Chapter 3

# Systems engineering

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Despite advances in engineering knowledge and technology the everyday experience of the engineered world provides, all too often, evidence of failure as well as success. For example, as a literate and healthy human is it unreasonable to expect:

- to be readily able to set the alarm function on my digital watch and to be confident that it will work?
- to be able to read the instructions on food packaging?
- to correctly change batteries, first time, on an electric toothbrush?
- not to have to move every few minutes to prevent the office being plunged into darkness by a motion sensitive, power-saving system?
- to have my 'patient's notes' present at the same time as myself in an otherwise high-tech clinic?

All these problems, and more, have beset our group recently. The list is long, the explanation occasionally obvious (for example, the batteries were inserted incorrectly because it is almost impossible to see the polarity signs embossed on the internal base of the toothbrush battery casing) but the implications for engineering are enormous. Quite simply, they force us to ask whether the engineering process itself is correct.

All engineered environments and artefacts have human involvement. Even so-called 'fully automated processes' are anything but that. On analysis we find that they are specified and designed by humans, tested by humans, commissioned by humans, maintained by humans, and subsequently decommissioned and disposed of by humans. The need for a systematic approach to design that is inclusive of 'the human factor' is evident, but is it acted upon?

All engineered environments and artefacts have human involvement.

Even when the 'human factor' in the system is considered, it is often forgotten that whilst humans may come as individuals, they always work as groups, teams, organisations and, even, societies. Understanding the resultant needs, behaviours and attitudes is integral to systems engineering. Pheasant (1996) identified five fallacies of engineering design (Table 3.1). The common thread that runs through them all is the need to recognise that design, to be successful, must adopt a systems approach. How then to avoid such traps and develop systems that truly reflect modern thinking and knowledge?

The following sections present an introduction to systems engineering and ergonomics, focusing on the way in which they should influence the design process. Examples are presented to illustrate the key issues. Many are from the healthcare industry, where safety can only assured if a systems approach is adopted.

| Fundamental fallacies regarding design |
|---|
| 1. The design is satisfactory for me – it will therefore be satisfactory for everybody else |
| 2. The design is satisfactory for the average person – it will therefore be satisfactory for everybody else |
| 3. The variability of human beings is so great that they cannot possibly be catered for in any design – but since people are wonderfully adaptable it does not matter anyway |
| 4. Ergonomics is expensive since products are actually purchased on appearance and styling, ergonomic considerations may conveniently be ignored |
| 5. Ergonomics is an excellent idea. I always design things with ergonomics in mind - but I do it intuitively and rely on my common sense so I do not need tables of data or empirical studies |

**3.1 Fundamental fallacies (Pheasant, 1996)**
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## Systems engineering and ergonomics

Systems engineering is a process through which the analysis of existing systems and appropriate knowledge can be applied to new design problems. The emphasis is placed very clearly on the process and not the product. In reality, this will require addressing the needs of all stakeholders, including the end users.

In August 2000, the International Ergonomics Association Council adopted an official definition of the discipline of ergonomics. This states that:

> *ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimise human well-being and overall system performance.*
>
> (IEA, 2000)

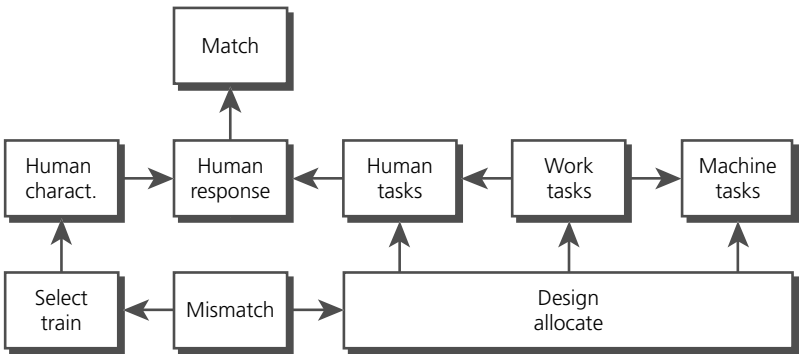
The very close relationship between systems engineering and ergonomics is readily apparent.

## Human factor mismatches in work systems

For existing systems, a simple model has been presented to enable an appreciation of the need to consider how to avoid mismatches between users and work systems, in particular the managed and the engineered environments. Whilst the examples worked through below focus on 'mismatches'

or problems that occur in systems, the same thinking may be applied to enhancing systems that are already deemed to be working 'satisfactorily'.

By way of explaining this model, we may start with the fact that in any work system work tasks are performed in order to meet specific goals. For example, cars are assembled, accounts are processed, customer enquiries are received and dealt with, software is installed, *etc*. On the right-hand side of Figure 3.2 we can observe that some of these tasks are allocated to machines (for example, production lines carry components around the workspace, tools exert high forces to secure components in place during assembly, computers store large quantities of detailed numerical data) whilst other tasks are allocated to the human operators (for example, saving and retrieving data, operating tools, fixing breakdowns, talking to customers). Task analysis is a specialised topic (see Annett and Stanton (2000)) and is an essential part of the process of understanding existing systems and subsequently developing new ones.




**3.2 Human factor mismatches in work systems**

Having undertaken such an analysis, the first critical question that often emerges is "on what basis are specific functions (and hence tasks) allocated to either people or machines?" Often the answer is "unclear!" Closer inspection frequently reveals a 'default' decision process, in that if there is a machine that can do it then, use the machine, and if not, get a human operator to do the task. Such an approach affords little attention to the relative advantages of people versus machines and is, in any event, unlikely to lead to coherent, meaningful jobs or sets of tasks for the worker(s).

On the left-hand side of Figure 3.2 is a box labelled 'human characteristics'. Most work systems employ, or engage with, a wide range of people. Usually, little attention has been paid to their capacities, needs or abilities (Coleman, 1999; Clarkson and Keates, 2001). Too often, much is assumed and little researched. The consequences of this are serious.

It would be inconceivable, for example, to imagine an engineer designing a control panel without careful consideration being given to, for example, the power required to illuminate a warning light and whether the circuit had power back-up. A legitimate question that follows from this is whether similar care and attention is paid to the component in the system that has to detect the signal, make decisions and act on it (i.e. the human operator).

**3.3 Warning lights**

At this point, many questions may be raised. For example, how conspicuous must the light be to be clearly visible under all operating conditions (see, for example, Figure 3.3), what other tasks is the operator required to perform that might interfere with his/her ability to detect or respond, will all operators behave in the same way, how might a history of earlier 'false alarms' affect the operator's performance in the event of a true alarm signal occurring and how might the culture of the organisation in dealing with false alarms affect the operator?

One framework for closer examination of these complex interactions is shown in Figure 3.4, where the interface between the operator and the machine at a given point in time is shown. Note, however, that such a model is best considered a state model, with inherent dangers if states are assumed to be steady and stable over time or if all operators are seen as homogeneous and identical. Corlett and Clark (1995) provide a thorough introduction to engineering/ergonomics design for workspaces and machines.

The reality of failing to take a systems approach is all too often evidenced as a failure or as an inefficient process. Indeed, much of the time it is the occurrence of mismatches (bottom centre of Figure 3.2) that triggers an awareness that not all is well with a given system. Thus, the accident, the injury, the poor output, or the uncompleted maintenance schedule all alert us to 'a problem'.

However, the response to this problem often shows further evidence of inappropriate systems thinking. The common practice of 'fixing' the problem by taking the route on the left-hand side of the model is best described as "changing the operator". This usually comprises either selection or training of the operator.

In the case of the visual alarm, taking this approach might lead to recruiting only those with a high degree of visual acuity or to train operatives to be 'more careful' when detecting or responding to alarms. However, it is well accepted, that reliance on both the selection and training strategies fails to recognise their inherent dangers. If the system contains latent design errors, e.g. a light that cannot easily be seen when the display has

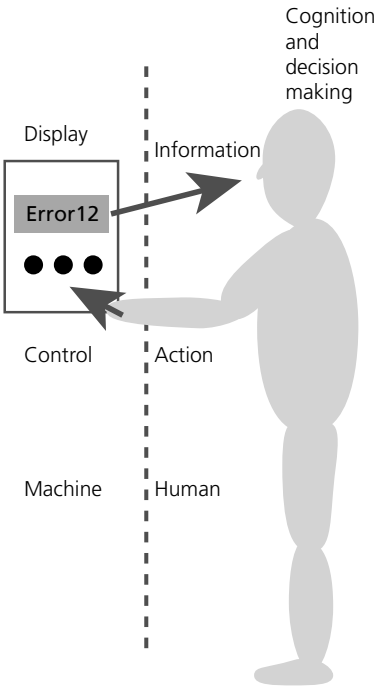
sunlight falling on it, then no amount of selection or training will make a substantial difference. On the contrary, the raised stress level of the operator (i.e. knowing that they "should be able to cope" when they cannot) might even exacerbate the situation and lead to a greater likelihood of error.

Those engaged in ergonomics and human engineering have long since recognised that the preferred route for preventing problems and enhancing systems performance in existing systems is to follow the right-hand pathway in Figure 3.2. This places the emphasis on design/re-design. This may require a consideration of a range of issues which include:

- the system goals;
- the task allocation;
- the equipment design;
- interactions between sets of equipment and groups of people;
- the work organisation;
- the job design.

Whilst methods (e.g. Wilson and Corlett, 1995) exist for the analysis of all these components of the system, the complexity of such an approach is, at first sight, daunting.

A recent model (Moray, 2000) attempts to draw together the components of systems that need to be considered if we are to take this systems design or systems engineering approach. This model enables the various levels of the system to be conceptualised for the purpose of understanding, interpreting, evaluating, information collection, and design purposes. Such an approach and understanding is required for successful systems analysis and design. Further understanding of the 'big systems' picture can be found in Hendrick and Kleimer (2002).




**3.4 Human–machine interface**

## Error and systems engineering

In order to see how systems might be analysed it is perhaps helpful to consider specific examples. A recent study (Cambridge, RCA, Surrey, 2004) took a systems approach when reviewing the problem of medical error. Each year in the UK an estimated 850,000 people are involved in an adverse event caused by a medical error. The Medicines Control Agency received 18,196 reports of adverse drug reactions and the Medical Devices Agency received 6,610 reports of adverse incidents. The evidence of adverse incidents is almost entirely based on occurrences in secondary care (hospital) (Leape *et al.*, 1991, 1995; Wilson *et al.*, 1999).

In a study of adverse events by Wilson *et al.* (1999), Department of Health categories were identified as:

- a complication of or failure in technical performance of an indicated procedure or operation;
- the failure to synthesise, decide and/or act on available information;
- the failure to request or arrange an investigation, procedure or consultation;
- lack of care and attention or failure to attend to the patient.

A review of the current knowledge base showed that the problem is extensive, that there is little information about these problems outside of the secondary care setting (hospital), and that any engineered design solutions should, as a minimum, consider how they will address each of the four adverse events categories shown above. Case study 1 (below) considers an equipment interface and illustrates current problems.

The relevant information needed to reduce error in the design of equipment to be used by humans is readily available.
(Moray, 1994)

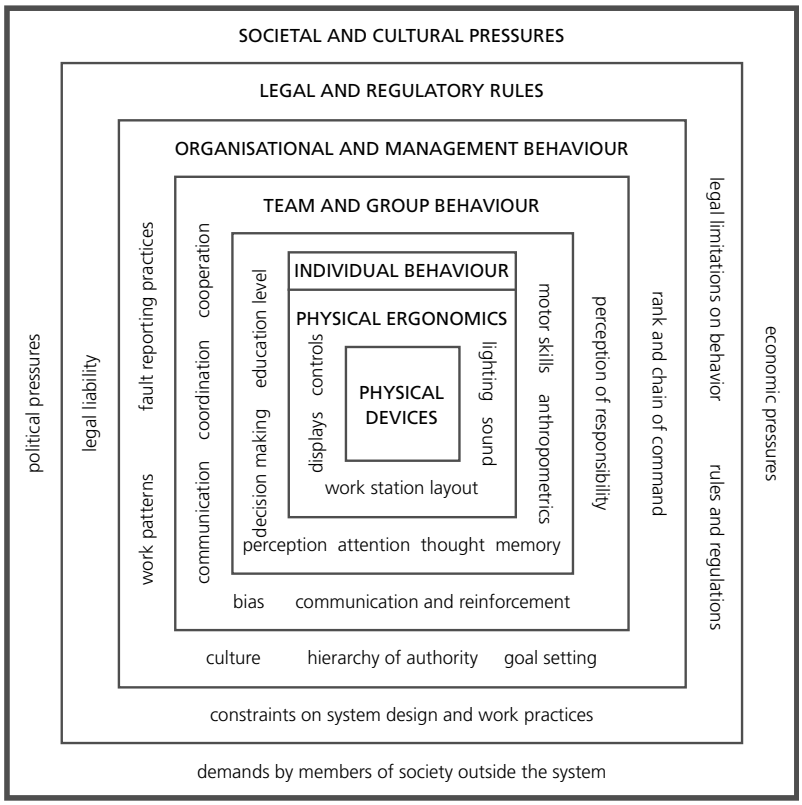
According to Moray (1994), the relevant information needed to reduce error in the design of equipment to be used by humans is readily available. However, even when all the ergonomic knowledge is applied to design of equipment the probability of error cannot be completely eliminated. The factors at work in a complex human–machine system have far greater potency for causing errors than do ergonomic factors. It is these factors that call for the notion of systems design.

Moray's model (Figure 3.5) is a representation of the causal structure of a complex hierarchical human–machine system. It is very general and is able to encompass bureaucratic organisations as well as the systems in which humans interact with complex machinery. By way of illustration, each level of the system is now briefly considered with respect to medical error.

### Physical devices

At the centre of the system is the physical device or tool being used. There are many illustrations and examples of errors and difficulties associated with the use of equipment (see Obradovich and Woods (1996)).

One particular category of equipment, *i.e.* infusion devices, is often cited in adverse incident reports (Williams and Lefever, 2000). Setting infusion devices at the wrong rate is a frequent occurrence. Explanations for this type of error include the fact that confusion can exist between mg/hour and ml/hour when setting the infusion rate (Poster and Pelletier, 1988). This problem is exacerbated because users are often hindered by a lack of




**3.5 A model of ergonomics systems (Moray, 2000**
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feedback from the display and are frequently unable to detect which operational mode they are in (Garmer *et al.*, 2000). A fuller exposition of the user issues associated with the design of the interface of these devices has been included in case study 1.

Other aspects related to using physical devices include, for example, such issues as the legibility of labels on bottles and equipment and confusion over the identity of bottles with similar shapes and colours. Anaesthesiologists report that the colour of the ampoule containing a drug to be used and its label were both "extremely important" for ampoule recognition, as were the colour of the vial and cap. The text colour and external packaging were the most important features for pre-filled syringes, whilst for self-prepared syringes the drug label and syringe size were the most important features.

Knowledge of such factors is therefore critical for the systems engineering approach.

### Individual behaviour

Omissions (i.e. the failure to carry out some of the actions required to achieve a desired goal (Reason, 1990)) were identified as the most common type of error (Poster and Pelletier, 1988). The role of such errors is evident when considering the giving of drugs to the wrong patient. This is frequently connected with failing to check the patient's identity bracelet and is often associated with distraction by other patients or interruptions because of the high level of ward activity. Administering the incorrect drug is most often associated with failing to read (or understand) the prescription chart or the drug label and the lack of knowledge of a particular drug (Gladstone, 1995).

Omissions are the most common type of error.
(Poster and Pelletier, 1988)

### Physical ergonomics

Noise levels in working environments may cause messages to be misunderstood and can lead to interruptions. Chisholm *et al.* (2000) studied the number and type of interruptions occurring in emergency departments. Emergency physicians were frequently interrupted (about 31 times in 180 minutes). In primary care settings (general practice), nurses reported that interruptions were distracting, affected patient flow, and that the confidential nature of some consultations was irrevocably damaged by constant disturbances (Paxton *et al.*, 1996).

### Team and group behaviour

Most people work within some kind of team, and so a consideration of factors such as communication, supervision and responsibility is required. Absence of, or poor, communication between and within teams is likely to contribute to errors (Dean *et al.*, 2002). For example, in a hospital setting the most junior medical officer is usually called upon to take a patient's medication history on admission. These doctors are often called upon to prescribe drugs and do so without asking questions under the assumption that this is the correct procedure. In some instances supervision is seen as inadequate, and other issues, e.g. overlapping responsibilities between teams, also contribute to errors (Dean *et al.*, 2002).

Absence of, or poor, communication between and within teams is likely to contribute to errors.
(Dean *et al.*, 2002)

Traditionally, information flows vertically through a hierarchy and orders are sent from the top down with the expectation that lower levels will implement them (West, 2000). Adverse events can occur because individuals of lower status experience difficulties challenging decisions of a person of higher status. Sexton *et al.* (2000), comparing medicine with aviation, suggest that poor communication is the equivalent of poor threat and error manage-

ment. Effective cockpit crews use one-third of their communications to discuss threats and errors in their environment, whereas poorly performing teams spend about 5% of their time.

### Organisational and management behaviour

Although factors affecting individuals have been highlighted, there is limited value in focusing on individual activity, as this tends to perpetuate a blame culture. The focus needs to widen to include systems issues underlying the problems that are present in any complex work environment (Anderson and Webster, 2001). Leape *et al.* (1995) carried out a study to identify and evaluate the areas of systems failure that underlie drug errors. They identified:

- drug knowledge;
- dissemination, dose and identity checking;
- availability of patient information;
- order transcription;
- allergy defence system;
- medication order tracking; and
- inter-service communication.

These failures were underpinned by impaired access to information and resulted from design faults. These included:

- defects in conceptualisation and planning;
- failure to recognise service needs; and
- failure to adapt systems to changing demands and changing technology.

Leape *et al.* identified other systems failures in such areas as:

- issues surrounding device use;
- standardisation of doses and frequencies;
- standardisation of drug distribution within the unit;
- standardisation of procedures;
- preparation of intravenous medications by nurses;
- transfers/transition procedures;
- conflict resolution;
- staffing and work assignments; and
- feedback about adverse drug events.

System failures are sometimes difficult for 'front line' staff to recognise because the decisions underpinning these systems may have been made in the past by those at a higher level of the organisation (Leape *et al.*, 1995). System changes suggested to reduce errors included adjusting work schedules to simplify work systems and enlisting the help of frontline personnel.

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(Leape *et al.*, 1995)

### Legal and regulatory rules

The behavioural options available to those working in a system may be tightly constrained by regulatory rules (Moray, 1994). For example, only certain drugs may be administered or procedures undertaken. As systems become more complex, the task of regulation becomes ever more difficult. For example, how do regulators cope with the issues that arise when multiple pieces of equipment are used conjointly or when 'intelligent' software is embedded within drug-delivery systems, thereby blurring the boundaries between equipment design and clinical decision-making?

The behavioural options available to those working in a system may be tightly constrained by regulatory rules.
(Moray, 1994)

Much has also been written on the role of standardisation in systems design. For example, West (2000) suggests standardisation and formalisation of tasks in an effort to reduce the complexity of work. The implications for systems design of such an approach again become apparent if specific contexts are considered. Equipment and environments would need to become standardised (for example, the aircraft cockpit) and the formalisation of tasks would require clarification of roles, rules and procedures.

Currently, many errors stem from the absence of controlled vocabulary for use in the medical setting (Senders, 1994). However, it is not inconceivable that all communication of medical orders and the names of medical preparations and devices could conform to the standards of a controlled vocabulary. This might help, for example, to reduce the number of prescription errors due to the use of non-standard abbreviations.

### Societal and cultural pressures

The development of any large system is also likely to be subject to economic and political pressures, and demands by members of society outside of the system. Therefore, it is important to be aware of the potential impact of these pressures on the desired behaviours by those within the system when specifying, designing and implementing it.

Currently, many errors stem from the absence of controlled vocabulary for use in the medical setting.
(Senders, 1994)

## A systems approach to patient safety

Design is the process by which something is created, whether it be a product, a protocol or a service. It is helpful to consider what design is in the context of systems development, since this will shed light on the role of design in improving patient safety.

There are many models of design that help to describe the nature of the process. One of the simplest may be found in British Standard 7000 Part 1. It describes the product life cycle as comprising of three key stages:

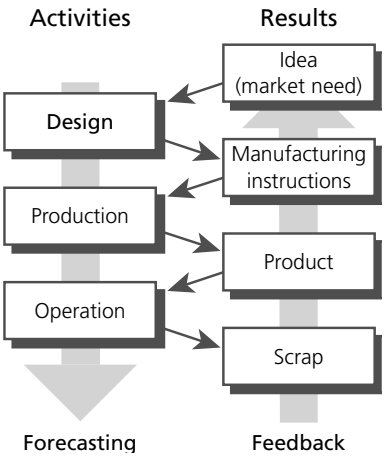
design, production and operation (these are illustrated in Figure 3.6). This model ignores the subtlety of design and paints a rather optimistic view of the process, and in reality there can be much iteration. Forecasting is necessary if the designer is to be able to design a product that can be made at the right price and used by the right people. Such forecasting is generally possible only if feedback is obtained about the performance of previous products or prototypes of the emerging product.

This model of design applies to products, services and systems. For example, if a new prescribing form is to be designed, a means must be defined to encourage the adoption of the form (production). In addition, the layout of the form must encourage its effective use (operation), both in terms of its ability to convey the required information accurately and its ability to be completed (and read) within an acceptable period of time.

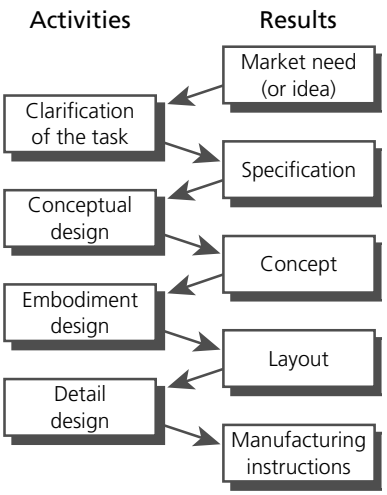
Design is often then subdivided into a series of activities that enable the initial market need or idea to be converted into the manufacturing instructions that fully describe the product that is to be made (Figure 3.7). In reality, these stages are not strictly serial and may show significant overlap. The simple model also hides many significant influences that may affect the design process. These influences begin to show that product design is not simply an isolated activity, but is critically dependent upon and critically defines the business process. Indeed, the model presented by Moray (2000) (shown in Figure 3.5), derived from an ergonomic viewpoint, is remarkably similar to that presented by Hales (2004) (shown in Figure 3.8), derived from an engineering design viewpoint.

It is important to note that one person's product may be another person's component. For example, the Rolls-Royce Trent 700 jet engine becomes a component for an Airbus 340-500. Thus, a product may be made up of a complex mix of components and/or be one of a number of products required to contribute to a particular task or service. For example, the provision of a domestic electricity supply relies on a number of products configured in the generation, transmission and supply system.

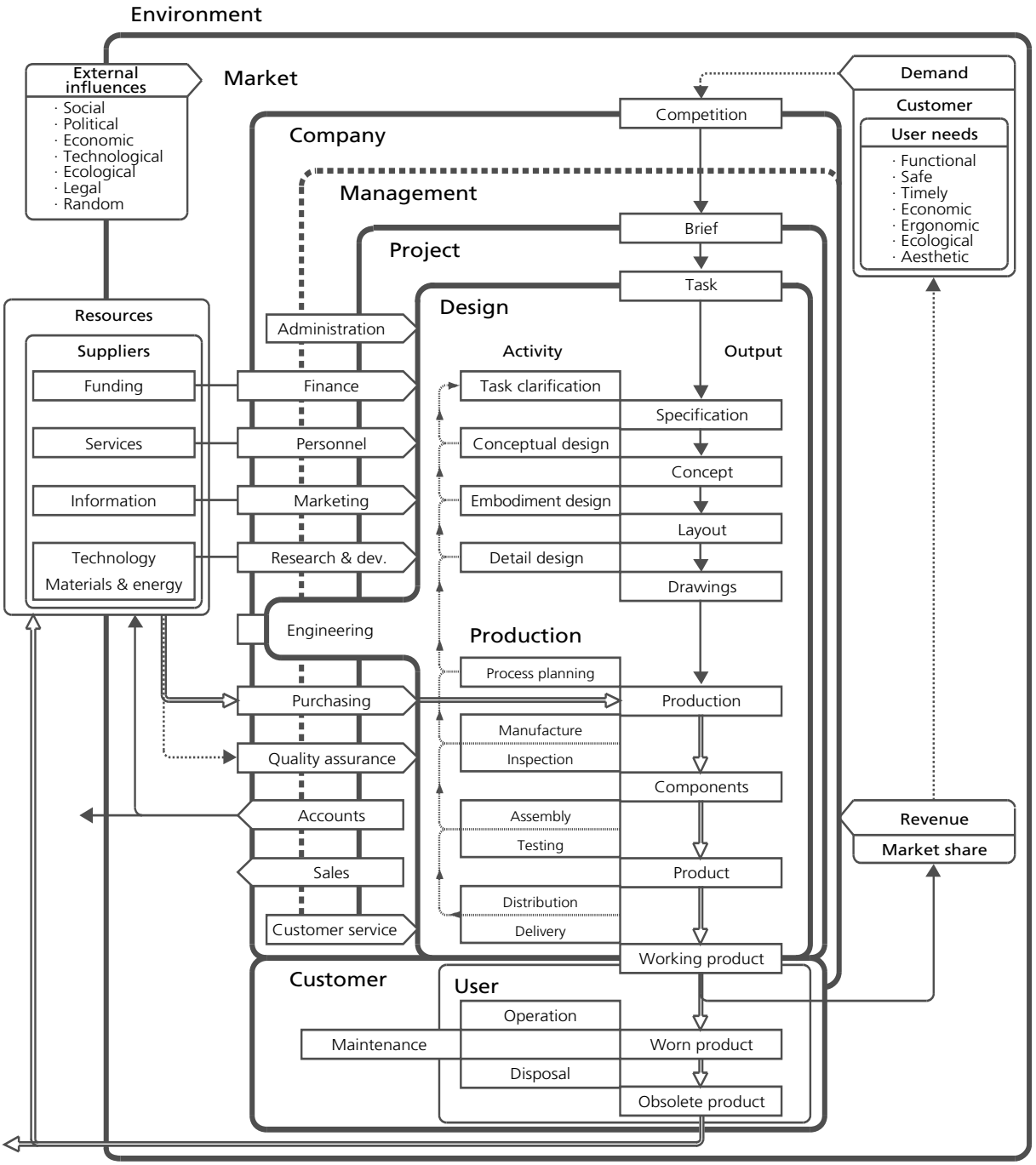
As far as design is concerned, nothing is changed in dealing with a system, although there are usually more users, more requirements, and generally more demands and influences on the product, but the stages of design remain the same. However, in the case of systems the simple models of design do not help the design team and more rigorous design strategies are required. In addition, there is a need to develop methods better suited to ensuring the safety of the final product.




**3.6 The product life cycle, adapted from the BS7000 product introduction process**



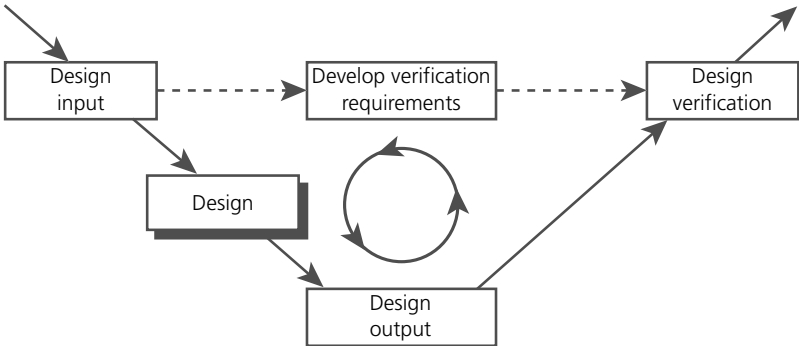

**3.7 Elements of design**




**3.8 Engineering design in an industrial context (redrawn from Hales, 2004)**

### Better models of design

Thus far, all the discussion has been based on common descriptions of product design. However, they generally do not map well to the requirements of medical device or equipment design. More emphasis is required on the product safety requirements, whether the product be a medical device or medical procedure. In both cases, one way of ensuring safety is to evaluate the performance of the emerging product or system rigorously. Methods adapted from software engineering are useful for this purpose. One such adaptation is shown in Figures 3.9 and 3.10.




**3.9 System verification – does it meet users' needs? (Alexander and Clarkson, 2000)**
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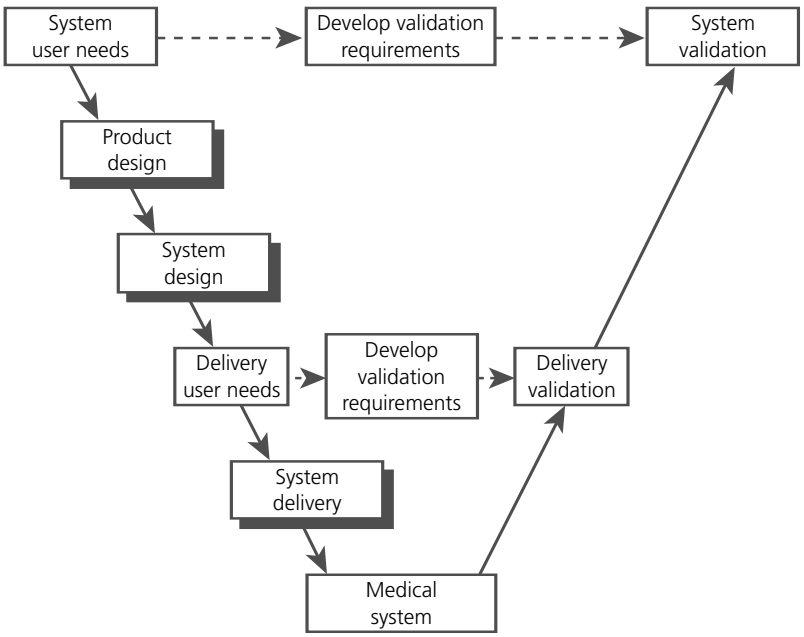


**3.10 System validation – is it to specification? (Adapted from Alexander et al., 2001)**

Figure 3.9 shows the role of verification in the design of a system. Figure 3.10 shows the development of the system along with its delivery, highlighting the need for validation of the system and its delivery process. Put simply, verification and validation may be defined by:

"*Verification: 'Are we building the thing right?'*"
"*Validation: 'Have we built the right thing?'*"
(Alexander *et al.*, 2001)

Evaluation, in the form of verification and validation, emerges as a critical component of all engineering design, in particular, medical device and equipment design.

Evaluation, in the form of verification and validation, emerges as a critical component of medical device and equipment design, ensuring that evidence of satisfactory performance is available. Of particular importance is the early definition of the evaluation requirements, which in turn may influence the design. The evaluation of medical devices or equipment must, in addition, be done in the context of their expected use.

Ideally, this involves a range of tests, including user trials, to provide representative performance data. Where a product is used as part of a system, the full system must be evaluated. The same is true for services, where every part of the service chain should be evaluated. For example, if a new treatment protocol is to be evaluated, all those activities required for the preparation, execution and monitoring of the protocol should be evaluated. Inevitably, this leads to the evaluation of human/equipment systems.

### The systems engineering approach to design

The International Council on Systems Engineering (INCOSE) states that:

*Systems Engineering is an interdisciplinary approach and means to enable the realisation of successful systems. Systems Engineering focuses on defining customer needs and required functionality early in the development cycle, documenting requirements, then proceeding with design synthesis and system validation while considering the complete problem: operations; performance; testing; manufacturing; cost and schedule; training and support; and disposal.*

Systems Engineering is an interdisciplinary approach and means to enable the realisation of successful systems.
(INCOSE, 2004)

*Systems Engineering integrates all the disciplines and specialty groups into a team effort forming a structured development process that proceeds from concept to production to operation. Systems Engineering considers both the business and the technical needs of all customers with the goal of providing a quality product that meets the user needs.*
(INCOSE, 2004)

It can be seen from these definitions that systems engineering is no different from design. However, its distinguishing feature is its complexity, brought about by its multi-disciplinary, multi-product or multi-user approach.

The validation model can be extended to provide the basis for a systems engineering approach to meet the needs of the NHS. The model, an extension of Figure 3.10, is based on the definitions and issues presented above (Figure 3.12). At the heart of this model is the innovation/procurement activity (within the inner box) which represents the design activity shown earlier. This process will be unique to a particular product or service, and should be informed by all the relevant stakeholders and agencies, and be actively managed to minimise technical and commercial risk.

**3.11 An unusually complex design**
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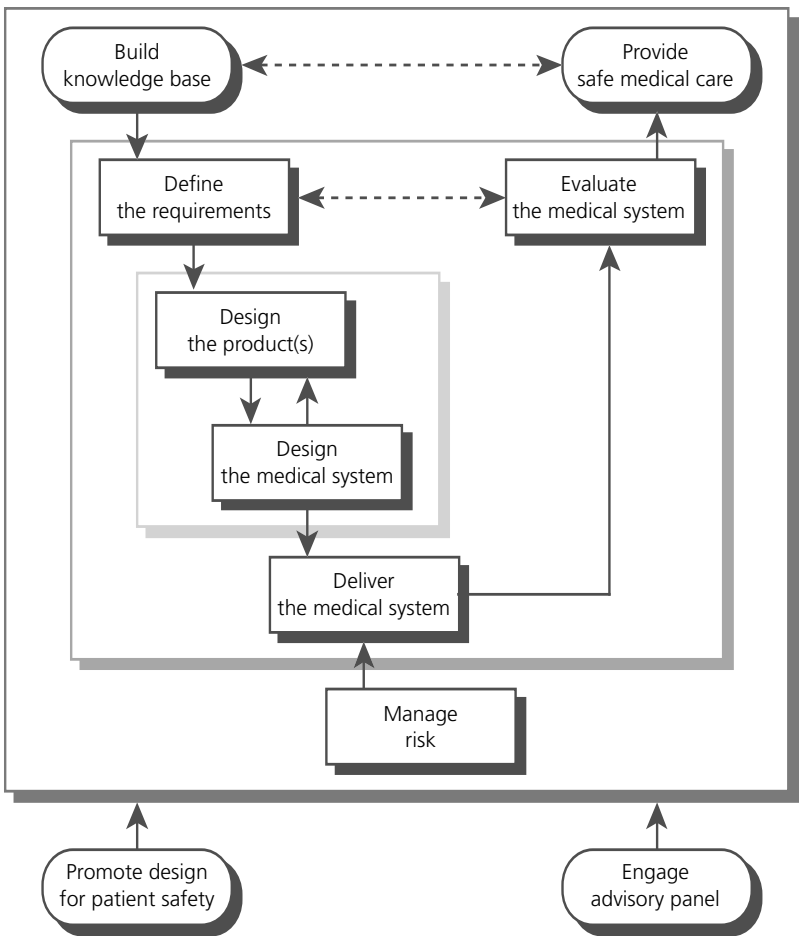



**3.12 A systems-based user-centred approach to healthcare design**

Successful product or service development cannot be done in isolation from the system or environment into which it will be introduced.

Successful product or service development cannot be done in isolation from the system or environment into which it will be introduced. Therefore, that system must be well understood, for instance by building an effective NHS knowledge base element. This improved understanding will in turn lead to the setting of more effective design requirements by the NHS, a prerequisite to improvements in procurement and innovation practice. This whole process could be informed and assisted by an advisory panel made up of industry and academic experts.

Figure 3.12 represents a convergence of views from the fields of ergonomics, engineering design and user-centred design. Thus, it presents a strong case for a systems-based user-centred approach to healthcare design.

## Systems engineering and ergonomics as a process

Three case studies are presented to illustrate some of the processes and methods available to inform the systems design approach. The first is the assessment of the usability of a commonly used drug-delivery system known as an infusion device. This device enables fluid medication to be delivered to a patient at a regular rate, without the need for constant intervention by the healthcare deliverer.

The second illustrates the benefits of engaging with the end users of systems during the design phase. As part of the development of a new supermarket checkout system, the designers worked with checkout operatives to help select appropriate technology, design the physical layout of the workstations and evaluate and test the designs in an iterative fashion from concept to installation.

The final case study illustrates the breadth of methods that might be used in tackling complex systems where the existing knowledge base is weak. This approach, used to map healthcare delivery systems, helped to obtain a clear understanding of the systems and of where changes might be beneficial.

## Case study 1: computer-based infusion devices

The design of computer-based infusion devices has been considered by Obradovich and Woods (1996). A study of devices adapted for terbutaline infusion showed how the device characteristics increased the potential for error. They also studied strategies that have been developed by users to protect themselves from failure. Amongst the conditions they identified as deficient were complex and arbitrary sequences of operations, mode errors

due to poor differentiation of operating modes, ambiguous alarms and the problem of the user 'getting lost' in multiple displays. There was also poor feedback on the device state and behaviour.

### Analysis of existing interface design

Garmer *et al*. (2002) have considered the development of a new user interface for an infusion pump using the human factors/ergonomics approach. Usability analysis was undertaken on existing designs based on observations, interviews, reported incidents and the theoretical basis for memory and human error. A new interface was developed based on a number of ergonomics principles (Table 3.13). An evaluation of the reduction in errors was undertaken. The number of errors was reduced but remained significant.

| Equipment design improvements for the existing interface (Garmer *et al*., 2002) |
|---|
| * Larger numbering in the display window |
| * Buttons for setting the numerical values to be placed on the display window |
| * Plainer messages to be left in the display window |
| * One button for volume to be infused and one for flow rate |
| * To replace symbols by words |
| * To avoid several functions on the same button |
| * To make it easier to see if the volume to be infused is activated |

**3.13 Infusions devices interface design improvements (Garmer et al., 2002)**


Garmer *et al*. suggest that further tests are needed to improve the interface. They have identified, in particular, the need to provide more effective mode operation (for example, with the use of spring-loaded buttons). With regard to the process for finding solutions, they emphasise the importance of usability testing with a wide range of methods. They also emphasise the need to study both competent, experienced users and novice or learner users.

Currently, both the range of equipment and variety of interfaces have serious implications for the transfer of skills and the need for elaborate and complex training.

Examples from the Garmer *et al*. (2002) study illustrate how basic, but important, some of the design changes might be. For example, they identified that the pump should always have the same start-up mode and that this should be the mode most frequently used. Other modes should be user

maintained. They also note that numerical information should be presented using only significant numbers, that if a decimal point is used, then it must be readable from all positions in the environment of use, and that all buttons should be marked with all of their functions. Many of these basic feedback and display topics are well understood and, through appropriate guidance, could lead to the development of far more effective/user-friendly interfaces.

It can be seen from Table 3.14 that many of the features imply simple design changes. However, these changes have hitherto not been reported in the literature, nor is there evidence that the medical device industry has researched these in any depth.

| New interface design requirements (Garmer *et al*., 2002) |
|---|
| * No decimal units, as these increase the risk of errors |
| * A different colour on the decimal unit in the display window |
| * It should be easier to see if an infusion is activated (with a movable line or movable drops in the display window) |
| * A sound that indicates set values |
| * When looking at the interface it should be easy to understand how to zero the device |
| * There should not be a requirement to press two buttons simultaneously when zeroing |
| * In the display window itself, it should be possible to get a description of how to set the volume to be infused |
| * When values have been set, the system should confirm when it has been done correctly |

**3.14 Infusion devices interface design requirements (Garmer et al., 2002)**


The design of the alarm systems for such devices also illustrates the need for a systems approach to design. The journal *Health Devices* reports frequent system error messages disabling one particular model of infusion pumps. It appears to be well recognised that alarms are frequently triggered in situations of normal 'use'. The users in these situations often learn to ignore these alarms without considering the possible implications should the alarm reflect a truly abnormal operating situation.

Currently, there appear to be no formal or informal standards available for the design of interfaces for infusion devices (Garmer *et al*., 2002). Thus, it is scarcely surprising that a multitude of interfaces exist and that many of these confuse the operators.

### Implications

This case study is one of very few that has examined the user interface of equipment used in healthcare settings. The information base that such studies generate is essential as part of informing the systems engineering approach. However, the need to recognise the role that humans play within the system remains imperative if safe, reliable and efficient systems are to be developed.

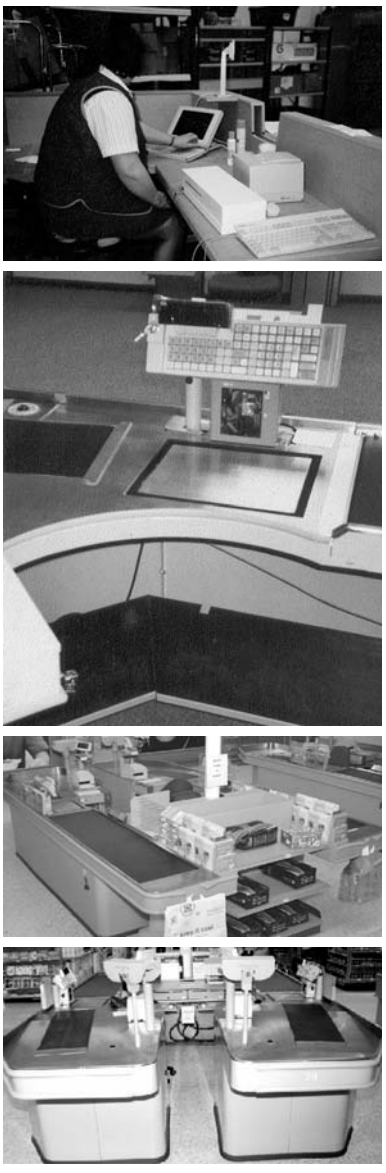
For example, Kim *et al.* (1999) describe an ambulatory infusion device, which has been developed to provide perinatal drug delivery at a precisely controlled rate. The device uses the concept of electro-hydrolysis of a negatively charged hydro-gel. The system comprises a pump unit and an electronic control unit. Whilst the accuracy and precision of the device have been verified, there has been little discussion of the potential user-related issues. Technological advances that have failed to recognise the importance of usability are indicative of an industry that has yet to fully appreciate the concept of systems and the place of technology within such systems.

## Case study 2: participatory design in a supermarket

A leading UK supermarket chain, employing up to 70,000 checkout operators, had concerns over the health and safety of checkout operators (especially musculoskeletal disorders of the back, neck and upper limbs). A new checkout carcass was drawn with the checkout operator area left completely blank. A participative approach was to be used to develop, test and agree the final design (see Figure 3.15). A series of earlier modifications to existing checkouts and a selection of individual new technological components had also used a participatory approach, but this project was the first to consider the complete design. The checkout design team was therefore mandated with a clear brief by the operational board to develop the new checkout to ensure the best possible operator environment, within specified cost and time restraints.

### Description of the system

The checkout was to be installed in all new large supermarkets and to be retrofitted into the existing larger stores according to a strict time schedule. The work of a checkout operator involves highly repetitive handling of goods, often with significant time pressures imposed by customer demand. The checkout operator is also seen as crucial in establishing and maintaining good customer relations. For many customers this is their only point of contact with the organisation, and staff wellbeing is recognised as being important to enhance this interaction.



3.15 Checkout operator areas

### The participation of users in the design process

Representatives of the checkout operators were selected from three stores. They included experienced and novice members of the workforce. Females and males were included. Representatives of each part of the engineering process were also part of the team, as were representatives of the organisation's health-and-safety team and customer relations department and an external ergonomist. The ergonomist acted as facilitator in the early stages. As the project progressed, other facilitators from the engineering project team were also able to adopt this role.

Regular meetings were held with the end users, the checkout operators. The response included comments that they "loved" the idea of only having bits of wood to look at and not a finished checkout to "comment on". They felt this really showed they could have some influence on the design. Mock-ups were built after each session and then commented on and tested through simulations at each subsequent meeting. Many changes were required. These were always agreed by all those present. This iterative process was used throughout.

User involvement can lead to high customer satisfaction and smooth project execution.

Final testing was carried out at a trial store over a period of several weeks. A number of minor modifications were made. It was noticeable that members of the team who were not checkout operators came to increasingly respect the views of those who actually used the equipment, as the project developed. Whilst the focus of the participation was the checkout operators, the requirements of customers (also end users) were also evaluated.

The project ran according to plan and to budget. The post-implementation report highlighted the role the checkout operators had played in the design and their preference for the new design, particularly for its space, layout of and design of equipment, choice of standing or sitting working posture and comfort. Customers also showed high satisfaction with the new design.

In this example, a wide range of stakeholders were involved throughout the design process. Much of the early work took place at the 'concept building' belonging to the organisation. This was important, as it was away from the shop floor and not located at the company's headquarters either. It was a 'neutral' location that encouraged each contributor to think in an open way and enabled all ideas to be received equally. As the project developed, the participatory process was moved to the checkout manufacturer's offices and the final meetings were held at the store where the in-store trials were being run.

### Design problems identified by end users

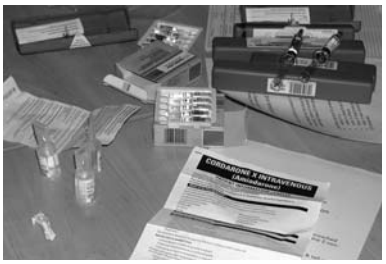
The first focus group showed there to be some 50 significant problems identified with the existing design. These related to both customer and staff problems. The richness of this information enabled most of the problems to be identified very quickly. These were then classified as to how easy the problem was to overcome, if possible, in the new design. The types of problem reported for staff included lack of comfort, too great reach requirements, postural demands (especially the need to twist), cleaning and maintenance difficulties, snagging of clothing on protuberances, inefficient operation, and feelings of insecurity.

### Improvements made

As a result of the participatory design approach, an ergonomically designed work space was designed including: the provision of sit or stand option, acceptable reach requirements, improved location of peripherals and technological devices (for example, scanner, scales, displays) through task analysis, improved customer interface, tested and improved scanner, better chair, a full footrest and a secure 'back-to-back' checkout design. Many improvements were also made for the customer, notably with regard to packing and ease of communication with checkout operators. In addition, the checkout operators felt they were co-owners of the new design. The post-implementation follow-up was reported. Some minor modifications were required and were to be addressed in subsequent checkouts.

### Wider implications for the organisation

The checkout operators were co-owners of the new design, which was significantly better than could have been achieved by the design team without their input. The additional cost was insignificant. All parties adjudged the process successful.



**3.16 A medication delivery system**

## Case study 3: mapping healthcare delivery systems

Many systems comprise a complex system of interactions between diverse stakeholder groups, the environments in which they work, the associated information, equipment and changes over time. Experience of such systems has demonstrated that successful design interventions are unlikely to be made without the introduction of a systems approach to the design process, design analysis and, where appropriate, risk assessment and risk management. Mapping the system is an important element in any such intervention.

## Methods

A recent study (Cambridge, RCA, Surrey, 2004) from the UK National Health Service illustrates the methods that were used to help achieve a suitable knowledge set on which to base design decisions. The methods used in this process are detailed in the Table 3.17 along with the objectives being sought. Inspection of the table reveals that all except one of the objectives has at least two methods associated with it. In this way, convergence between methods can be identified, thereby allowing greater confidence in the findings.

| Method \ Objectives | 1 Mapping the problem | 2 Investigation of special cases | 3 Identifying problems | 4 Identifying best practice | 5 Facilitating change | 6 Solving the problems | 7 Making recommendations | 8 Communicating findings | 9 Achieving action |
|---|---|---|---|---|---|---|---|---|---|
| Systematic literature review: journals | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | | |
| Literature review: reports and 'grey' literature | ✓ | ✓ | ✓ | ✓ | | ✓ | | | |
| Information exchange with international experts | ✓ | | ✓ | | | | | | |
| Prior experience of research team | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ |
| Workshop: other safety critical sectors | | | | ✓ | ✓ | ✓ | ✓ | | |
| Input from senior health service and agency personnel | ✓ | | | ✓ | | | | | ✓ |
| Interviews with healthcare practitioners | ✓ | ✓ | ✓ | ✓ | | | | | ✓ |
| Focus groups with healthcare practitioners | ✓ | ✓ | ✓ | ✓ | | | | | ✓ |
| Workshop with primary/secondary healthcare deliverers | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ |
| Workshop with supply chain stakeholders | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ |
| Workshop with patient support group | ✓ | | ✓ | | ✓ | ✓ | ✓ | | ✓ |
| Workshop with designers | | | | | ✓ | ✓ | ✓ | | ✓ |
| Systematic consensus/priority setting by the research team | | | | | ✓ | ✓ | ✓ | | ✓ |
| Iterative review of report with stakeholders | | | | | | | | ✓ | |

**3.17 Methods and objectives for understanding and mapping healthcare**

One extremely productive method was that of stakeholder workshops. In building the map, it became apparent that the intricacy of the systems they worked in surprised even the participants and pointed to key underlying

problems related to fragmentation, parochialism and lack of communication and integration. As the interfaces between stakeholder groups became apparent, then so too did the potential for the emergence of error and hotspots. Such mapping exercises allowed key challenges to be identified and prioritised.

### Summary

The use of a range of soft and hard methods enabled an understanding of the problems to be reached. For complex systems it is often not possible to include all stakeholders. Bias that might result from the selection of stakeholders or that arising from experts can be minimised by using multiple methods to address each objective and by prioritising data that are congruent.

## Conclusions

This chapter has outlined the need for systems engineering and shown how the process can be achieved. It has also demonstrated that systems engineering and ergonomics are closely allied. Both are characterised by the interrelatedness of components relevant to the successful operation of the system in question. Developing an understanding of the human factor throughout the systems design process is essential, whether it be the implicit biases of those involved in the design process or an analysis of the use (and users) of existing systems.

The process of systems engineering demands rigorous use of appropriate methods and the objective evaluation of resultant information. To apply the approach successfully will almost certainly require multi-professional teams, engagement with relevant stakeholders and iterative stages in development. The benefits of applying this process are great, whereas the failures associated with any other design approach remain all too evident.

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