



A Case Study of Design Methods Applied to Researching Medical Device Purchasing Processes

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CASE STUDY

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Abstract

Design and engineering concepts are increasingly welcomed by healthcare communities for developing products and environments. With the recognition of healthcare as a safety-critical industry, design processes can also be used to develop services, organisations, and management systems in healthcare. The case study reported on here forms part of a wider research study of medical device purchasing practice, and provides an example of applying systemic design methods to one healthcare context. Collaboration between the researchers and a hospital provided an opportunity to explore design approaches as part of the research process, in terms of data collection, analysis, synthesis, as well as in the implementation of new practices. The paper firstly gives justification for using design and systems approaches, and specifies the particular aspects of design approaches used, including a discussion on their applicability to the purchasing of medical devices. Design approaches used included diagramming methods, participatory design, and risk analyses techniques, which were used in conjunction with qualitative methods. A description of the techniques used with the collaborating hospital then follows, including some of the methodological challenges encountered. The case study shows a practical example of how design methods and tools can be used to research within a healthcare context, and is

deliberately descriptive, as the intended goal is to provide a framework for future design of purchasing systems. Good research practice in this study is therefore also taken to be the first steps in good design practice.

Key Words

Design, systems, engineering, purchasing, medical device, risk, procurement.

Background

This Case study forms part of a larger study of medical device purchasing practice within the UK's National Health Service (NHS) (1). The full study builds a knowledge base of current purchasing practice in five typical NHS hospitals, which highlights the challenges faced by purchasing stakeholders. This then leads to an analysis to identify inefficiencies in the purchasing system, compared to guidance in policy documents and literature, and illustrates how such practice can lead to risks in the delivery of care (1). Risks identified range from injury to individuals, impacts to the healthcare delivery service and financial and litigation consequences. The hospitals used in the full study served to generate general issues in current practice, while the hospital reported on in this case study provided an opportunity for in-depth engagement with the relevant stakeholders. These next two introductory sections describe how design was viewed in this case study, and give an overview of the wider project to provide its context.

Design

Design, human factors, and ergonomics have long been used in safety-critical industries. In 2004, the UK Department of Health highlighted the value of design approaches for healthcare settings in its report on Design for Patient Safety (2), and these are now increasingly being introduced into healthcare contexts. Examples include the design of a hospital with 'patient safety' as the key driver (3). Healthcare publications are encouraging the use of the word 'design' for health (4), for example quality by design (5) and safety by design in terms of safe medical device design (6). While many of these examples concentrate on equipment, device or architectural space design, work in the healthcare service design and process has also begun. In the UK, learning from design-led approaches has led to the Experience-Based Design publication (7). Design approaches have been



demonstrated in use to improve healthcare delivery practice (8) and re-designing healthcare services (9). Design in healthcare has been described as being an extension of the incremental improvement efforts underway in many healthcare organisations today (10). A healthcare system has even been said to be 'designed to achieve the results it achieves' (11).

The term 'design' can be used to describe either an artefact or product characteristics (noun form), or stages resulting from a process (verb form). Elements of a design process can include exploration, creation and implementation or the tools to both conduct research and then practically plan services. For this study, the term 'design' is used in two ways: the process of designing a purchasing system, and the process of researching the current purchasing system (with the intent of designing future systems). It is this second approach that is reported in this case study, as the focus is on the learning gained in practically engaging with a healthcare-related community to aid the research process. Both these concepts are elaborated in the Research Methods section. Some of actual methods used for collecting and analysing data originate specifically from *engineering design* practice (in particular, the process mapping and risk analyses techniques). In such cases, these are simply referred to as 'design tools' in a generic sense.

Purchasing as a Case study

Approaches in which a whole system is considered for design can be particularly helpful for studying settings in which the stakeholders involved make decisions for the same purpose, but may have different backgrounds, training and even agendas in their particular line of work. Purchasing is one such system, given the range of stakeholders involved in making a purchase (1). Yet this setting is chosen not only because its applicability to design and systems approaches, but because of its critical position in wider clinical care. Purchasing activities can either facilitate or impede the delivery of safe, effective and efficient patient care. Previous studies on patient safety have alluded to the re-design of purchasing systems (2), but few recommendations have been found of how to implement these in practice. In purchasing literature, most of the studies are based on strategic purchasing, but there is little research in examining the process of purchasing medical devices from a hospital's perspective (1). Some examples do exist, for instance, the 'disconnects' in the wound dressing supply chain in the UK have been investigated, but this study is limited to one product (12). Other studies have been conducted as stakeholder analyses for infusion pump purchasing in the USA (13), but these are again limited to one device, and are based in the US healthcare system and its associated purchasing procedures. In the full study from which this case study is taken, a systems approach to designing medical device purchasing systems is suggested to mitigate the risks associated with medical device errors. This approach is also embedded into the approach to the study itself, by adopting a framework that focuses on understanding the current system first.

Methods

Taking the view that designing can be applied to products, services or systems, including healthcare processes, the approach taken in this study is the application of engineering design methods to both the research outcome (designing a purchasing system), and the research process (conducting the study), with an emphasis on reporting on the latter. This section describes the general methodology employed and the actual research methods and design tools used.

Design Research Methodology

Design research methodology (14) includes the research process by which 'as-is' data is gathered with the intent to design future systems. This approach is similar to what is known as 'systems analyses' techniques in the context of process-centred improvement work, where boundaries for the system need to be set, its stakeholders defined, cycles times, drivers for decisions and constraints identified, and potential risks in the process highlighted (15). In the Design for Patient Safety report, the steps required for good design practice include the building a knowledge base of current practice, and the definition of requirements for designing new practice (2). While their report recommends taking a systems/design-led view to improving services across the whole healthcare system, such approaches can also be applied to sub-systems, such as purchasing systems (1). Cross-referencing to Figure 1, in this study, the equivalent sub-systems steps taken are:

1. Designers of the purchasing system *build a knowledge base* of purchasing practice.
2. Based on this knowledge, the *requirements* for designing the purchasing system are defined (step '6' feeds back into this step so that the requirements for evaluation are also established here).
3. The purchasing system (or sub-system) is *designed*.
4. The design of the sub-system occurs with consideration to the *design of the medical system* (or greater system).
5. The new purchasing system embedded into the medical system is *delivered*.
6. The process is *evaluated* (feeding back to the requirements is step '2').
7. Safe medical *care is provided* (further building the knowledge base).
8. *Risk management* underlies all design and delivery

This case study reports only on the process of conducting steps 1, and parts of steps 2 and 8, which form the basis on which other steps can be conducted. The learning



reported in this study is presented in headings referring to these steps.

Research Context

This case study was conducted in an NHS University teaching hospital of roughly 7000 staff serving a catchment population of about 500,000. The focus in this paper is to report on the learning gained of using design and systems approaches to conduct research within a healthcare environment, rather than report on the findings of current practice in purchasing activity. Insights and observations from both the process of developing the systems view, as well as the identification of risks, are shared.

The stakeholders that took part in the study evolved as the study progressed. Stakeholders' views were elicited as and when needed to add to the knowledge base. The roles of these key purchasing stakeholders, internal to the decisions in the hospital, were:

- Head of Clinical Engineering
- Head of Medical Physics and Clinical Engineering
- Deputy Director of Finance
- Head of Procurement
- Medical Electronics services manager
- Equipment library services manager
- Device trainer, Clinical Skills

Data Collection Methods

The specific design research tools used include ethnographically enriched process maps (16), diagrams for graphic elicitation (17; 18), modelling tools for healthcare processes (19), and diagrams specific for researching healthcare systems (20). These are complemented by more conventional methods such as interviews and observational studies.

Diagramming and Mapping: Using diagrams and mapping methods both as illustrations of current practice and as methods for data collection are common in many practices. An advantage of process mapping is that each activity can be systematically evaluated in an attempt to improve the process (21). Crilly et al suggest the use of diagrams as interview stimuli (18), a method employed for this study. However, the choice of diagram and modelling method is vast. A study focussing solely on the applicability of modelling techniques to a healthcare setting noted the importance of using the correct process model for the right context to be investigated (19). In this study, flowcharts or process maps were found to be the easiest diagrams to understand by healthcare professionals, also the ones used the most extensively, though other diagrams might point out hazards and risks in the process better. Given the variety of stakeholders interviewed and their differing experiences with diagramming methods, the most important criteria was for them to understand the diagrams and feel comfortable with their use. For the purposes of this study, the diagrams serve as tools not to describe the process accurately, but as graphic elicitation tools to engage the healthcare professionals through a common visual language. For this reason, the usability of the tool was more important

than its ability to accurately depict processes. Simple flowcharts, developed over time into process maps, were therefore chosen in favour of the many more sophisticated and complex process representations available.

Interviews: Given that the study aims to focus on both explicit and implicit issues within purchasing practice, and relies heavily on the perceptions of people involved in current practice, semi-structured interviews were chosen as the main method for data collection (22). These provided the advantage of a general structure and guideline to the interview (i.e. the use of diagrams to initiate discussion), while leaving the interviewer free to follow emergent themes according to the responses given. This allowed for in-depth and rich data to arise from the interaction, while keeping the aim of the meeting focussed.

Observations/Ethnographic studies: The research process included being embedded in the device management environment in the Clinical Engineering department. This allowed for attendance at meetings over a two-year period with the Medical Equipment Committee (MEC) Procurement Subgroup as well as follow up interviews and meetings for conversations on more specific decisions. This subgroup comprised of a few of the more senior stakeholders listed earlier, as well as some temporary clinical representatives brought in for specific device purchases. Their remit was to examine and sometimes administrate the process of purchasing for particular revenue and capital projects.

Risk Workshop: Formal risk management has become a requirement for a range of industries, and has affected developments both in design practice and in the social sciences (23). In practice, different industries have developed their management processes to manage risks according to their requirements. Early studies came from the nuclear, aerospace and construction industries, while later studies developed around project and technical risk in software design, defence, medical engineering, as well as in even more uncertain industries such as flood and coastal defences and the oil and gas sector (24). The characteristics for each of these industries have led to the adoption of particular methodologies or frameworks for risk management. The methods adopted can be both qualitative and quantitative. The methods will not be discussed in detail here, as no particular method was used in its entirety for this study due to the context of the research. Methods that can be applied include fault-tree analysis, event-tree analysis, decision-tree analysis, influence diagrams, Failure Modes and Effects Analysis (FMEA), Root-cause analysis (RCA), Human Reliability Assessment (HRA), and others developed for specific contexts and purposes. For this case study, on consultation with the risk manager at the hospital, it was felt that participants were more likely to respond accurately if they used a method familiar to them within the hospital. It was learned that a consequence-likelihood



'risk assessment matrix' was already in use at the hospital for monitoring clinical incidents. The benefit of using this tool was that the workshop would fall under their current governance structure and the subsequent control measures would be more likely to be reinforced and followed through. However, it was learned that the formal risk assessment methods even within the organisation are not always followed in practice. Risk assessment of the procurement process itself had never been explicitly considered. To add to the constraints, the team members were only available to meet for two hours. Given the constraints required to truly justify the use of any formal risk assessment methods, no claim is made here to have adopted a method in its totality. The aim of this exercise was to arrive at some consensus as to where *potential* risks in the current practice exist. Therefore, a compromise was reached in the method applied: elements of traditional risk analysis methods were adopted, but the exercise was conducted by a representative from the Risk Department in the hospital's own format. The limitations and learning of this compromise are discussed in the Evaluation section later.

The 'risk assessment matrix' tool requires the stakeholders to begin with map of the service to be assessed, which in this case was the purchasing process. At the workshop, a selection of 'what if' questions were used as prompts. A particular hazard was identified and its potential causes and consequences assessed. The team assessed the risk associated with each hazard, and determined if further mitigation is required. The team then developed relevant recommendations to control the high/medium risk hazards, and re-assess the risk with these recommendations in place. If the risk was still high, further recommendations were developed. According to the tool, if the team cannot identify any practical means of mitigating the risk, the risk should be escalated for acceptance in accordance with the organisation's risk management department. A review or follow-up is then recommended for the team to examine the new control measures. The tool was used at a workshop towards the end of the study once the interviews, observations, and process maps were completed. The workshop was co-moderated by the researcher and the risk manager, and lasted just over two hours. Attendants included all those previously stated stakeholders, plus two extra participants who expressed interest in attending (from Clinical Engineering and Procurement Department respectively).

Data Analysis Methods

Recording and Transcription: Interviews and workshops were recorded and transcribed for later analysis. In the cases of workshops, where many people were present, it proved more difficult to identify the exact speaker and so more generic statements describing the topics of discussion were noted instead. While such transcripts are good for analysis of what was mentioned in an interview, and gathering responses to diagrams shown to the respondent, extra notes were sometimes necessary to capture the gestures and objects pointed at during the interview.

Coding: The purpose of coding in this study was to classify and synthesise qualitative data (such as statements by the

participants) for analysis, to allow for the process of data selecting, focusing, simplifying and abstracting (25). The approach taken in this study is that the starting point is not an empty code list from which to build theory, but rather a limited number of preliminary codes were drawn up, which formed the basis of new codes in the data (26). This full list of 167 codes follows the literature review and exploratory phase in the full study (1). This list was used as a guideline for future coding. Allowance was made, however, for new codes and themes that may not have been expected from this first list. That is to say, the respondents were given freedom to comment around the questions or interviews or diagrams, and these comments were collected and analysed together with the very direct explicit answers to the interview questions.

LEARNING FROM METHODS

The results are presented in the context of the design framework presented in Figure 1, which includes statements of how this particular step was implemented in this study. The emphasis was on building a knowledge base, managing risk, and defining the requirements for future designs of purchasing systems. Figure 1 sets the context for a wider design process activity in relation to purchasing, where it is the purchasing system which is ultimately designed, delivered, and evaluated. This section reports on the learning in three particular aspects of that design process: building the knowledge base, defining the requirements, and managing risk.

Building the Knowledge Base

Process maps were developed from the beginning of the study and populated with further observations, anecdotes, and interviews. No particular model is the exact depiction of the process, but these were the closest resemblance to the process as a whole that served the purpose of the discussion and initiated conversations on how to improve the process.

Initial 'rough sketch' process map (Figure 2): The first process map is a skeleton of the process introduced as a very rough draft, drawn by one of the participants themselves from the Clinical Engineering department. This was then populated by interviews with the participants themselves. Various iterations of the diagrams resulted in many more diagrams (1), but a description and a few examples are included here. As the interviews progressed, participants not only described the process 'as it is' but also gave suggestions of how the process is 'to be', from their perspectives.

Comprehensive process map (Figure 3): This diagram was created through the analysis of the process 'as is' combined with hypothetical 'to be', and further refinement through participation at the MEC Procurement Subgroup meetings. The colour key shows the different aspects of the process depicted.



Simplified process map (Figure 4): In preparation for the risk workshop, it was felt by the participants in the map developments that a simplified version of the process would be more comprehensible for the required discussion. In order to provide this focus, a few modifications were made to include only the essential steps in the process and cluster process steps as occurrences in particular areas of the decision-making process. For instance, the 'user identifies need' and its associated steps occur mainly at the ward, and these were depicted as the first grey-shaded area. The final version shown in Figure 4 was the one used for the workshop.

Overview of purchasing process cycle (Figure 5): As well as the detailed diagrams completed first, an overview of the main sub-processes in device purchasing were collected, which helped frame the process steps involved at a higher level. These are shown in Figure 5 and were used for the discussions on risk later. The numbered steps correspond to the process steps in identifying failure modes (demonstrated later in Table 2 under Managing Risk).

Defining the Requirements

Having completed a process map that could be used as a means to both generate discussion around the purchasing system, and elicit potential process risks, the process was also described in systems terms to help create the boundaries and focus of the particular system studied. To ensure that the focus of the design requirements would adhere to existing principles in engineering and systems design, guidance was sought on how systems analyses work. Karsh and Alper describe how to apply systems theory in practice and execute systems analysis in healthcare, in order to analyse for system-wide problems (15). The steps suggested start with deciding on a system boundary for analysis, which in this case is the purchasing of all medical devices in the NHS, but as applied to this particular hospital. In complying with this, the system was characterised by the attributes shown in Table 1. These system attributes were established both in discussion with participants and through analysis of the previous observations made during this study. Having established the system attributes, the boundaries for the study, and the anticipated inputs and outputs of the system, the participants at the workshops were presented with a more coherent understanding of the intention of the workshop. Table 1 was presented to the stakeholders invited to the final workshop as a guideline for the upcoming discussion. Further requirements for the re-design of a purchasing system, which incorporates the comments elicited in the full study, are reported elsewhere (1).

Managing Risk

In addition to preparing the map of the process itself, some work was completed to ensure an accurate and thorough investigation could be achieved in the time available. In this study, a modification of formal risk assessment methods was necessary due to the existing methods used within the organisation and the time limitations available for this part of the study. Preparation prior to the workshop was therefore required both to familiarise the participants with the method and obtain individual responses to risk assessments. The risks

identified in all the parts of the study are described, with the main observations summarised in Table 2.

From observations: During the studies described in the full study, early observations were made that suggested the presence of risks in the process. Similarly, from the analyses of the observations and diary notes made during participation at these meetings, a set of recurring themes very similar to those brought up at the workshop were observed and voiced by the very same stakeholders. A selection of these issues voiced or observed for the full duration of the study are ticked under the heading 'From Observations' in Table 2, if they were encountered as areas of risk with reference to the corresponding process step in Figure 5.

From Interviews: In order to maximise the knowledge gained during the workshop, a set of preliminary interviews were conducted with each stakeholder prior to the workshop. This allowed for some direction for the discussion and a chance to elicit individual participants' views without influence or bias from other members in the group. The following people were interviewed in these preliminary interviews (on average 30min each) to go through the whole process:

- Head of Clinical Engineering and Medical Physics
- Head of Clinical Engineering
- Deputy Director of Finance
- Head of Procurement

The map used for these interviews was the simplified version shown in Figure 4. The system may be more complex than what is presented in the diagram, and other barriers may exist not shown on the diagram. These were deliberately omitted to prompt discussions. Another prompt used during the interviews was the mention of potential scenarios of failure modes of risks in the process. These comments, if also indicative of risks identified, are ticked under the heading 'From Interviews' in Table 2.

The potential incidents in the list above were then re-written as 'Failure Modes' with associated consequence and likelihood. Any of these failure modes were said to be at least possible and, in some cases, occur frequently. Depending on the device purchased and its own associated risk, the consequences may be completely different. The extent of the consequences is dependent on the rigour of the current control measures. This highlights the need to conduct a risk assessment on the process as a whole (to identify stop-holes in later processes) as well as an assessment of its sub-components (to identify the specific stakeholders involved at sub-process level). In terms of consequences, those identified from the table as being most relevant, and most frequently elicited above are:

Impact to service
Potential financial losses



Harm to patient (in extreme cases)

Participants also offered possible causes for these failure modes. Any one failure mode can be traced back to a number of causes, which were also recorded.

From Workshop: The decision to hold a workshop was also supported by the Medical Equipment Committee to highlight the risks and control measures in the purchasing of medical devices. The result was a discussion around the failure modes and causes identified in earlier interviews, to discuss their prioritisation and obtain consensus on their importance. These are noted under the heading 'From workshop' in Table 2. Although various failure modes were identified in any of the process steps 1-10, at the workshop it was agreed that most of these risks occur early in the process (steps 1-4). Therefore, for these essential steps identified, new control measures were proposed during the workshop, with suggestions of how to regularly identify and evaluate these measures.

Discussion

Given that the focus of this paper is on the use and value of design methods and tools within the research process, these must be placed in the context of other methods adopted in healthcare research. The approaches and tools used in this case study are evaluated against general qualitative research in a healthcare domain, and the use of design tools. This section ends with comments from the participating stakeholders on their views of the methods adopted.

Research in Healthcare

The study would not have been possible without the relevant contacts made at the collaborating NHS organisations. The collaboration established with the hospital for the in-depth studies provided a richer source of data and opportunities for observance which would have been difficult to grasp in a removed survey or remote study of any other kind. In particular, the relationship established with the hospital was important as the stakeholders viewed this interaction as more than an audit, which consultancies had conducted in the past. The balance achieved by gaining the trust of the stakeholders and yet maintaining an external academic gaze on the research topic provided a research challenge, but was invaluable for collecting the data. Some of these aspects are discussed here.

Research in the healthcare domain is subject to varying expectations in terms of its methodology, design, and outcomes. The community largely refers to evidence-based practice and seeks research outcomes that either directly influence both clinical outcomes or at least provide impact to current practice. In a real world scenario it is far more complicated to provide a controlled environment in which to test a hypothesis rigorously (27). Inductive research strategies do not start with a hypothesis; but rather generate a theoretical framework of understanding where none previously existed (28). Qualitative methods can help understand some of these clinical outcomes in a holistic

sense, since complexity is placed at the centre of the research (29). However, as with any research project, Sim and Wright point out that in order to sustain an evidence based mode of practice, the evidence needs to be: up to date, objective, verifiable, relevant and applicable to practice, and intelligible (28). Such criteria are also applicable to research if it is to create the same rigour as other healthcare-based research. A few pointers to note during this study, given its adoption of qualitative methods, are discussed in this section. Issues of sampling, dependability or reliability, generalisability not addressed in this particular case study, given that it is a more in-depth study in only *one* setting. Those issues relevant to this particular case study are: validity, confirmability, and ethical conduct.

Validity: The term validity can refer to any feature of the inquiry that ensures internal credibility or 'trustworthiness' of the results. This can include accuracy of the description of the study, valid interpretation of the phenomena, or not considering alternative theories to explain the results (22). Strategies can be adopted to address such threats to the research. In particular, prolonged involvement with the subject material/participants can help create validity, as well as peer debriefing and member checking (both pertaining to sharing the results of the study back to the members and re-visiting the same context at a future time). In particular, a concept called iterative triangulation is applicable to this research. This involves systematic iterations between literature review, case evidence, and intuition in order to derive conclusions from case studies (30). These were addressed mainly in the wider study, where the codes emerging were linked back to the initial codes found in the literature throughout the research process. Such concerns were also avoided by ensuring that results were presented back to stakeholders both separately in the same hospital for this case study, but in other hospitals for the wider study, as well as regularly triangulating against existing theory.

Confirmability: Confirmability refers to the potential biases and subjectivity that may arise through the research process. A large consideration for this study is the effect of the researcher on the process being examined, particularly in the case of the hospital where ongoing collaboration was established. Such interactions can affect interpretation of information in the course of a process that involves interaction between research subject and the observer/researcher. Miles and Huberman recommend taking a self-reflective approach by expressing potential bias and assumptions, consideration of possible and alternative conclusions, and the presentation of results together with the underlying original data (25). For this purpose, diary notes were kept throughout the study to reflect on what was observed, and transcript excerpts are also included as quotes from respondents in the wider study.

Ethical conduct: Ethical problems arise in social research



as a result of conflicting sets of values concerning the goals, processes or outcomes of an investigation which involves people (31). For the purposes of this study, the scope of the study was presented to the Research Ethics Committee for each hospital involved in the study. Although formal ethical clearance was waived since the committee decided this served as an 'audit of current service', due consideration of ethical issues were considered in the design of the study. In particular the guidance given by Sim and Wright served as a guideline to the types of issues that were kept in mind in the design of the study (28), such as *informed consent, privacy and confidentiality, anonymity, deception, risk of harm and exploitation*. All personal details were kept confidential and are anonymised in this report. The aim of the study was stated clearly at the start of each interaction to avoid unintentional deception. Although the ultimate real effect on healthcare practice, or of specific detailed effects on the service as a result of the research process were not monitored, the intent of the research (to improve long-term healthcare service and delivery) was communicated to all participants.

In general, given the action-research characteristic of this study, some other points are raised on the limitations and credibility of the approach. While it can be seen that prolonged involvement with the research participants helped increase validity of the insights gained, it is also acknowledged that the researcher's presence within the setting may have had an effect on the process in itself. This is an unavoidable (and sometimes desirable) characteristic of similarly designed action-based research projects, where the separation of the researcher's involvement from the natural evolution of the subject is not clearly defined. The validity of the data is also stronger in the hospital given longer term involvement. In synthesising the findings, the concepts in the final framework were chosen on the merit that these issues were those voiced across the hospital examined to achieve at least some generalisability, but it is acknowledged that the culture of each organisation may still affect its uptake and relevance. Finally, it must also be mentioned that, given the iterative nature of the project, to repeat this study with the exact same methods may not be possible. It is also acknowledged that the findings of this study can only claim to show empirical evidence of current practice within the current political climate in the healthcare system in the particular hospital examined at the time.

Engineering Design Tools

In line with the previous statements made on design, the approach taken in this case study is that the design methods can facilitate the research of current practice, and establish the knowledge base and requirements needed for future practice design. Any such collaborative, participatory design requires practical engagements with the healthcare community and the stakeholders involved in planning, delivering, and using the final service design. Such aims from engineering design principles have therefore been fulfilled within this case study. However, given the limitations of the context studied, some compromises were inevitable, especially for rigorous risk analyses. Both the benefits gained

and limitations learned from applying design methods and tools are shared in this section.

Diagrammatic methods: Jun et al.(19) have pointed out that a single diagram cannot effectively capture all aspects of complex healthcare delivery, which consists of stakeholders, information and tasks. The need has been raised for better application of diagrammatic representations to the design of healthcare systems (20; 32). This project has demonstrated one application of using diagrams in collecting data and tested responses from participants in healthcare settings. The value of this method was felt both by the researcher and those involved in the process (comments quoted in stakeholder responses section), but valuable lessons were learned of how to use such methods, and what level of detail is required per interview, depending on their background. The diagrams clearly provided a point of focus, both in individual interviews and in the workshops. During an interview, each stakeholder was given the opportunity to reflect on their understanding of the process and choose to agree or disagree with the diagram shown to them. Notes were constantly made, arrows and text questioned, and further comments welcomed. All of this helped enrich the existing data and probe for more information. At the workshop, the use of the more simplified diagram provided focus for the discussion, also allowing participants to question any inaccuracies they discovered while examining the process.

Risk Analysis Methods: Risk assessment, although an essential component of health and safety management, is subject to pitfalls (33). The healthcare sector is no exception and the limitations in this study also proved to be such an example. The main driver was the limited time available from participants, which was limited to 2 hours to both show the process map and achieve agreement on it, and then conduct the risk analysis on the process. The interviews held before the workshop proved to be very helpful, as these served to already gain some consensus of the current process map with the stakeholders which later came to the workshop. The researcher also gathered preliminary risk ratings during these interviews. Nevertheless, the format of the workshop itself required the participants to come to a consensus on the overall risk of the process fairly quickly, which leaves to question how reliable the risk scores were.

Another observation, especially noted during the individual interviews, was the clarification required on the types of risks implied in the exercise. Some participants did not immediately associate purchasing activity with clinical risk. It was therefore useful to have the hospital's risk assessment matrix tool available so that the range of litigation, service, clinical, financial risks could be highlighted. Drawing on the data collected in previous interviews and observations helped the researcher come up with scenarios that would prompt discussions on potential consequences.



The International Standards Organisation includes terms within risk management such as risk assessment, risk analysis, hazard identification, risk estimation, risk evaluation, risk treatment, risk control, risk acceptance, risk acceptance, risk communication (34). Elements of these terms were identifiable in the study, but more time and engagement could have ensured they were followed to completion. These limitations are understandable, however, given that the 'purchasing process' as one process had never been addressed with this approach. Some of those participating stakeholders may previously have interacted individually, but never as one group or team in one meeting room. The workshop, even if a small step towards an appropriately rigorous risk management process, served to highlight the potential for risk, and the need for new controls to be set in motion.

Healthcare Stakeholder Response

Some comments were invited from participants in the research on the collaborations established and the methods employed. A few are quoted here,

"My feeling is entirely positive; we wouldn't have had these discussions around processes without ... [the work]. It took a while to get to the stage we wanted to get to, but that is simply how long these things take. It's a piece that we wanted to do, and perhaps we would've done it much quicker, but we did not have the resources for that. It's a useful process – and it was interesting that to some extent this was partly using analysis to either prove or disprove people's preconceptions about what went on! ... To those that doubted that this was a complex process, they were proved right to some extent. At the same time it caused us to justify the process we do have in place and to test how that could be changed. All that was entirely positive. For the future, perhaps we'd have done it more quickly and project managed to do it."

- Deputy Director of Finance, the hospital

"The whole collaboration has been very useful. It also questions us to look at what we are doing and how we might be able to change our processes or practices as a result... and I think it has changed in the last 2 years. We're actually checking in terms of what is ordered in terms of medical devices. We still end up with things within the hospital where we don't know about them and it's not [purchased] through any formal procurement process, they just seem to appear... That is something we need to look at in more detail."

- Head of Clinical Engineering, the hospital

The feedback from the workshop was overall positive and highlighted how the research process as well as the systems techniques acted together as catalysts to make improvements:

"This was good as I have now been in this hospital for ten years and some of these same issues kept coming up. Only now did we have the focus to address them."

- Head of Procurement

"I think the process map gave us the focus to concentrate on

the issues in a more holistic sense."

- Clinical Engineering (Senior) and Medical Physics

Whether or not this particular method was the best tool for eliciting such risks and putting new control measures in place cannot be proved, and no comments were provided on alternative methods for having assessed the process. However, the raising awareness of these critical failure modes in the purchasing system raised by the research process was agreed upon. The MEC Procurement Subgroup has subsequently included 'Purchasing Process' as a regular item in the agenda for their monthly meetings.

Conclusions

The value of using design approaches in both researching and designing healthcare systems is recognised in various circles, and further demonstrated in this study. These methods are especially useful in contexts where various stakeholders are involved in decision-making and yet aiming towards the same vision of providing safe and efficient care. In this case study, the design research methodology adopted included three basic components: building a knowledge base of current practice, defining the requirements for future practice, and managing risk throughout the process. Diagrammatic mapping tools, alongside qualitative methods, were used to collect and analyse the data. Given the methodological challenges in accessing healthcare participants, such methods show limitations compared to settings where more time and engagement is possible. However, the methods have demonstrated to be useful in synthesising and framing research in healthcare services, and allowing participants to focus on a particular aspect of the healthcare service and its connections to other parts of the system. This was evident in the interviews and individual interactions throughout the two-year period, as well as in the more focussed meetings and workshops held towards the end of the study. Positive comments on the process were received from the stakeholders involved, and awareness of risks were highlighted in the purchasing process, which had never before been studied at the hospital as one such a focussed, whole process.

The outcomes from the research process also served to give suggestions and pointers towards future design of a purchasing process, appropriate to the particular needs of the hospital. Design approaches have therefore served both to describe current practice, as do many other research methods, but with the added framework and intent to systematically design future practice. This case study is one example of the application of these methods, but is limited to its own characteristics specific to purchasing in terms of stakeholders involved, timescales, and types of risks. Further work in using these approaches in other healthcare settings, such as the front end of clinical care, would add greater value to learning how to apply such methods for better healthcare research.



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PEER REVIEW

Not commissioned. Externally peer reviewed.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests

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Tables and Figures

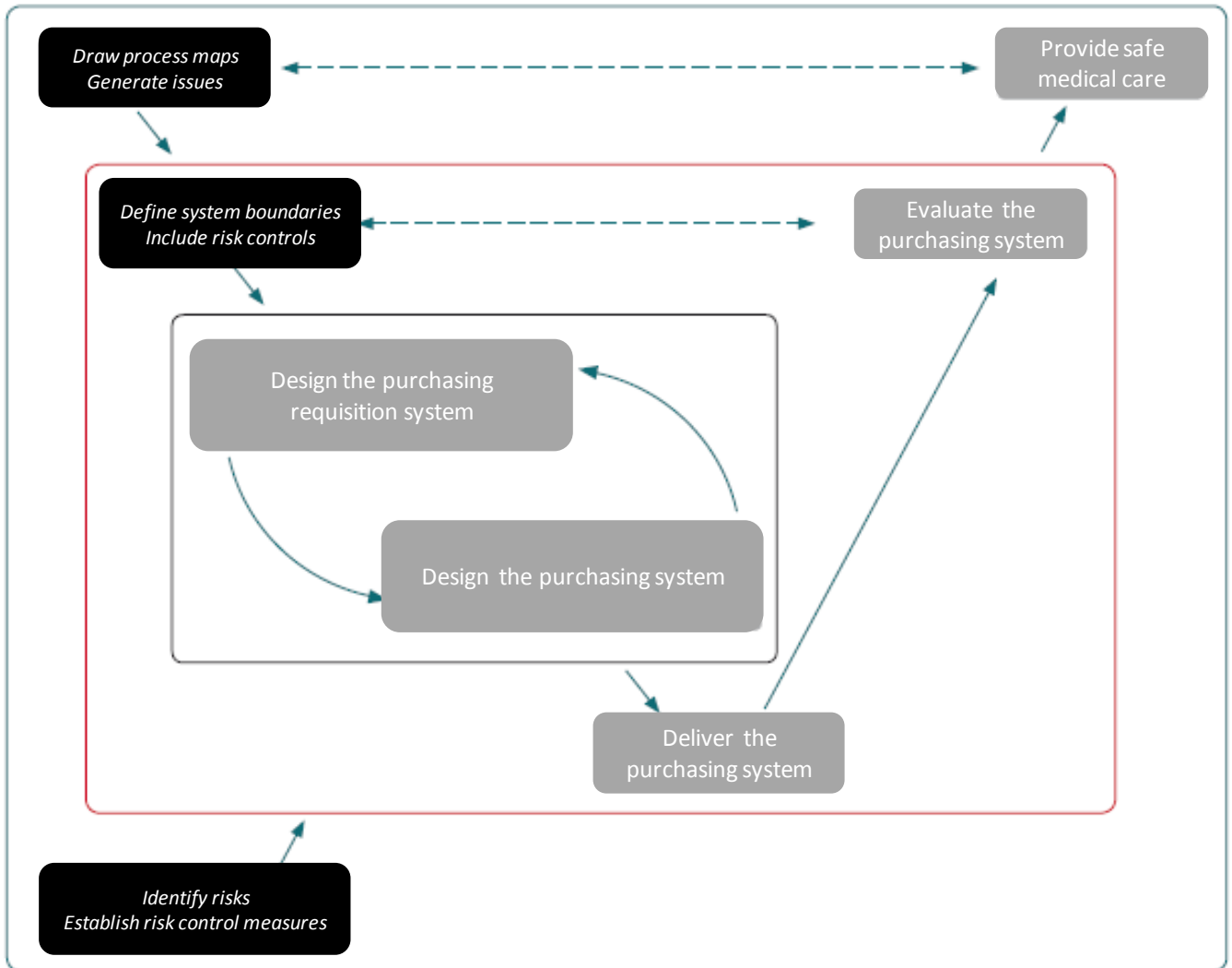


Figure 1: Research steps within purchasing system design

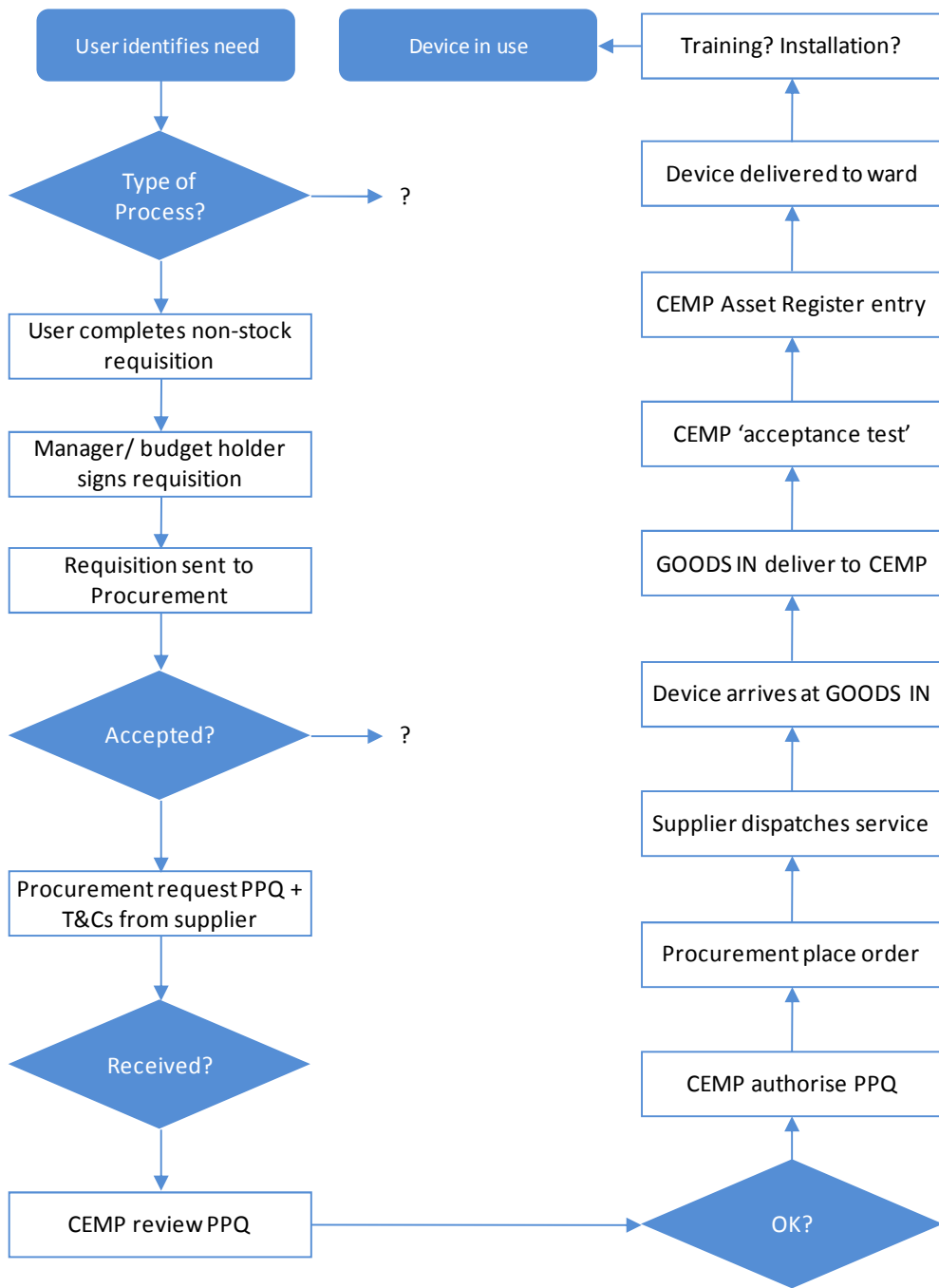


Figure 2: Initial 'rough sketch' process map (1)

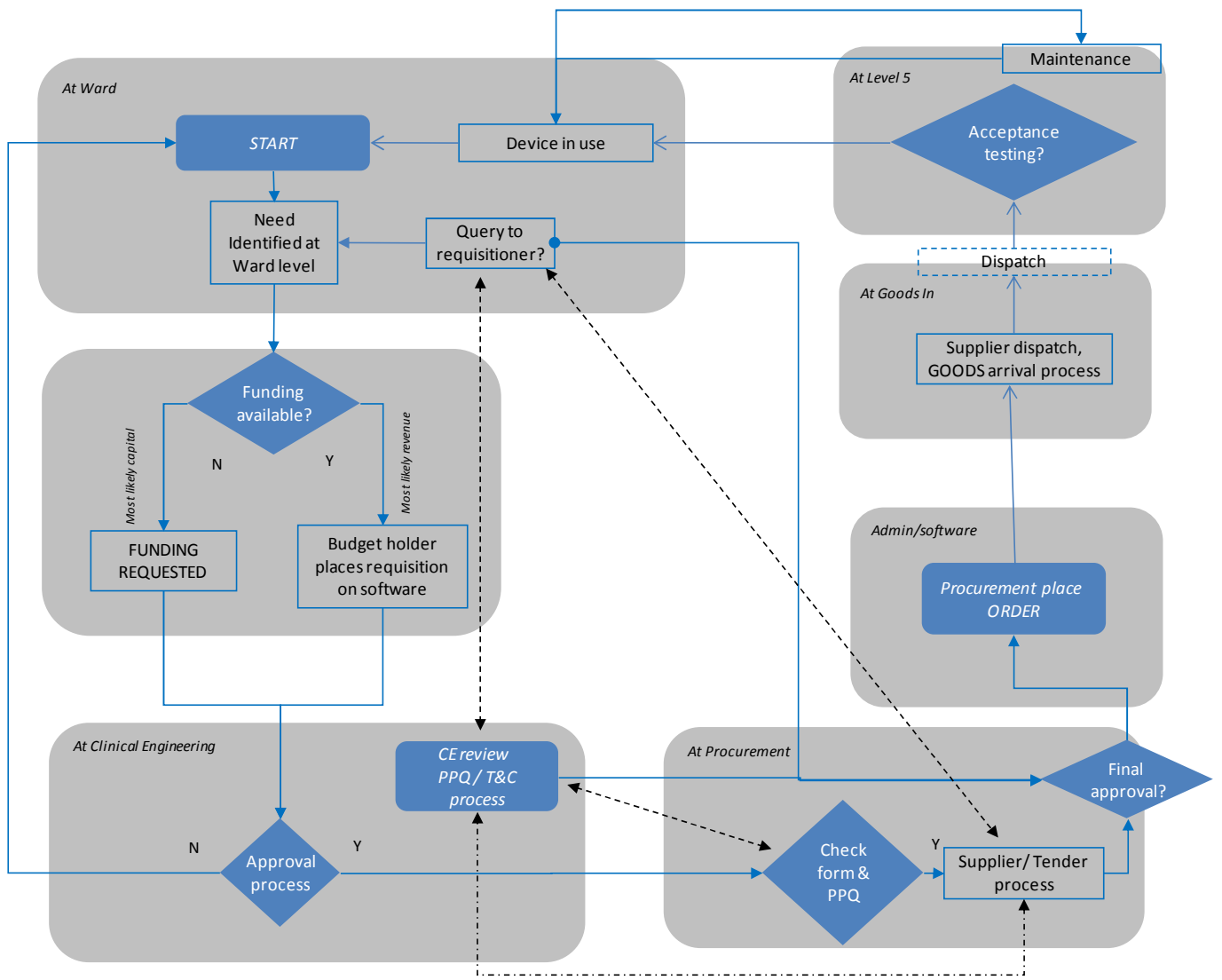


Figure 4: Simplified process map (1)

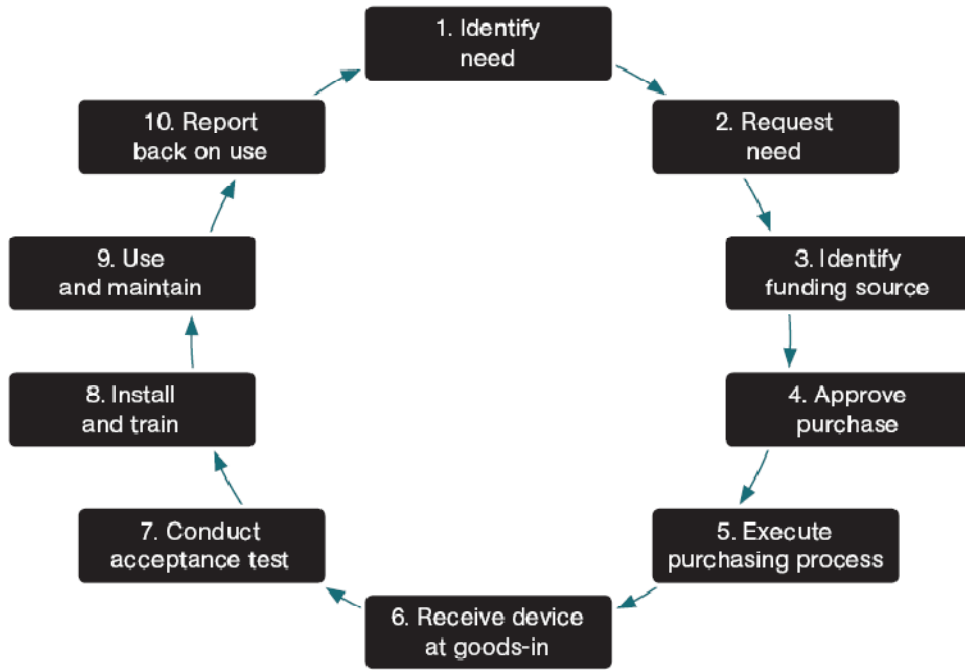


Figure 5: Overview of purchasing process cycle (1)



<i>System attributes</i>	<i>Description</i>
Stakeholder Participants	Clinical Engineering
	Clinical Requisitioner
	Medical Equipment Committee
Customer	Patient
	Clinical Requisitioner
	Medical Equipment Committee
Process Owner	Undefined
Inputs	Need for device (capital or revenue)
	Funding sources
	Received equipment (loan/donation)
Outputs	Safer patient care
	Equipment in working order
	Efficient purchasing process
	Mitigated risk
Boundaries	Purchasing and decision-making of medical devices, from the moment need is identified to the time the equipment is used and maintained
Cycle times	Varying times depending on individual purchases
	Anecdotal evidence available for various delays

Table 1: Attributes of medical device purchasing system



<i>Process Step</i>	<i>Failure Modes Identified</i>	<i>From Observations</i>	<i>From Interviews</i>	<i>From Risk Workshop</i>
1. Identify need	To end-user, medical device could be consumable			
	Information available to end-user incomplete	✓	✓	✓
	Sales reps instigate purchase			
2. Request need	User can bypass system as non-medical device	-	✓	✓
3. Identify funding source	Funding source divides process taken (capital/revenue device)			
	Job description interpretation varies	✓	-	✓
	Funding to standardise not readily available			
	Funding to run library not readily available			
4. Approve purchase	Non-involvement of maintenance			
	Delays to the service exist through approval process			
	Training involvement at start known in theory, not in practice	-	-	✓
	Certain departments can order capital items outside process			
	Training involvement at start known in theory, not in practice			
	Individual personalities can drive process			
5. Execute purchasing process	Delays to the service exist through approval process	-	✓	-
	Purchasing also handles non-medical device purchases			
6. Receive device at Goods-In	Receipt of medical devices not always identifiable	-	-	-
7. Conduct acceptance test	<i>None so far</i>	-	-	-
8. Install and train	End-user unaware of different device models available	-	-	-
9. Use and maintain	Delays to the service exist through understaffed maintenance			
	Delays to the service exist through understaffed library	✓	✓	-
	Policy to reach practice takes time			
	Full audit of asset base not available, 3 registers exist			
10. Report back on use	Devices not fully traceable in hospital			
	Servicing reports incomplete	✓	-	-
	Non-involvement of end-users			

Table 2: Failure modes identified from various sources