early 20th century in fields as diverse as engineering, economics and ecology. With the increasing emergence of complexity, these and other non-health disciplines developed systems thinking to understand and appreciate the relationships within any given system, and in designing and evaluating system-level interventions.

Systems Thinking for Health Systems Strengthening offers a practical approach to improving health systems through a systems thinking lens. It works to reveal the underlying characteristics and relationships of systems, which are described as dynamic architectures of interactions and synergies. Such systems typically exhibit non-linear and unpredictable behaviour, are resistant to change, and provide a challenge where seemingly obvious solutions can worsen a problem.

The framework describes 10 practical steps in a two-stage conceptual process that can be adapted to many different situations. Intervention design includes convening stakeholders, brainstorming, predicting performance, and adaptation and redesign. Evaluation design includes identification of indicators, choice of methods, selection of design, planning, budgeting and funding.

www.who.int/alliance-hpsr/resources/ 9789241563895/en/

Experience-based co-design

Experience-based co-design (EBCD) is an approach that enables staff and patients (or other service users) to co-design services and/or care pathways in partnership. The approach was designed for and within the NHS to develop simple solutions that offer patients a better experience of treatment and care. However, similar user-centric design techniques have been used by leading global companies for many years.

EBCD gathers patient and staff experiences, through interviewing, observations and group discussions, and presents the insights gained in the form of a short edited film. Informed by this, staff and patients collaboratively design and implement activities that will improve the service or the care pathway. Within health and care, the approach has been used in a range of clinical services, including cancer, diabetes, drug and alcohol treatment, emergency services, genetics, inpatient units, intensive care, mental health, orthopaedics, palliative care and surgical units.

The EBCD toolkit outlines an approach to improving patients' experience of services. As well as step-by-step guidance, the toolkit includes videos of people who have taken part in EBCD projects. These help bring to life the successes and range of benefits that can result from implementing this type of improvement project. The toolkit also includes downloadable resources such as template forms, letters and presentations.

www.pointofcarefoundation.org.uk/resource/experience–based–co–design–ebcd–toolkit/

Lean in healthcare

Lean thinking is an approach to improvement developed at Toyota in the 1950s to create the Toyota Production System. It is a strategic approach that focuses on dramatically improving flow in the value stream and eliminating waste. It initially came to prominence in health and care systems through *The Productive Series: Releasing time to care*, a programme developed by the NHS institute for Innovation and Improvement.

Lean is typically a team process involving many people across an organisation. The Virginia Mason Medical Center in Seattle, Washington has been using lean management principles since 2002. By working to eliminate waste, they have created more capacity in existing programmes and practices so that planned expansions were scrapped, saving significant capital expenses. Using lean principles, staff, providers and patients have continuously improved or redesigned processes to eliminate waste, reduce rework and improve quality. Five UK Trusts are now piloting Virginia Mason's approach.

Lean thinking is founded on five principles designed to:

- specify the value desired by the patient
- map the value stream and identify those steps that do not create value
- create a smooth flow through the value-added steps
- establish pull between the steps
- seek perfection so that the number of steps and the amount of time and information needed to serve the patient are minimised.

In essence, it focuses on improving patient flow, reducing opportunities for error, developing standards and engaging teams in improvement. It is increasingly used in conjunction with Six Sigma.

productiveseries.com/lean-healthcare.html

www.ncbi.nlm.nih.gov/pmc/articles/PMC4833201/

Risk assessment made easy

A risk assessment seeks to answer four simple, related questions: What can go wrong? How bad? How often? and Is there a need for action?

It is not usually possible to eliminate all risks within a system, but healthcare staff have a duty to protect patients as far as 'reasonably practicable'. In practice, this means that there is an imperative to avoid any unnecessary risk. It is best to focus on the risks that really matter, such as those with the potential to cause harm.

This tool is intended to encourage greater use at practice level, and increased awareness and understanding of risk assessment at all levels. It comprises five simple steps:

- identify the hazards
- decide who might be harmed and how
- evaluate the risks and decide on the precautions
- record the findings and proposed actions
- review the assessment.

It is applicable and easily adapted for use in all care settings. Frontline staff may use this tool to identify hazards and decide whether they are significant and whether appropriate and sufficient controls or contingencies are in place to ensure that the associated risks are properly controlled.

www.nrls.npsa.nhs.uk/resources/?EntryId45=59825

Systems engineering

Systems engineering has its origins in the 1930s and was conceived in response to the growing complexity of engineered products and their associated systems. It is a discipline that concentrates on the design and application of the whole (system) as distinct from the parts. It involves looking at a problem in its entirety, taking into account all the facets and all the variables and relating the social to the technical aspect.

Systems engineering is an iterative process of top-down synthesis, development, and operation of a real-world system that satisfies, in a near optimal manner, the full range of requirements for the system. It is an interdisciplinary approach that focuses on defining customer needs and required functionality early in the development cycle, documenting requirements, and then proceeding with design synthesis and system validation while considering the complete problem: operations, cost and schedule, performance, training and support, test, manufacturing and disposal.

The INCOSE Systems Engineering Handbook defines the discipline and practice of systems engineering for novice and practising professionals. It provides an authoritative reference to understand the discipline in terms of content and practice.

incoseonline.org.uk/Normal_Files/Publications/SE_Handbook.aspx?CatID=Publications&SubCat=INCOSEPublications

Human-centered design

Human-centered design (HCD) offers problem solvers a chance to design with communities: to deeply understand the people they're looking to serve; to dream up scores of ideas; and to create innovative new solutions rooted in people's actual needs. It encourages the belief that all problems, even the seemingly intractable ones, like poverty, gender equality, and clean water, are solvable. Moreover, it means believing that the people who face those problems every day are the ones who hold the key to their answer.

HCD is defined by its mindsets: empathy; optimism; iteration; creative confidence; making; embracing ambiguity; and learning from failure. Together, these encourage fearless yet grounded creativity, leading to innovation and solutions never dreamed of when projects are started. HCD has been used to successfully tackle an array of design challenges, from social enterprises to communication campaigns to medical devices.

The field guide to HCD from IDEO presents design as an iterative process comprising three main phases:

- inspiration – understanding people, their hopes and desires
- ideation – generating ideas, testing and refining them
- implementation – taking the idea to market and maximising its impact.

Numerous practical tools are provided to assist each stage.

www.ideo.com/us/post/design-kit

Six sigma

Six sigma is an approach to improvement developed at Motorola in the 1980s, which focuses on removing the causes of defects and reducing variation in processes. It has a meticulous focus on understanding wide-ranging customer needs, prioritising these and designing processes and systems to deliver to those needs. Its purpose is derived from the desire to achieve a performance level equivalent to a defect rate of 3.4 defects per million opportunities. Six sigma uses a disciplined and systematic approach look at the improvement journey from a number of related perspectives: define; measure; analyse; improve; and control (DMAIC).

Six sigma is typically a facilitated process where experts use qualitative and quantitative techniques to drive process improvement. Although the tools themselves are not unique, the way they are applied and integrated as part of a system is. Six sigma professionals undergo extensive training to be able to select and use tools to evaluate a process from various perspectives and determine which activities are to be improved. It has been embraced by a number of US companies, while application in the UK health system is more limited.

Six sigma tools help to:

- define a problem, improvement opportunity or requirements
- measure process performance
- analyse processes to determine root causes of variation, defects or poor performance
- improve process performance by addressing root causes
- control the improved process and future performance.

It is increasingly used in conjunction with lean thinking.

asq.org/learn-about-quality/six-sigma/tools.html

Inclusive design

Inclusive design (ID) is the design of mainstream products and/or services that are accessible to, and usable by, as many people as reasonably possible without the need for special adaptation or specialised design. It applies to all parts of a user journey, not only to the recipients of care, but also the providers of care and care services.

At the core of ID is a user-focused systems design process and the realisation that every design decision has the potential to include or exclude people. Inclusive design emphasises the contribution that understanding user diversity makes to informing these decisions, and thus to including as many people as possible. In this context, user diversity covers variation in capabilities, needs and aspirations, while care is also taken to address broader issues relating to people, profit and planet.

The ID toolkit provides a step-by-step guide to the use of the *explore, create* and *evaluate* design cycle, embedded in the context of the *identify* and *locate* activities that relate to the people engaged with the systems and its location. This process is directly informed by the *purpose* of the system, a deep understanding of stakeholder and user needs and a sense of what *success* looks like.

www.inclusivedesigntoolkit.com/

Risk management

Risk management is the coordinated set of activities used to direct and control an organisation with regard to risk. All activities within an organisation involve some level of risk. Successful organisations manage such risk by identifying it, analysing it, and then evaluating whether the risk should be modified in order to satisfy their risk criteria. Such risk management can be applied to an entire organisation, and its many areas and levels, at any time, as well as to specific functions, projects and activities.

The practice of risk management has been developed over time and within many sectors to meet diverse needs. The adoption of consistent processes within a clear framework ensures that risk is managed effectively, efficiently and coherently across an organisation. Risk management should be both proactive and reactive, and an integral part of an organisation's governance, management, culture and practice.

ISO 31000:2009 and IEC 31010:2009 are international standards for risk management that provide comprehensive principles, guidelines and tools to help organisations manage risk. They are designed to:

- assist proactive assessment
- improve identification of opportunities and threats
- increase the likelihood of meeting risk targets
- improve the engagement of all stakeholders in the management of risk.

www.iso.org/standard/43170.html

www.iso.org/standard/51073.html

System safety assessment

System safety assessment (SSA) is a method designed to help health and care professionals think about 'what could go wrong' in a system, which could be anything from a care pathway to a project plan for a service improvement, to a new ward or even the movement of a service from acute care to the community. SSA is a process for proactively thinking about and addressing potential problems, either so they can be prevented from happening in the first place or so that their consequences can be reduced to an acceptable level.

At the core of SSA is a standard process for managing risks. The principles are likely to be familiar to many people involved in health and care, but the systematic and proactive way in which it is done may be less so. Current healthcare risk assessments typically focus on 'health and safety' risks, such as the risk of slips, trips and falls. Conversely, SSA is flexible and can focus on a wide range of risks, including clinical, project management, financial and organisational risks.

The SSA toolkit provides a step-by-step guide to the use of proactive risk assessment, beginning with the *trigger* and assessing risks through the *examine (organise), assess* and *improve (create)* stages of the risk management cycle.

www.ssatoolkit.com/toolkit/

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About the project

The project was based on an extended conversation within a unique forum of experts. The Royal Academy of Engineering led the forum, in collaboration with the Royal College of Physicians and the Academy of Medical Sciences. It generated thought leadership from a group of people who would never otherwise have met and generated a network of engaged organisations and individuals committed to taking this framework into action. Designed and facilitated by Emma Adams and Pete Dudgeon, the project ran a suite of workshops in autumn 2016 focusing on different perspectives of a systems approach.

Workshop 1: A systems perspective
21 September 2016 at the Royal Academy of Engineering

Workshop 2: A design perspective
28 September 2016 at the Academy of Medical Sciences

Workshop 3: A risk perspective
5 October 2016 at the Royal College of Surgeons

Workshop 4: Integration and dissemination planning
2 November 2016 at the Royal Academy of Engineering

The majority of participants attended all workshops and included:

- patient leaders
- acute trust clinicians and physicians who are leading transformation programmes
- system engineers (including INCOSE UK members)
- RCP Future Hospital Programme
- NHS Improvement
- improvement charities and funders
- service providers including pharmacy, mental health services and housing
- clinicians and managers involved in quality improvement and service design.

This work was the continuation of a preliminary study conducted by *Engineering the Future*, led by the Chartered Institution of Building Services Engineers (CIBSE), the Institute of Healthcare Engineering and Estate Management (IHEEM), and the Institute of Physics and Engineering in Medicine (IPEM) that explored the importance of engineering to health and care.

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The report was reviewed by a group of external experts. Reviewers were asked to consider whether the evidence and arguments presented in the report were sound and supported the conclusions. Reviewers were not asked to endorse the report or its findings.

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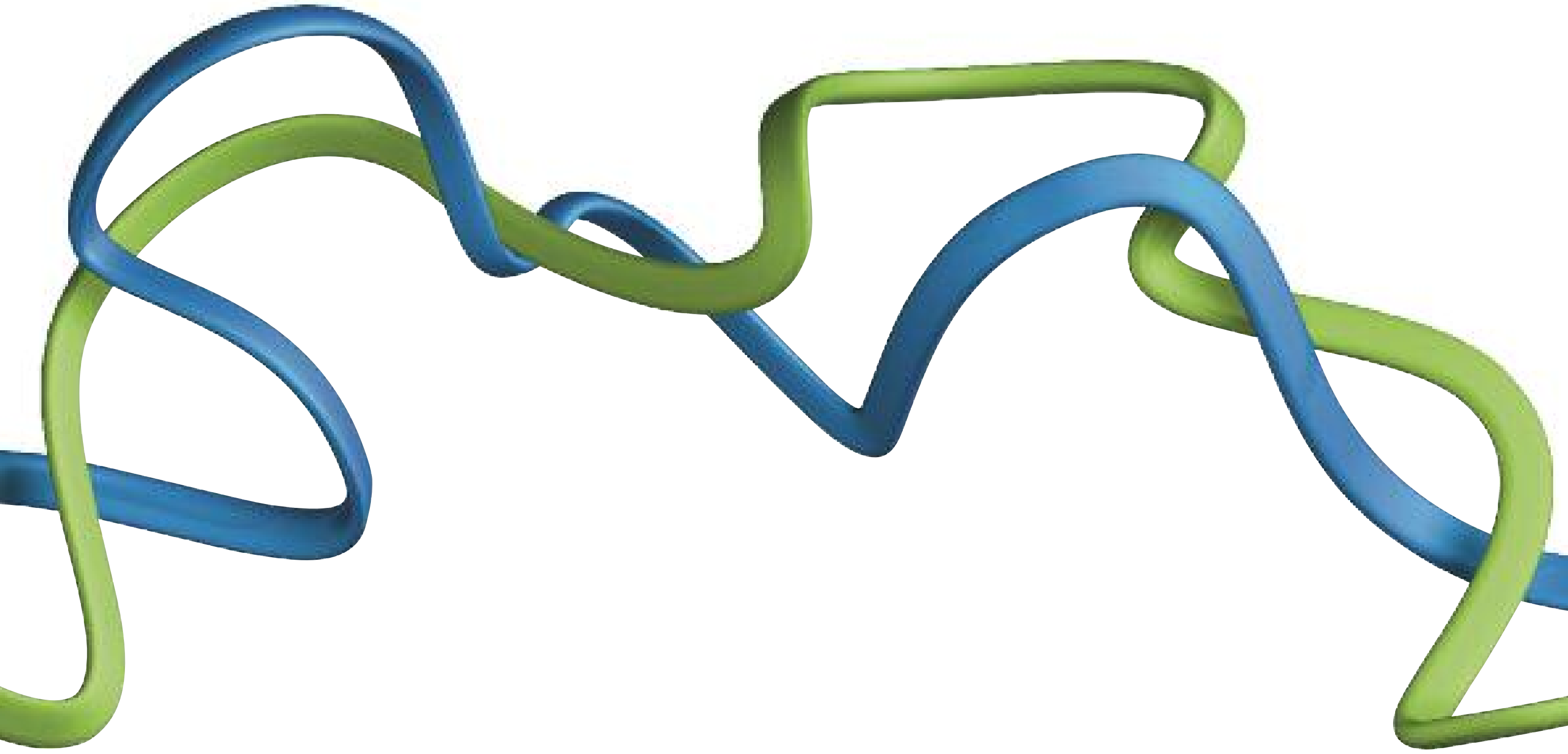

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