

A Systems Approach to Improving Patient Safety through Medical Device Purchasing

A Thesis Submitted for the Degree of Doctor of Philosophy

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December 2009

To my parents

For when a man excels by gifts of nature,
It is no wonder if his life is blessed;
In him we worship the Creator's power,
Through feeble human clay made manifest;
But he who overcomes himself has gained
The greatest triumph, stood the hardest test,
And well may he to all the world be shown:
Yea, this is he, this deed is his alone!

Goethe, *The Mysteries (Die Geheimnisse)*

Summary

The purchase of medical devices involves engaging various stakeholders as well as balancing clinical, technical and financial requirements. Failure to consider these requirements can lead to wider consequences in the delivery of care. This study first builds a general knowledge base of current purchasing practice in a sample of NHS Trusts, which confirms the direction and guidance given by policy documents and literature as to the extent of the challenges faced by purchasing stakeholders. This then leads to an analysis to identify inefficiencies in the purchasing process, and how such practice can lead to risks in the delivery of care. These risks range from injury to individuals, impacts to the healthcare delivery service, and financial and litigation risks. Finally, a framework that highlights these potential risks in the life-cycle of medical devices in hospitals is presented.

Key policy guidance has encouraged both researchers and implementers of healthcare services to approach patient safety from a systems perspective, acknowledging that medical device errors are not only directly related to device design, but to the design of the healthcare delivery service system in which the device operates. Little evidence exists of successfully applying systems approaches specifically to medical device purchasing practice. Medical device purchasing, because of its implications to patient safety on the one hand, and the uniqueness of the healthcare context, requires a unique approach. By demonstrating the influence of purchasing practice to service delivery and patient care, the thesis made is that taking a holistic systems approach is one method to improve device purchasing practice, and hence influence better care.

Acknowledgements

It is inconceivable to think how I would have completed this project without the help, support, guidance and encouragement I received from many individuals. My very first expression of gratitude goes to my supervisor, Professor John Clarkson, who encouraged me to dream from our very first meeting, and then proceeded to employ me to continue dreaming. A close second gratitude goes to Dr Terry Dickerson, who kept me grounded (when I got carried away dreaming) and was always available for advice. Those close to my heart and memory in the early phases of my project are Dr Zöe Morris for encouraging me to question and sharpen my research skills, Dr Natasha Campling for her guidance in steering the research, Dr Christopher Monk for encouraging me to constantly challenge myself, Dr Nathan Crilly for keeping my focus clear, and, finally, my personal tutor in college, Dr Metaxas, for keeping me smiling during my studies. Thank you to my dear colleagues in the Engineering Design Centre who kept me sane and revised sections of this thesis: Dr Tomás Flanagan, Tabassum Jafri, Dr Thomas Jun, Dr Warren Kerley, Dr Anja Maier, Dr James Ward, and Dr Bernd Wittner; and Bernhard Dusch and Adel Hinrichs for the invaluable graphic design support in the final stages.

This research would not have been possible without invaluable opportunities to engage with healthcare practitioners. In particular, I would like to thank John Warrington, Samantha Forrest, Dr Paul White, Dr Peter Jarritt, Dr John Amore and Lawrence Ashelford for creating these opportunities. I am also grateful to Patrick and Frances Colquhoun and *Medical Support in Romania*, who served as inspiration and support for my transition into Cambridge and the world of Healthcare.

Finally, no project is possible without the help of family and friends. I owe my family all my gratitude for their loving encouragement and patience, my dance colleagues for their support, and my beautiful community of friends in Cambridge for acting as family.

This project was supported by the UK Engineering and Physical Sciences Research Council.

Declaration

I hereby declare that this thesis is the result of my own work and includes nothing which is the outcome of work done in collaboration except as declared in the Preface and specified in the text. This thesis is not substantially the same as any that I have submitted or will be submitting for a degree or diploma or other qualification at any other University; except as declared in the Preface and specified in the text.

Furthermore, I declare that this thesis contains fewer than 65,000 words (including appendices, bibliography, footnotes and tables) and fewer than 150 figures.

Saba Hinrichs

December 2009

Abbreviations

ABHI: Association of British Healthcare Industries, UK
CEP: Centre for Evidence-based Purchasing, UK
CPH: Collaborative Procurement Hubs, UK
CRiSPS: Centre for Research in Strategic Purchasing and Supply, UK
DoH: Department of Health, UK
DPS: Design for Patient Safety
ECRI: Emergency Care Research Institute
EDC: Engineering Design Centre
EBME: Electro-Biomedical Engineering (also referred to as Clinical Engineering)
FDA: Food and Drug Administration, USA
HFE: Human Factors Engineering
HITF: Healthcare Industries Task Force, UK
HRA: Human Reliability Analysis
HTA: Health Technology Assessment
MAPSAF: Manchester Patient Safety Assessment Framework
MDA: Medical Device Agency, UK
MEC: Medical Equipment Committee
MHRA: Medical and Healthcare products Regulatory Agency (previously MDA), UK
MOD: Ministry of Defence, UK
NHS: National Health Service, UK
NPSA: National Patient Safety Agency, UK
PASA: Purchasing and Supply Agency, UK

Terminology

Clinical Engineering: This refers to the department in a hospital that deals with maintenance and repair of medical equipment. In some cases, they include a research and development department where new clinical products can be developed. Other terms used in literature for this group are ‘medical engineering’ or Electro-Biomedical Engineering (EBME).

Clinician: This is the term used to define any healthcare professional, including doctors and nurses.

EBME: This is the main term used to describe Clinical Engineering department, as above.

End-user: This refers to the person using a medical device at the front-end of the healthcare system (e.g. clinician, doctor, nurse). End-users are distinguished from the term ‘user’ in this thesis, which is used in a more general sense, to mean any user of a process, device, or the healthcare system (e.g. patients, purchasers, management staff, and end-users).

Medical Device or Equipment: This refers to any product or technology designed and intended for use in a healthcare setting.

Medical Equipment Committee (MEC): Also termed the Medical Device Committee, this is a body responsible mainly for allocating funds to capital device purchases. A sub-body of this group, the MEC Procurement Subgroup, was a subject of study at the NHS Trusts.

Medical Physics: This is a department in a hospital that oversees Clinical Engineering department but also encompasses other clinical technology areas such as radiology, imaging, and may include its own research and development.

NHS Trust (or ‘Trust’): The UK’s National Health Service (NHS) includes both primary and secondary care. Primary care is the first point of contact for most people and is delivered by a wide range of independent contractors, including general practitioners (GPs), dentists, pharmacists and optometrists. Trusts fall into the category of secondary care and include services in acute healthcare and can be either elective care or emergency

care. The Trusts referred to in this thesis usually refer to either one larger hospital or a collection of hospitals governed by one such Trust.

Procurement: This refers to the process of managing activities associated with the purchase of goods and services required to operate the organisation. Procurement also refers to the department in an NHS Trust that deals with administering purchases (also termed Supplies). To avoid confusion, the holistic process of procurement in this thesis is therefore referred to as ‘purchasing’, and usually placed within the phrase ‘purchasing process’ or ‘purchasing system’.

Purchasing: This usually refers to here as the transactional placement and processing of purchases, i.e. buying and selling. In this study, purchasing is used as the generic term for procurement and purchasing activities (as above). When used in this context, the term ‘purchasing process’ or ‘purchasing system’ is used to distinguish between administrative purchasing and the more holistic purchasing perspective.

Purchaser: A large part of this study consisted in establishing who would be considered a purchaser in relation to medical devices. Traditionally named ‘purchasing administrators’ who sit in the Procurement or Supplies department as above, are included as ‘purchasers’, but this term also extends to anyone who initiates a purchase (requisitioner), or has the authority to approve a requisition (budget-holder), which may include a variety of end-users and other stakeholders.

Risk: The general definition for risk is the chance of hazards or bad consequences; or exposure to chance of injury or loss. The level of risk is expressed in terms of hazard probability and consequence of failure. Risks in this study can refer to risk to the service, injury to any individual, and financial and litigation risks to the hospital.

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Chapter 1

INTRODUCTION:

Overview and Motivation

In the 1990s, most hearing aids supplied by the UK National Health Service (NHS) were out of date by over a decade, compared to the newer digital ones available in private practice. In response to growing pressure from patients and the public, the NHS secured a contract to buy new digital aids in bulk, providing patients with better technology and a long-term cost saving for the taxpayer, despite the greater immediate costs. Patients received the hearing aids they wanted and Trusts achieved a cost-effective deal. Around this time, the Purchasing and Supply Agency¹ (PASA) was formed, and the power of the NHS as a purchaser to influence the supply chain was highlighted (Phillips et al. 2007), which suggests that if the correct drivers are in place, the supply chain could be influenced to provide better products at lower cost. In short, purchasing policy changed practice through patient need.

However, such an exercise has not been repeated since, perhaps largely due to the changing national agencies in the NHS and the fact that most purchasing is conducted locally. In the above example, although there was a common understanding of what the patient desired, there is no record of the assessments made to demonstrate the safety of the

¹ At the time of writing, PASA announced its closure for 2010. Most of the references in this thesis refer to its jurisdiction between 2005-9. Some of its regional and local agencies continue to exist.

new product in the user context. Furthermore, clinicians and purchasers were initially hesitant to change practice, due to the initial costs involved, and the changes to clinical practice that would have to take place (Phillips et al. 2007). A decade later a study was conducted to explore the representation of user needs at the interface between the NHS and the wound dressing industry (Browne et al. 2004), concluding that methods are still needed to be able to truly communicate user needs to manufacturers.

The questions remaining after such a story may include: Does such lack of incentive still exist for other medical devices? What are requirements of other devices and should they also be standardised and undergo a similar exercise? Do medical device purchases in the NHS take into account safety metrics? And, finally, who is the purchaser, if there is not one organisation such as PASA to make similar national deals? Such general questions led to the motivation behind this research project.

In this chapter, the motivation for studying medical device purchasing is introduced, together with some background to “purchasing” in the context of healthcare and patient safety improvement, to explain the topical and methodological gap filled with this research.

1.1 Research Motivation

Motivation for this project consists of policy, financial, and healthcare incentives for a change in purchasing practice. This follows an underlying assumption that changes in practice are possible, and that the end-user can be part of purchasing decisions. This is illustrated in the previous section - a success story for the NHS - but is also alluded to in publications on patient safety improvement.

1.1.1 Policy-driven Motivation

At the start of this project, October 2005, purchasing in the NHS had just undergone changes in its structure and policy. The All-Party Parliamentary Group on Patient Safety

had just been inaugurated (APPGPS 2005), and at one meeting focussed solely on purchasing, the following questions were posed:

“How many buyers evaluate a technology before making a purchase? If patient safety is to be a consideration in procurement decisions alongside criteria such as clinical performance, maintenance and of course budget, evidence and data need to be readily available to support these decisions. How easy is it to make informed risk assessments when buying in the NHS?” (APPGPS 2005).

At a steering meeting for this project held in October 2005, John Warrington from PASA gave more details on the topics brought forward that represented the prevalent issues at the time. In particular, he highlighted the need for understanding the value of new technology, the available access points for entry into the NHS for suppliers, and even the lack of clarity on who makes purchasing decisions in the NHS.

Drivers for changes in purchasing led to the establishment of Collaborative Procurement Hubs (CPH) and Centres for Evidence-based Purchasing (CEPs), both of which are described in more detail in Chapter 2. Additionally, he mentioned a working party consisting mainly of industry, CEPs, clinicians, among others, which at that time had met to address the following questions:

How can we (PASA) provide clarity on what happens in the NHS?

How do we get clinicians more involved in decision-making in the NHS?

How do we turn procurement from being a blocker of innovation to actually being a supporter of innovation?

How can we change the way we measure efficiency to accomplish this?

And, finally, what is the best level at which to coordinate this in the NHS? (i.e. appropriate balance between national and regional control)

It was recognised therefore, that best practice purchasing is still to be identified and embedded into the NHS. However, given that current purchasing practice is not regulated through a consistent set of guidelines, it is difficult to see if any recommendations made either by PASA or as a result of research findings would lead to a change in practice. A recent publication commenting on healthcare policy adoption in the USA also echoed these sentiments, by highlighting that healthcare leaders cannot be expected to improve technology decisions without systematic changes to support their efforts (Coye & Kell

2006). As also observed in a Institute of Medicine Committee publication on the quality of healthcare in the USA, “simply trying harder” will not succeed when there is a lack of a business case for the adoption of new policies (IOM 2001). Research is needed to assess how to adopt best practice, and cross the policy-practice bridge.

1.1.2 Financial and Healthcare Motivation

Modern medicine has changed dramatically since the introduction of new technologies to aid diagnosis and treatment (Le Fanu 2000). Whilst such innovations have improved care, they have also contributed to rising healthcare costs (Neumann & Weinstein 1991; Altman & Blendon 1977). Given the increased demand for medical services, there was also an indirect increased demand for medical technology (Gelijns & Halm 1991). Acting as an integral part of the healthcare system, the device purchasing system therefore plays an important role in making savings for the healthcare industry. But making the business case for appropriate technologies can be challenging given its variety and the complex combination of financial, clinical and technical expertise needed to assess true value:

“Just as there was no business case for quality until networks of providers, purchasers, and payers changed the requirements and incentives for quality improvement, today there is no business case for rapid adoption of beneficial and cost-effective technologies.” (Coye 2001)

Furthermore, evidence shows that not all purchasing decisions take into account the necessary specifications for appropriate clinical care. Certain practices in the health industry actually create conflicts of interest that potentially compromise on safety. For example, it has been suggested in previous studies that physicians are distracted by marketing strategies from pharmaceutical and medical device firms, which may provide conflicts of interest in patient care and integrity of the profession when faced with a choice of product (Brennan et al. 2006). Approximately 90% of the \$21 billion marketing budget of the pharmaceutical industry in the USA continues to be directed at physicians, despite a dramatic increase in direct-to-consumer advertising (Kerber 2004). These interactions between drug companies and doctors start in medical school, continue during residency training and persist during physician’s careers (Blumenthal 2004). When faced with ‘gifts’ from pharmaceutical companies, it can be difficult for end-users to be unbiased in their purchasing choices (Dana & Loewenstein 2003). It could be assumed that in the UK the NHS has larger control of sellers’ behaviour in hospitals, but a few early conversations

held by the researchers together with stakeholders in preparation for this study suggest that this is not the case. Physicians and nurses will also develop subjective opinions about suppliers.

Even if correct intentions are there, there is also evidence to suggest the increase of poor quality of care, use of ineffective and untested technology, and overuse and inappropriate use of technology (Banta & Luce 1993). Ineffective use of technology affects both healthcare practice and future purchasing decisions. It is widely acknowledged, for instance, that both drugs and device errors do account for increased hospital costs. The costs of adverse drug events (ADEs) are one of the leading categories of patient injury, accounting for 19% of all adverse events in the Harvard Medical Practice Study (Brennan et al. 2004). These estimates are considered conservative because they do not include the costs of injuries to patients or malpractice costs (Bates et al. 1997). In the UK, a report from the National Audit Office noted that an analysis of 256 (96%) NHS Trusts survey showed that in 2003-4 they recorded 885,832 incidents and near misses. In 2004-5 there were 974,000 reported incidents and near misses. The cost of settled clinical negligence claims in 2003-4 was £423 million and provisions for outstanding clinical negligence claims as at end of 2003-4 were in excess of £2 billion (NAO 2005). Studies such as these have led the NHS to note the savings possible if errors were to be prevented. Similarly, in the USA, one study involved a cost-benefit analysis showing that net benefits from lowered incidence and severity of injuries and decreased workers' compensation claims was \$200,000 per year (Siddharthan et al. 2005).

The motivations so far can therefore simply be summarised in the assumption that purchasing decisions can help to both a) reduce errors and b) assess value and bring overall benefit and hence safety.

1.1.3 Background to Patient Safety

Studies in patient safety date back to 1960s and have increased considerably in the last two decades (Lilford et al. 2006). Current statistics by the NPSA quote as many as 459,500 safety incidents from October 2008 to March 2009 - the highest rate since records began (BBC 2009). Two key US publications formed the basis of many other studies in latest literature: *To Err is Human* (Kohn et al. 2000), and *Error in Medicine* (Leape 1994). In the UK the document *An Organisation with a Memory* (Department of Health 2000) was

a pivotal publication that led to the creation of the National Patient Safety Agency (NPSA) and, subsequently, PASA. These publications encouraged us to approach patient safety as a systems error. Incident reporting culture increased as a means to highlight errors, although it was acknowledged that reporting errors was still not firmly established within the Trusts (Alberti 2001). Investigation into device errors by the Medicines and Healthcare products Regulatory Agency (MHRA) in 2003 reported that problems with medical devices were the major contributory cause in patients' death in around 20% of cases within a year; in the other cases the other contributory factors were non-device related (MDA 2003). A significant proportion of the remaining 80% is attributed to human error or systems error (Lowe 2005). In an attempt to understand systems approaches better, various sources in healthcare now quote Reason's Swiss cheese model of error - the existence of 'holes' within each defence layer does not normally cause a bad outcome, but an incident occurs when the holes line up to permit a trajectory of accident opportunity (Reason 1990). The process of purchasing medical devices may well provide some of these holes in our system, which leads to the emergence of the term 'Purchasing for Safety' as one layer of this system.

1.1.4 Purchasing for Safety

Responding to *To Err is Human*, the USA launched the Leapfrog Initiative in 2000 (Leapfrog, web source). It was driven by organizations that buy healthcare who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans. Although their remit is to improve the power of purchasing in the delivery of healthcare and not specifically devices, the ultimate goal is patient safety and their methods of identifying good spending proportions and patterns of hospitals could be helpful to examine. Since then, there have been other incentives for addressing purchasing and patient safety from other sources.

Policy and National Initiatives for Purchasing for Safety

The Department of Health published an influential report highlighting the importance of improving purchasing practice in the NHS (HITF 2004). The Cox Review also highlighted the potential for purchasing to shape public services (Cox 2005). Trusts themselves could be competing on quality of service, patient safety and level of innovation, as suggested further by Warrington from PASA (Sansom 2006a).

While there is some published guidance on how to ‘purchase for safety’ or to purchase efficiently for hospitals, most of this is out of date and may not be applicable in practice. According to a review by Coye and Kell, the lack of detailed, neutral information about candidate technologies leave hospital administrators poorly prepared to make appropriate decisions on potentially beneficial technologies (Coye & Kell 2006). *Healthtec* in the USA emerged precisely because there was a need to research emerging technologies, forecast their evolution and potential impact on healthcare, to facilitate planning and long-term strategies with respect to new innovations (Becker 2003).

Empirical evidence for purchasing for safety

On a local level, challenges to the implementation of good purchasing practice also exist, notably the complications associated with tendering procedures (Hughes 1996). Furthermore, the link between purchasing and patient safety in practice has not been formally established through an evidence base.

There is a large body of literature available from the Centre for Research and Innovation in Strategic Purchasing and Supply (CRISPS), but their studies largely refer to risk to the organisation, not explicitly direct risk to patient, and is also centred around the whole supply chain. ‘Risks’ in terms of risk to patients and end-users due to device design have also been highlighted and mitigations for these are addressed by regulatory bodies, but studies have shown that this is not enough to ensure safety in user context (Clarkson et al. 1999). Only few have taken the research a step further by looking at the stakeholders involved in purchasing decisions and how to better identify their role in safety. For instance, the ‘disconnects’ in the wound dressing supply chain in the UK have been investigated but this study is limited to one product. Other studies have been conducted as stakeholder analyses for infusion pump purchasing in the USA (Johnson et al. 2005; Keselman & Tang 2004), but these are again limited to one device, and are based in the US healthcare system which is different to that of the UK. In both cases the studies were product-specific and they did not try to generalise to the wider purchasing process.

The supplier’s role in safety

While the demand side of the supply chain may initiate safe purchasing practice, the supply side also has a role to play in producing patient-safe devices. However, little is provided in

the way of practical guidance to help the device developer meet these safe device design requirements (Alexander & Clarkson 2000). According to Ward, interviews with medical device companies in the UK have shown that such advice would be helpful not only in achieving good design, but also to comply with the essential requirements of the medical device directives (Ward 2002).

Regulation standards provide one way of monitoring safe design practice in the design process. These standards have reached far and wide but these considerations alone are not enough to ensure the safety of devices in the patient environment (Clarkson et al. 1999). Furthermore, despite differences in the manner in which regulations standards are practiced in the USA and the EU, these do not seem to affect the rate of incidents or reported percentages quoted in the UK compared to the USA (Davies & Marshall 2000). The direct correlation between more stringent standards and reports of incidents is still to be investigated. What has been shown, however, is that not all standards may imply the same level of safety when it comes to device use. A study on applying standards to the design of nuclear medical devices claims that because the directives were misleading, some of the radiation detectors (which ideally should be classed as Class I devices) could not even be considered medical devices if the standards were to be read literally (Bury 2000). Gamma or beta counters could also be manipulated differently since the standard to be applied would have to depend on where the manufacturer specifies its destination for use. This shows that there are still flaws in the vocabulary used in the standards, which could either confuse manufacturers or mislead those attempting to not cause harm with their design.

It has also been shown that regulations and standards are not completely understood by designers and purchasers (Kreuzer 1998). The connection between regulation and clinical appropriateness may also have been lost. Despite its mandate to ensure safety and effectiveness, the FDA was forced by the tremendous volume of device applications to prioritise its resources towards ensuring the safety, rather than the effectiveness, of new devices in clinical practice. This has been a direct effect of taking a limited and possibly misunderstood ‘engineering approach’ to evaluation of devices, focusing on technical capabilities and on failure rates, rather than clinical endpoints, such as a decreased pain, improved function or amelioration of disease (Ramsey et al. 1998).

When addressing patient safety as part of a greater aim for healthcare improvement, the literature is much larger and ‘purchasing’ is also mentioned in the context of culture and organisational behaviour. Such literature is introduced in the literature review. However, as elaborated above, the concept of ‘purchasing for safety’ at the local decision-making level presents a topical and methodological gap.

1.2 Research Approach

Given the lack of studies on ‘purchasing as it happens’ in the NHS as highlighted above, approaches to patient safety improvements through improved purchasing measures therefore also show a methodological gap to the research topic. The research approach is described in detail in Chapter 3 but an overview is provided here.

1.2.1 Research Aim

Despite the few studies mentioned here, more empirical evidence was needed at the time of this study to show firstly whether purchasing practice currently presents a problem in the NHS, and, secondly, how such practices are contributing to risks in the service. It is therefore not the intention to re-design purchasing practice, but rather observe current practice before the need and method for improvement is suggested. The second part of the investigation consists in assessing the effect of these practices on the healthcare delivery service, to then provide recommendations on possible interventions.

1.2.2 Research Questions

The detailed research questions are elaborated further in Chapter 3, following a literature review. Following the above aim, the main research question for this study is as follows:

What are the characteristics of a medical device purchasing process that effectively focus attention on patient safety?

To investigate this question, three questions were derived which are investigated throughout this study:

1. *What is current practice in medical device purchasing?*
2. *(How) does current practice present risks to healthcare delivery services?*
3. *Where are areas for improvement on current practice?*

1.2.3 Overview of Data Collection

The challenges faced in researching in a healthcare context are introduced in Chapter 4 together with the research methodology and general approach. Access to data in a healthcare context provides one of the major challenges and can even influence the approach taken to the research. Due to collaborations established for this study, opportunities for various stages in the data collection process were possible.

The sources of data were a result of the following collaborations:

Trust A: Collaboration with this Trust provided most of the detail in the data and deeper understanding of the healthcare context.

Trusts B, C, and D: Collaboration with a PASA project on Purchasing for Safety² gave access to three further Trusts, while examining the safe purchase of infusion systems.

Trust E: An invitation to a Scottish NHS Trust to examine the process of evaluation of new infusion pumps provided a third opportunity for access.

The opportunities provided by the above Trusts allowed for the data to be collected in two dimensions: a general analysis and overview providing a broader scope of general purchasing practices across the Trusts, and a series of case examples that gave a deeper analysis of particular elements of purchasing practice. These in particular led to the

² Full details of the Purchasing for Safety project by PASA can be found in <http://www.pasa.nhs.uk/PASAWeb/NHSprocurement/Purchasingforsafetyinjectablemedicines/> (Accessed 01/12/2009)

identification of risks to healthcare delivery that arise from poor purchasing practice. A diagrammatic representation of these two dimensions is shown Figure 1.

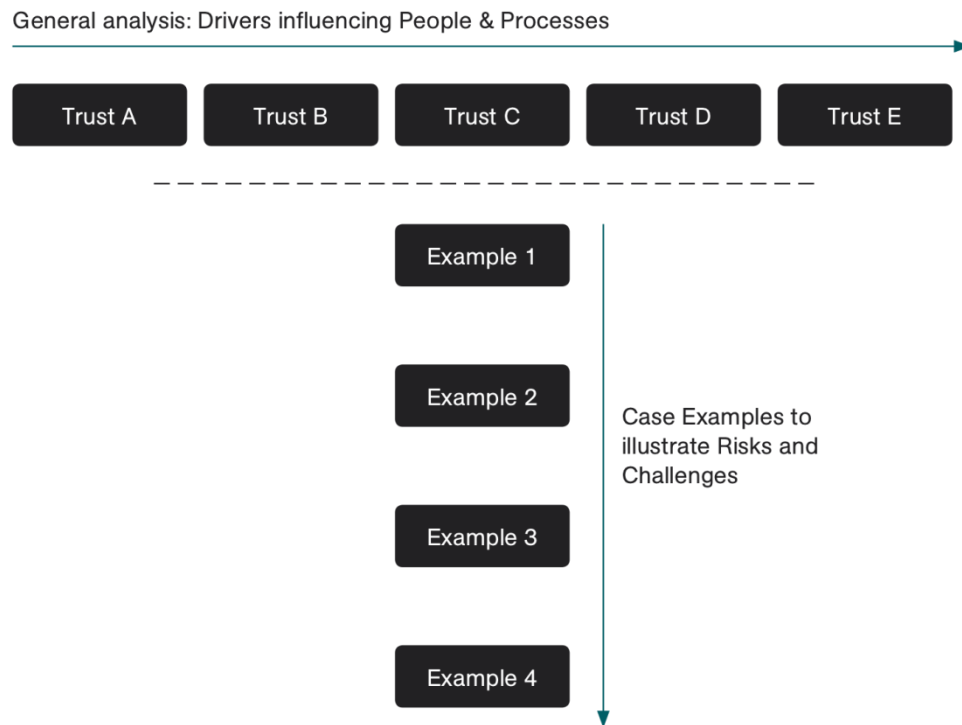


Figure 1: Sources of data and general approach to study

The data was collected, and hence presented in this thesis, in the sets of results described next.

Results I: Exploratory Studies (Trusts A, B, C, D)

The aim of this stage was to establish who the main stakeholders are, the ranges of products involved, and an outline of the processes followed. It also elicited the main issues encountered by the participants. Research in this section were conducted at Trusts A, B, C, and D, and the focus was largely on the people and processes involved. In part, the studies also focussed on the products and included a literature review of the types of products available to hospitals and interviews with medical device sales representatives.

Results II: Observations of current practice (Trusts A, B, C, D, E)

The aim of this stage was to gain a deeper understanding of the drivers and influences behind purchasing decisions. All sample Trusts were involved in this study to gain a broad

understanding of the processes. The insights obtained were cross-referenced to the initial Exploratory Studies to obtain valid conclusions.

Results III: Risks and Challenges through Case Examples (Trusts A, E)

Given the opportunities provided for more in-depth analysis and observations of practice within hospitals, Trust E and Trust A were examined in more depth and allowed for case studies to be developed with specific research questions following the generic study in Results II. Specific challenges in the process were examined and the implications of these challenges to the general healthcare service are discussed.

Synthesis and Framework

All results emerging from each part of the studies were analysed to provide a framework covering the main issues in medical device purchasing. This framework also served as a way of presenting the main issues back to the participants in the study, as a form of validation of the ideas developed.

1.2.4 Research Process Framework

On a conceptual level, this project aims to follow good design practice in its investigation as well as in its approach to the research matter. A design research framework is adopted, which advocates an understanding of current practice to then be able to prescribe the requirements needed for good purchasing practice. Before best practice can be implemented through change, good design practices dictates that a clearer picture of the current context is needed, which is where most of the contribution of this research lies. Taking the approach suggested in Design Research Methodology (Blessing & Chakrabarti 2009), this project covers the following:

- a. Sets the criteria for the research success.
- b. Describes elements of current practice of medical device purchasing in the NHS.
- c. Establishes the requirements needed to prescribe good purchasing practice.

Each of these stages is embedded within the dissertation outline described next.

1.2.5 Dissertation Outline

The approach to the research gives an indication, firstly, of what contributions this research aims to achieve, and, secondly, the adopted approach taken in order to satisfy these aims. The aim of each section was as follows:

Chapter 1: This first chapter has provided an overview of the research and motivation for its undertaking.

Chapter 2: This chapter reviews the current available literature in this field, drawing from different disciplines, and concludes that there is a gap to be filled in current knowledge.

Chapter 3: The direction and evidence gathered in the previous chapter are used to arrive at research questions, followed by a general research approach to then draw upon a suitable methodology for the research.

Chapter 4: Presented as Results I, the Exploratory Studies answer the very simple question “What is going on in device purchasing?” in a very general sense, to be in a better position to ask further questions for the study.

Chapter 5: The results presented in Results II answer general questions on current practice, followed by a short discussion on potential challenges in current practice.

Chapter 6: The case studies in Results III provide examples where elements of poor practice, as concluded in Results II, are demonstrated through real life examples. The chapter concludes with further analysis to examine inefficiencies in current practice, and whether and how such practice can lead to risks in the healthcare service, drawing on findings from Results I, II, and III.

Chapter 7: The suggested frameworks serve to then bring out the main issues in current practice in diagrammatic form, with the aim of serving potential improvements as elicited in the above stages.

Chapter 8: All conclusions are re-stated, together with recommendations that inform future ‘prescriptive studies’.

Figure 2 summarises the structure of the dissertation in context of the design research approach introduced earlier.

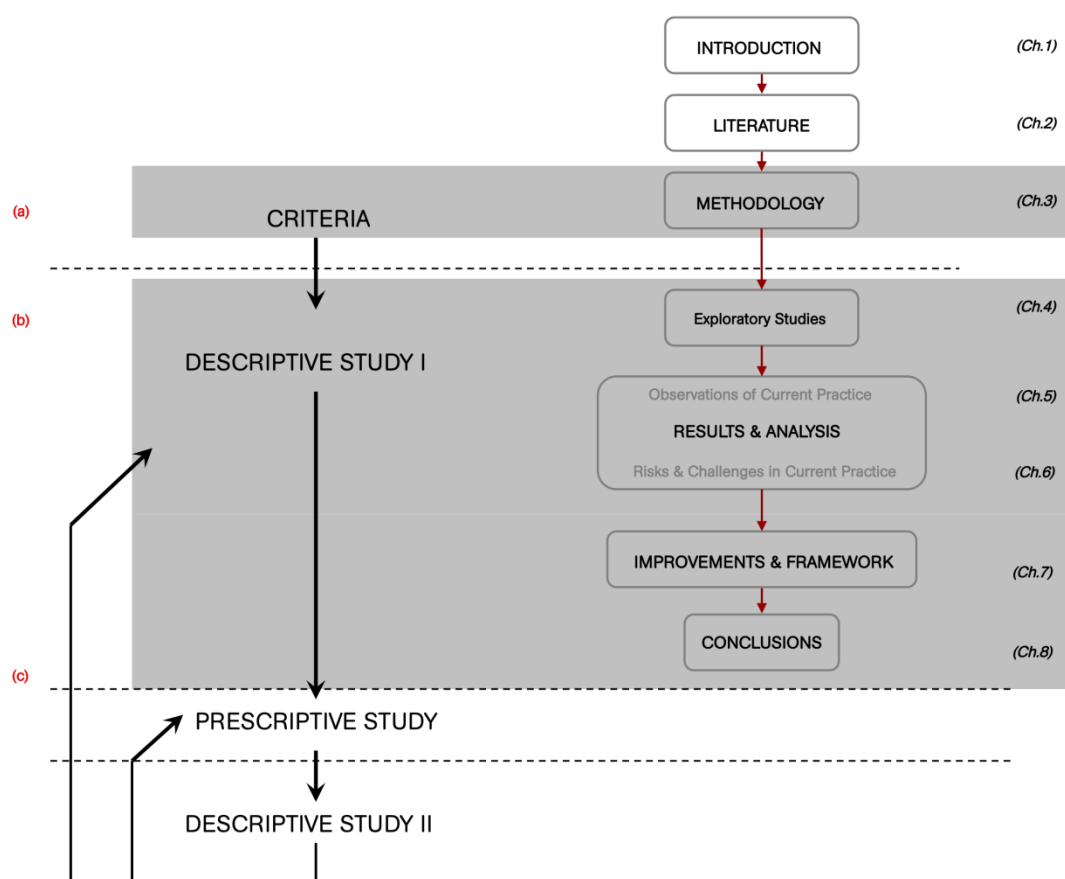


Figure 2: Dissertation outline embedded into research approach

The left part of the diagram closely resembles the design research approach suggested Engineering Design research (Blessing & Chakrabarti 2009), as an overall framework to the study. Steps a, b, and c, refer to the three steps in Section 1.2.4. Setting the criteria for research success (a) is established together with the description of the methodology in Chapter 3. The study largely constitutes a description of current device purchasing practice (b). The contributions made towards future design of ‘prescriptions’ (c) are made throughout the thesis and reiterated in Chapter 8.

1.3 Summary of Introduction

This study aims to investigate the current situation with regards to purchasing in the NHS, and link these practices to patient safety. The research topic presents both a methodological gap and topical gap in the literature. Patient safety has been examined but not in context of purchasing, yet plenty of financial and ergonomical incentives exist to suggest this is worthy of investigation. Given the diversity and complexity of the research context, the NHS, a systems approach is adopted both to the methods required to conduct the research, and as a conceptual approach to the topic itself. Systems approaches are not new to patient safety, but appear to be new to purchasing in healthcare.

PASA has had purchasing power in the NHS in the past, and now recently undergone some changes, but it is unknown if they are becoming better at purchasing medical devices, in response to policy drivers for such change. In particular, PASA is faced with understanding the ‘value’ of new technologies, gathering entry points into the NHS, and understanding who actually makes purchasing decisions. Previous studies on patient safety have alluded to re-design of purchasing systems, but few recommendations have been found on how to implement these in practice. In purchasing literature, most of the studies are based on strategic purchasing, and although it is emphasised to address patient safety, there is little research in examining the process of purchasing medical devices from a hospital’s perspective. Given the various decision-makers involved in making a purchase, a holistic a systems approach to purchasing a medical device 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. A chapter outline that delineated the route taken in the various research stages to achieve this aim, was then presented.

Chapter 2

LITERATURE:

Purchasing, Patient Safety, Healthcare Design

The research subject falls under a number of different topics and research fields. This also constituted in the initial challenge for the research, which was to identify the core literature that pertains to the topics of study. The literature study was completed through the following strategies:

Database key word search: General search through medical literature database PubMed, which covers not only research in front-end clinical applications, but covers service, management, and technological aspects of healthcare. This service was initially used to obtain relevant search terms using a set of controlled vocabulary (Medical Subject Headings or MeSH terms)³

³ Search for terms [Search ("Equipment and Supplies"[Mesh] OR "Equipment Failure"[Mesh] OR "Equipment Failure Analysis"[Mesh] OR "Equipment Reuse"[Mesh] OR "Equipment Safety"[Mesh] OR "Equipment Design"[Mesh] OR "Equipment and Supplies, Hospital"[Mesh] OR "Disposable Equipment"[Mesh])] AND [Search "Materials Management, Hospital"[Mesh] OR ("Group Purchasing"[Mesh] OR "Practice Valuation and Purchase"[Mesh] OR "Purchasing, Hospital"[Mesh] OR "Financial Support"[Mesh] OR "Economics, Hospital"[Mesh])] yielded 4193 of which 984 were marked as relevant based on abstract/title (September 2009)

General search engine: Using web-based search engines, general policy documents and media publications were found, especially on changes in the NHS

Reference chasing: Further material identified in the reference lists from other key publications

Periodic automated list services: Subscriptions to relevant journals or discussion forums were followed for current debates on the following topics: Electro-Biomedical equipment engineering forum (EBME), Health Services Journal (HSJ), Safety-critical industries email list, and design research (PHD-DESIGN) email list

2.1 Overview of Literature Review

Theory and insights were drawn from these various fields of previously published work with two intents. It was first necessary to identify whether or not medical device purchasing had been investigated before, and by what methods, and secondly to gather theory on established disciplines of purchasing practice, not to analyse and apply them in their totality, but to understand their possible influence on current practice in a healthcare context.

The survey of literature presented here falls under the following categories:

- *Purchasing and Improvement* (drawing on Purchasing and Operations Management, and Process Improvement), which provides background to general purchasing practice and relevant management theory, and is compared to process improvements specific to healthcare and patient safety
- *Medical Device Purchasing*, which provides background to available knowledge on device purchasing and identifies the challenges specific to medical device purchasing

- *Design in Healthcare*, which introduces previous knowledge on general process improvement measures and how to approach patient safety and healthcare improvements with ‘design’ concepts

2.2 Purchasing and Improvement

Aim: To provide background to general purchasing practice and relevant management theory, and compare these with literature on improvements specific to healthcare and patient safety

Research in healthcare improvement has drawn on guidance from general purchasing practice as well as theories in supply chain operations management. Both subjects are introduced here to provide an introduction to these original sources of knowledge. Operations management is the activity of managing the resources that are devoted to the production and delivery of products and services (Slack et al. 2007). Lessons from operations management are important to consider for purchasing practice as they underpin the general context under which device purchasing occurs. The type of literature included is mainly core and general books on purchasing and management theory, and not analytic publications on these theories. The focus is on the implications and adoption of methods specific to healthcare.

2.2.1 Purchasers and Purchasing Process

The term procurement has been referred to in industry as the process of managing activities associated with an organisation’s need to purchase goods and services, required to deliver their products and services or operate the organisation (ICG, web source). ‘Procurement’ therefore usually implies a broader sense of ‘purchasing’ which is the simple act of buying, and could involve determining which commodities or services are best, choosing the right suppliers, negotiating the best prices, and awarding contracts to ensure that the correct amount of the product or service is received at the appropriate time. In this study, both terms could be used interchangeably. However, to avoid confusion, the term purchasing is used as much as possible throughout, since it is usually placed in context of

‘the purchasing system’ or ‘purchasing process’, to emphasise the more holistic aspects of purchasing practice. It should be noted that the term ‘Procurement’ is also used later in the results chapters to refer to the department that deals with administering purchases, but this would always be used as the phrase ‘Procurement Department’.

A Purchasing Cycle

Integral to the operation of the supply chain is the purchasing cycle, as exemplified by Figure 3 adapted from guidance compiled by the Chartered Institute of Purchasing and Supply (CIPS 2006):

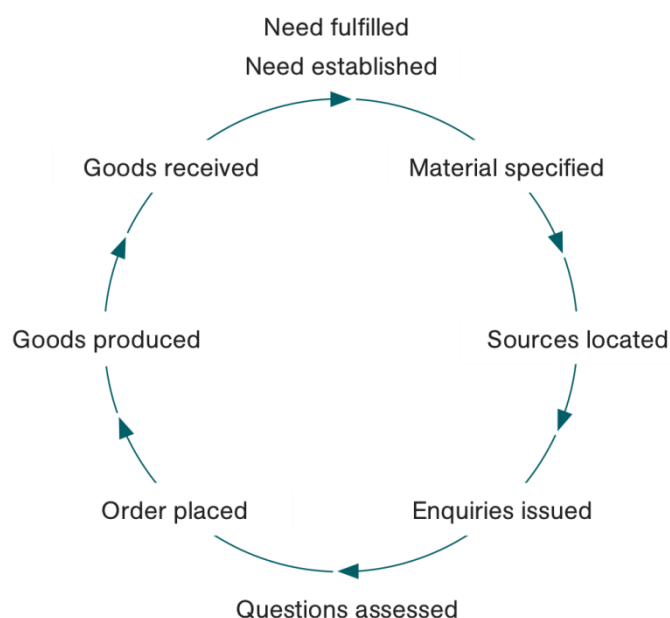


Figure 3: The Purchasing Cycle, adapted from (CIPS 2006)

Even a simplistic model such as the one above, if followed accurately, would enable appropriate articulation of end-user needs in healthcare, but this may not always be the case. The emphasis in this cycle is on the role of the purchaser, and the articulation and communication of end-user needs throughout the cycle.

The articulation of end-user needs resonates with guidance from other industries. Mass-market products, such as mobile phones and computer games have their end-users at heart in design, and it is well understood that such devices will not sell to the general public if they are not ergonomically designed. Further to device usability and aesthetics, safety features must also be taken into consideration given the context of use of medical devices. A parallel can also be established between other safety-critical industries and healthcare: the end-user and receiver of the service is in a critical position that may have implications on their health and well-being. Safety-critical industries, such as aviation, rail, and defence, can share lessons about the standards and expectations of purchasers. One such standard is that of the Ministry of Defence (MoD) in the procurement of safety-critical software systems (MOD 1997). Several bodies are responsible at various stages of the purchasing process, and ultimately the software designers work hard to meet the high standards set by the purchasers. Checks are made by the designated Design Authority and a MoD Safety Assurance Authority.

The purchaser's role

The buyer, if following the purchasing cycle adequately, and ensuring that the correct needs are being communicated throughout the cycle as shown in Figure 3, is a focused individual working in a pro-active situation. The role of the purchaser is therefore an important one that carries much greater responsibilities and authority. As well as considering the role and responsibility of the purchaser, creating a purchasing process that integrates into a safety-critical system is therefore also of paramount importance. As learned from CIPS, creating a 'purchaser' is required that is proactive and aware of the rest of the cycle. Similar concepts exist in operations literature. Supply chain management has as its objective to satisfy the end customer, which in a healthcare scenario could be the end-purchaser. What the customer originally had in mind as requirements may be different by the time the goods are received, because of the different points in the decision making process that have had to take into account specific requirements common to the organisation (Slack et al. 2007; p. 403).

Given this displacement between end-user and supplier, the purchasing manager provides a vital link between the operation itself and its suppliers. It is their duty to "understand the requirements of all the processes within the organisation and also the capabilities of the suppliers who could potentially provide products and services for the operation"

(Christopher 2005). Identifying this purchaser therefore constitutes an initial part of this study.

2.2.2 Operations Management

Any changes in purchasing practice affects, or is affected by, the overall strategy and objectives of the organisation. In healthcare, the functions of the organisation include aspects of general industrial organisations such as product or service development function, the fulfilment of customer needs, and support functions such as accounting, finance, and human resources. However, ultimately, the product of this particular operation is intangible: *a service*. Some of these concepts are introduced below and discussed in the context of medical device purchasing.

Inventory Control

Inventory or stock can refer to the stored accumulation of material resources in a transformation system. In operations management literature, the term refers only to transformed resources, particularly materials in a company (Slack et al. 2007). However, there are particular aspects of inventory control that can apply to devices in a hospital. In particular, the setting of priorities for use of inventories, applying a degree of control to each item; and then investing in an information processing system that can cope with their particular set of inventory control circumstances (Slack et al. 2007; p. 365-399) The details of which method to use in inventory control are not mentioned here as it suffices to simply highlight its importance for managing assets, particularly when considering purchasing as a more holistic process that requires due consideration of existing stock, as introduced next.

Asset Management

Asset management is defined by management practitioners as the “integrated, joined-up management of physical infrastructure (or other items of value such as human assets, knowledge, reputation, etc) with the aim of raising whole life value-for-money” (Woodhouse, web source). According to the Woodhouse Partnership, a UK-based organisation working with local companies on their asset management systems, only few UK companies have fully succeeded in such integration (Woodhouse, web source), and some of the reasons they have identified from working with companies have been:

- “Silo” thinking that prevent collaboration or shared solutions
- Short-termism that bases success on delivering ‘on time’ and ‘on budget’, irrespective of performance and value
- Conflicting performance measures that create competing priorities between departments
- Business skills lacking for engineers/facilities managers, especially if not in line with finance director
- Risk evaluations not done properly
- Fire-fighting: firstly in not having time to think in advance, but then awarding competence in crisis at the expense of avoiding the fire in the first place
- Poor data, both in quantity and accuracy

To achieve integration in the armed, nuclear and airline sectors, strategies such as Integrated Logistics Support and Reliability Centred Maintenance have helped maintain a certain level of control for asset management. From the manufacturing sector, which highlights the importance of team working, shared responsibility and continuous improvement processes, has emerged the practice of Total Productive Maintenance and Total Quality Management (Woodhouse, web source). These will not be explained in detail here; it is unknown to what level such developed approaches would be applicable to device purchasing with no knowledge of current practice. Simply identifying some of those same challenges mentioned in the list above in current practice in healthcare already provides insights on where device purchasing stands in comparison to good practice in asset management.

2.2.3 Process Improvement

Key steps towards process improvement are: understanding the current process (process knowledge) and setting criteria for improvement on current performance.

Performance Measurement

Performance measurement can be defined as the process of quantifying action – where measurement means the process of quantification and the performance of the operation is assumed to derive from actions taken by its management (Slack et al. 2007). A comparison

of different approaches was completed in a review (Bourne et al. 2003) that concludes that to demonstrate performance and measure it, the following steps must be taken:

1. Identify generic or detailed factors to include as performance measures - e.g. cost, speed, dependability, quality, flexibility
2. Identify which are the most important performance measures - e.g. Key Performance Indicators (KPIs) as used in some healthcare organisations
3. Identify what detailed measures to use to assess performance

Improvements can be of two types: *breakthrough improvement*, which occurs through the innovation of a major and dramatic change in the way the operation works, or *continuous improvement*, assuming several smaller incremental improvement steps. These two concepts relate closely to the ideas presented in the first chapter - whether or not this project aims to design a purchasing process with a 'blank sheet of paper' and provide breakthrough improvement ideas, or suggest ways of re-engineering the system that already exists. Given the long-standing structure of the NHS as an organisation, and the approaches and methodological restrictions addressed in Chapter 3, the approach here tends towards continuous improvement. Within continuous improvement, performance is measured regularly and in cycles. One popular cycle used in healthcare literature is the Plan-Do-Study-Act (PDSA) cycle (Berwick 1996). The potential for these indicators and improvement performance measures are discussed in context of patient safety improvement in Section 2.2.4.

Design Process Improvement

Design process improvement guidelines also have contributions on generating improvements in an organisation:

“Organisation change concerns the transition from an initial ‘as is’ organisation situation, which is unsatisfactory in some aspect, to a desired ‘to be’ situation where the problem is resolved. Both the future state and possible change routes that can be followed to reach this state have to be specified. To this end, organisational stakeholders develop hypotheses (termed scenarios) as to the nature of the desired solution.” (Clarkson & Eckert 2005)

According to these sources, in order to create improvements, the organisation needs to take into account: *Current-state goals*; *Stakeholder intentions*; *Contextual forces*. Such approaches are particularly useful in this context, where the purchasing decision is made by stakeholders belonging to different teams, with varying knowledge of the process and of the product being purchased. An extra dimension specific to the healthcare context recognised that there are attitudes and cultures in a healthcare environment, risks particular to the healthcare service, and further factors that increase the complexity of medical device purchasing systems.

These three considerations were incorporated into the design of the questionnaire used as the basis of the semi-structured interviews in this study, as well as taken into considerations in the design of the research questions, as explained in Chapter 3. The current-state goals as well as stakeholder intentions were elicited through discussions on drivers and intentions and attitudes towards purchasing for safety, and the contextual forces formed the basis of many of the parameters on which the findings were clustered.

2.2.4 Patient Safety Improvement

The particular challenges in firstly ‘measuring’ and then ‘improving’ patient safety are discussed in later sections, but a mention is made here on how improvement measures have been discussed in healthcare. Most medical publications are based on evidence-based medicine, although Leape, Berwick et al (Leape et al. 2002) question this formal method which places heavy emphasis on data from randomised control trials. However, it has been pointed out that in aviation practice neither empirical evidence nor controlled experiments were needed to suggest sound principles for safer practice, and yet the effect of Crew Resource Management in aviation has had a huge cultural effect and established safer practice. (Helmreich & Merritt 1998)

With the aim of creating a process-centred tool for evaluating patient safety performance and guiding strategic improvement (Akins 2005), one study suggests that no system-wide approach or model has been agreed upon thus far for patient safety approaches, and suggests that this field is “in particular need of rigorous qualitative and consumer-oriented research to fill an existing methodological gap”. Some of the published measures for healthcare and patient safety improvement are introduced next.

Safety Culture

According to a review of improvement scoring systems by Nieva and Sorra, “while a variety of levers – clinical training and guidelines, information technology, organisational structures and industry regulations – are being pushed in healthcare organisations to improve patient safety, the belief is growing that an institution’s ability to avoid harm will be realised only when it is able to create a culture of safety among its staff” (Nieva & Sorra 2003). This allusion to culture was already made by Reason stating that incident reporting requires a “flexible and learning culture”(Reason 1997). The definition of organisational culture, according to Helmreich and Merritt, who have spent years examining different safety-critical cultures, is “a complex framework of national, organisational, and professional attitudes and values within which groups and individuals function”(Helmreich & Merritt 1998).

Such methods date back to 1991 with the examination of the Chernobyl disaster, with Pidgeon’s paper arguing that safety culture presents “a new way of conceptualising processes of risk handling and management in organisational and other contexts.” (Pidgeon 1991) The emphasis is made not only on the norms and rules for dealing with risk, but the attitudes to safety and reflexivity on safety practice. In other words, safety practice no longer is something that needs to be controlled externally by an organisation, but entails a proactive participation by the individuals that are part of that organisation.

Organisational Scoring Systems

The organisational culture is defined as “a complex framework of national, organisational, and professional attitudes and values within which groups and individuals function” (Helmreich & Merritt 1998). This can differ per organisation, and implies that each one has its particular method of attaining its goals. The final state of a system may be reached from different initial conditions and in different ways. Therefore, an organisation with a particular set of cultural attributes may be successful in achieving patient safety, while another organisation with a different set of cultural attributes can also potentially achieve the same levels of success.

Organisations with a cross-functional nature in industrial markets, such as the NHS environment, can provide a challenge. A conceptual model has been tested by Lonsdale and Watson who present a model supplemented by a real-life case showing how it can help

managers interpret their environment. They conclude that “organisational power has been shown to be critical to the decision-making process” (Lonsdale & Watson 2005). Organisation scores are therefore one possible way of measuring patient safety maturity:

“Safety climate questionnaires need to achieve as high a standard of measurement as possible so that healthcare managers can use the resulting data to design effective safety management systems and interventions” (Flin et al. 2000).

Nieva and Sorra have conducted a survey of the different tools available for survey tools, and they conclude by recommending to look out for the following in designing organisational scoring systems (Nieva & Sorra 2003):

1. The domains of culture that are assessed
2. The types of staff who are expected to complete the tool
3. The setting for which the tool was developed
4. The availability of reliability and validity evidence about the tool

A suggested approach for using an organisational scoring system for purchasing is suggested as follows:

1. Organisation’s own awareness of the role of purchasing in patient safety
2. Organisation’s own assessment on actual use of purchasing in improving patient safety
3. External assessment of organisations awareness of the role of purchasing in patient safety
4. External assessment of organisations actual use of purchasing in improving patient safety

These suggested points are theoretical, but were kept in mind while exploring the potential for organisational scoring specific for purchasing in Results I. The particular tool tested out is MAPSAF, described in the next section.

Maturity Assessment Frameworks

Quantitative measurement is appropriate when the relationship between inputs and outputs is known or can be modelled, and parameters can be modified accordingly (Kaplan & Norton 1996). A balanced scorecard, introduced by Kaplan and Norton, is a method that balances financial objectives with operational measures of customer satisfaction, internal process, innovation and other improvement activities (Kaplan & Norton 1996). These measures need to be carefully designed to meet the overall strategic objectives of the organisation. A different technique is the maturity grid approach; a flexible technique that is used by practitioners in industry, consultants and researchers in academia for diagnostic, reflective and improvement purposes (Maier et al. 2009). The Manchester Patient Safety Assessment Framework (MAPSAF) is an example of such a framework for healthcare (Parker et al. 2002). In the framework, examples are given in a range of potential safety cultures, from worst-case (Pathological) to best (Generative). MAPSAF uses 9 dimensions to assess patient safety. It has not yet been validated and only provides a tool for hospitals to assess their own improvements and ‘maturity’. However, the tool does claim to do the following:

- Raise awareness about patient safety
- Illustrate differences in perception between staff
- Stimulate discussion about the strengths and weaknesses of patient safety culture within the organisation
- Identify areas for improvement
- Evaluate patient safety interventions and tracking changes over time

The theoretical framework behind MAPSAF came from Westrum (Westrum 1992). This Manchester team then adapted it even further to be applied to community pharmacies. They had already created one for PCTs and their constituent general practices in the UK (Ashcroft et al. 2005). A copy of the tool as used in this study is available in Appendix I. As mentioned in their article, the main selling point about MAPSAF is that it encourages proactive behaviour, which they advocate, is that “increasing trust and informedness allow us to get on with our work without requiring extra supervision and control; audits become more efficient and directed, taking less time; managers can be left to manage, workers get on to do the work”. Anecdotal evidence from among pharmacists suggests that the tool does, at a minimum, raise cultural awareness (Ashcroft et al. 2005).

In this study, the future development of a maturity framework with regards to purchasing is noted but not necessarily advocated. As indicated by Maier et al.'s guide to maturity grid development, the planning and development phases for these grids require an understanding of the context, its target audience, and exact requirements (Maier et al. 2009). This is the stage fulfilled in this study, but the MAPSAF tool is used merely to explore its potential future use in the initial Exploratory Studies.

Overall, these safety culture approaches seem a viable route towards organisational change, and may be one tool used for purchasing practice improvement. Ultimately, as noted in these articles, behavioural change cannot be pushed onto people. The people both driving and facilitating the change must believe in the process; and through their commitment, a pull is generated among the workforce. If policy has alluded to poor purchasing practice and decisions, some cultural changes might be one way towards improvement.

2.3 Medical Device Purchasing

Aim: To provide background to available knowledge on device purchasing and identify the challenges specific to medical devices

2.3.1 Purchasing in the NHS

Established in 1948, the NHS is the largest organisation in Europe and has actually enjoyed exceptional popularity. According to one Wanless report, 80% of those polled regarded the NHS as critical to British society (Wanless 2002). However, its approach to purchasing and the costs of patient safety incidents have also been subject to scrutiny:

"Currently, clinicians argue the clinical case, but procurement managers and finance directors will typically argue cost and therefore price. The two worlds do not always come together." (Dr George Findlay, previously clinical coordinator for the National Confidential Enquiry into Patient Outcome and Death (Sansom 2006b))

Given that the public sector spends over £150 billion a year on the goods and services needed to deliver public services, it is essential to achieve value for money for the taxpayer

and effectively manage procurements (OGC 2008). Yet devices are still contributing to unnecessary costs in healthcare. A recent report from the National Audit Office in the UK, noted that an analysis of 256 (96%) NHS Trusts survey showed that in 2003-4 they recorded 885,832 incidents and near misses. In 2004-5 there were 974,000 reported incidents and near misses. The cost of settled clinical negligence claims in 2003-4 was £423 million and provisions for outstanding clinical negligence claims as at end of 2003-4 were in excess of £2 billion (NAO 2005)⁴. Studies such as these have led the NHS to note the savings possible if errors were to be prevented.

Such allusions to the importance of addressing purchasing decisions must, however, stem from some form of evidence or proof that good purchasing practice can be implemented, adopted and disseminated. In terms of actual technology or ideas adoption, the UK may not be best placed. According to a later Wanless report, the USA is an “early” and “fast” adopter of technology, France, Australia and Canada are also “fast” but “late”, and the UK lags behind all of them by being “late” and “slow” (Wanless 2003). A recent empirical study of adoption of e-commerce in the health sector supply chain found that adoption is influenced by contextual variables, in particular ‘external pressure’ and ‘internal readiness’ which create trade-offs in adoption decisions (Harland & Knight 2008). But if no concrete evidence of its effectiveness is available and little recommendations on exactly how to implement safe purchasing practice in healthcare, what could this notion be based on? The hearing aid example was given at the start of Chapter 1, but another example, Greening the Supply Chain, also shows that procurement policy can respond to need and have an influence on the supply chain in the long run. In 2000, PASA became the first public sector purchasing organisation to achieve ISO14001 Environmental Management Standard (BSI 1996), making sure that suppliers are environmentally aware too. As an organisation, they have proven that their policies can have an influence on the behaviour of suppliers. An extract from the project’s Executive Summary further emphasises this influence:

It has been increasingly recognised in recent years that public procurement can play an important role in contributing to the achievement of other Government policy targets. The Agency is therefore not purely a "contracting" body - our remit is constantly expanding to

⁴ The implications of these figures on the total cost of NHS spending was not found in the quoted reference but further information on financial activity for the year 2003/4 in the NHS can be found at http://www.pasa.doh.gov.uk/annualreport/2003_4/financial/financial-p2.htm (Accessed 01/12/2009)

recognise wider issues on the national agenda... On the path towards sustainability we have realised that our greatest contribution is through our procurement activities rather than estate management. However, our work goes beyond what is required by the framework in order to respond to our stakeholders needs and maximise our positive contribution to a sustainable society. (PASA 2000)

The question remains whether or not this example of ‘purchasing for sustainability’ can be replaced with ‘purchasing for patient safety’ as successfully as it has been done for the environment.

National UK Purchasing Agencies

The NHS Purchasing and Supply Agency (PASA) had been an Executive Agency of the DoH since April 2000. The organisation replaced the previous NHS Supplies and has as its general goal to provide “best value for money” (PASA, web source). Currently, they work with 400 NHS Trusts, manage 3000 purchasing contracts, and influence half of the £7 billion spent in the NHS, potentially a huge responsibility. As part of their business plan on inception in 2000, they had planned on:

- Ensuring that the changing requirements of the NHS are identified and that they drive national purchasing and supply activity
- Ensuring delivery of planned results and agreed targets through performance monitoring across the NHS
- Developing and improving the provision of comparative information on the purchasing and supply performance of the NHS
- Maintaining an overview of supply markets and advising the NHS on market issues
- Providing strategic direction to NHS Logistics Authority in order to ensure support for national supply strategies

What remains unanswered is to what extent this occurs, and what systems have been put in place in order to carry out the above⁵. The NHS is constantly undergoing reform and continues to have strategies for beyond 2010 (Stevens 2004). As a result of the Wanless

⁵ The PASA Framework document can be downloaded from their website (2009): <http://www.pasa.nhs.uk/PASAWeb/NHSprocurement/AboutNHSPASA/Publications/Corporatepublications.htm> (Accessed 01/12/2009)

report (Wanless 2003) there followed a key publication by the Healthcare Industries Task Force (HITF) which was followed by innovative and key changes to procurement strategies followed by the DoH (HITF 2004). These plans for implementation were the main focus of the business plan, which looked similar to the one existing now. The previous Supply Chain Excellence Programme now known as NHS sourcing and Supply Chain Improvement Programme was targeted to deliver £1.5 billion of “efficiency gains” by 2008/9. It was really this HITF document that brought about many of these changes. In theory, therefore, most of the strategy planned did call for more risk management, clinician and patient engagement, intelligent purchasing and considerations of ‘value’ to the patient. The question remains whether or not these implementations all took place on a grass-root level, and whether or not patient benefit (and thereafter patient safety) has been increased. Given the recent changes in PASA structures, as well as the outsourcing of many logistical functions for NHS Supplies, much of the collaborative activity and decision-making actually occurs at a local and regional level. The main bodies that can be identified as being responsible for these considerations are:

- Collaborative Procurement Hubs (CPHs): Intended to ensure value for money and implement strategic procurement plans, eventually taking over some areas of procurement responsibility currently managed by PASA
- Centres for Evidence-based Purchasing (CEPs): Intended to help and inform procurement decisions, and encourage the uptake of useful, safe, innovative products and procedures used in health and social care. It is hoped that they will guide purchasing decisions throughout the NHS, but the effectiveness of this approach is yet to be experienced.
- National Institute for Innovation and Improvement (NIII): A nationally coordinated institute that “supports the NHS to transform healthcare for patients and the public by rapidly developing and spreading new ways of working, new technology and world class leadership” drawing its ideas via co-production with the NHS and drawing from industry and international organisations.
- National Innovation Centre (NIC): As part of the NHS Institute for Innovation and Improvement, and working together with innovations hubs, it intends to speed up

the development and adoption of technological innovations that deliver the best results for the patient.

- Commissioning⁶: The process by which the NHS decides what services are needed, acquires them and ensures they are provided (Davies 2008).
- National Institute for Clinical Excellence: Provides technology appraisals on health equipment, clinical guidelines on managements of specific conditions, and clinical audit methods to support the other two aims.
- Adoption Hubs, Innovation Hubs, and Training Hubs: Working together to help make better use of new technologies to increase ‘pull’ of innovative products, help with challenges of innovators to enter the NHS, and develop training tools for the safe use of advanced medical technologies.
- MediLink UK & Health Technologies KTN: National network of regionally-based independent programs working for a common goal of raising the profile of the medical and healthcare sectors in the UK. They have produced *www.clinicalneed.com*, which is based on a SOCN (Statements of Clinical Need) process; a tool for healthcare professionals to express real needs and to communicate those needs to industry effectively and efficiently.
- Supporting organisations such as the Bath Institute of Medical Engineering (BIME), providing guidance on selected equipment.

At face value, the framework is there, but their success is yet to be experienced. One of the challenges faced by these various bodies is in truly collecting evidence that can inform policy and good practice. A publication developed by authors from the Centre for Research in Strategic Purchasing and Supply (CRISPS), examines what “evidence-based purchasing” might mean in terms of PASA’s strategies for purchasing improvement criteria. The paper first examines evidence-based management, evidence-based law, and

⁶ Origins of commissioning can be traced back to the internal market in 1991 when the NHS was divided into purchasers and providers. It was actually referred to as ‘purchasing’ then, not to be confused with the more specific ‘medical device purchasing’ as used in this thesis.

evidence-based medicine, evidence-based policy making, and suggests what “evidence-based purchasing” might be (in line with the inception of centres of evidence-based purchasing in PASA), and then this is to “provide an initial conceptual framework for evidencing value in public procurement decision making” (Harland et al. 2007). Their key message is that evidence-based medicine for public procurement is particularly important for procurement in public sector healthcare provision, but has wider applicability to evidencing procurement decisions across complex public sector systems.

“The recognition in medicine that strict adherence to single, scientific methodologies is not always appropriate supports some form of contingency approach to choice of evidencing method.” (Harland et al. 2007)

The UK Efficiency Review (Gershon 2004) of public sector called for a focus on generating efficiency savings in public procurement, so that resources would be released back to front line services. It was in response to HITF that researchers at CRiSPS completed some work on what evidence based purchasing in healthcare might mean. In the context of developing such evidence, Harland et al point out that observational, qualitative and case study research is needed in the context of healthcare purchasing practice, but this can be difficult to disseminate in context of a randomised-control trial (RCT) community (Harland et al. 2007). Certainly the challenge of both conducting and disseminating qualitative research in a medical community is an issue to consider for medical device purchasing practice too, and is addressed further in later sections as well as Chapter 3 on methodology.

Gathering evidence, informing policy, adopting policy measures, and understanding the national networks in NHS purchasing, forms part of a whole body of literature in itself. Gleanings from such themes have been provided in this section, serving as contextual background to the focus in this study, which is purchasing decision-making at the local hospital level.

Purchasing Devices at Trust-level

Given the ever-changing political landscape, this study is not focussed on the policies and governance issues within NHS Purchasing. The focus here is what happens on the ground, which constitutes a gap in research for the NHS. It can be challenging to describe the exact

workings at Trust level because it is not entirely clear who really makes the decisions about what to buy (PASA 2004). Currently, the procedures in place include the following:

- Larger purchases, e.g. European Tenders: Published in the Supplement to the Official Journal of the European Union (OJEU), this is an eight-step process for tendering for purchases above a certain cost⁷
- The NHS Supplier Information Database: The setting up of this arose from PASA's purchase "once only" principle. It is free to all suppliers and purchasers but being on the database does not mean they have been accepted into contracts scheme, i.e. not necessarily been vetted or approved by PASA
- NHS logistics: Operate through Electronic Data Interface or email, single point of contact. Much of the complexity of trading within NHS Trusts is therefore removed; even the supplier delivery performance is monitored. Much of these services are now provided by a private outsourced company.
- Pre-purchase Questionnaire: A checklist provided to suppliers, mostly for electro-medical equipment. Among the information asked is the following:

CE marking or other safety standards (e.g. ISO9001, 12001, 13485)?

Service/spares, installation information?

Training required, if provided or not?

Year product on market?

Repairs, third party or not?

Is installation necessary?

Software upgrades notification availability?

Ionising radiation hazard?

Decontamination procedure?

Will it be reprocessed?

Can be cleaned/ autoclaved?

⁷ This is an eight-step tender and contract process to award competing supplier the contract with the hospital, starting from identifying customer needs, to tender development, analysis, clarifying issues with suppliers, deciding and finalising on the tender award, and launching the agreement.

The list is comprehensive but does not necessarily give an indication to the purchaser on design safety features to look out for. It is also not clear is how these requirements are assessed.

Device Purchasing Process Routes

In a given Trust, the purchasing process route taken varies according to various factors that relate to the device itself. These include: cost, funding source, consumable/device, old/new device, and current asset content. All of these factors can affect who is involved in making the purchasing decision, how long the decision can take, and what final product is selected.

Furthermore, it must be noted that the purchase of a medical device may not necessarily be differentiated from other purchases in a hospital, at least not to the end-user or original requisitioner. However, to the end-user, this is part of a larger list of any item that is requisitioned for use in their department. The NHS Supply Chain, which handles most of PASA's logistical work, provides hospitals with a database for devices with a categorisation system (e-class codes), which facilitates ordering items. The product categories are:

- theatre/surgical services
- medical
- food and facilities (including office supplies)
- clinical markets (orthopaedics, cardiology, pathology, ophthalmics, renal, dental, resonance imaging)
- capital equipment

The Key Facts page does not mention safety once – but more noticeable than that is how all products are grouped into one supply chain, until the e-class codification is used for tendering purposes, as shown in Table 1.

Code	Description
A	Provisions
B	Staff Clothing
C	Patients Clothing & footwear
D	Pharmaceuticals blood products and medical gases
E	Dressings
F	Medical and Surgical Equipment
G	Patients Appliances
H	Chemicals and Reagents
I	Dental and Optical Equipment
J	Diagnostic Imaging and Radiotherapy Equipment & Services
K	Laboratory Equipment & Services
L	Fuel Light Power Water
M	Hotel Services Equipment Materials & Services
P	Building & Engineering Products & Services
S	Gardening and Farming
T	Furniture Fittings
U	Hardware Crockery
V	Bedding Linen & Textiles
W	Office Equipment Telecomms Computers & Stationary
X	Transportation
Y	Recreational Equipment & Souvenirs
Z	Staff & Patient Consulting Services & Expenses

Table 1: PASA classification for all supplies⁸

As seen in Table 1, ‘medical equipment’ is only one category among many other items supplied by PASA. Within a particular purchasing department of a hospital, the only differentiating factor is that a medical device purchase receives an ‘F’ e-class code. What is also noted above is that pharmaceutical blood products enter a different category (‘D’ e-class code), which makes it no wonder that the pharmacy supply department is separate to medical devices. Yet a pharmaceutical product might be supplied with a set of consumables that link to a particular device that falls under F for ‘medical equipment’. Communication and collaboration are therefore key to achieving standardisation.

⁸ The complete list is available at www.doh.pasa.nhs.uk (Accessed 01/12/2009)

On entering a hospital, once this F classification has been made in the purchasing process, another degree of categorisation made is made according to whether or not the devices that are bought or maintained by the Clinical Engineering Department (mainly responsible for maintenance and servicing of devices, introduced later). If this Department is aware of all medical devices bought (and indeed, if all items are assigned an F classification on purchase) a certain degree of control can be achieved in the full life-cycle of the device. Certain 'ad-hoc' purchases can then be avoided. This means, however, that the Engineering team should employ an updated, fully working asset management system.

An example of good practice may be that shown by the US Air-force's medical facilities (Keller & Walker 2005). They use the Emergency Care Research Institute (ECRI, web source) device coding system to manage their asset base. As a starting point, they claim that a common nomenclature is important to such a dispersed organisation, since information about previous notices need to be fed back to ECRI for dissemination. For example, ECRI has frequently produced safety notices regarding intensive care ventilators. The ventilator reports, which typically involve a breathing circuit failure or alarm problem that can put patients at serious risk, are provided to all Air Force facilities as part of the ECRI member information program. "Intensive care ventilator," a standard term used by ECRI, has been adopted by the Air Force for its medical technology inventories. If some hospitals were to use a non-standard term such as "breathing machines" or "mechanical resuscitators" to describe the same machines, there is a chance that an ECRI safety notice regarding intensive care ventilators would be overlooked, and patients might be placed at risk. Equally, the same service provided by ECRI can include a purchasing assistance tool – a Healthcare Product Comparison System - that allows one to compare device features, incident history, device outputs, dimensions, key purchase considerations, and safety and use considerations.

Tools such as this by ECRI above may be useful for hospitals, but not all the Trusts used in this study use them (ECRI charges for their services and the release of this database). Furthermore, if designers are driven purely by regulations; the purchasers have a standardised list offered by PASA driven by 'purpose of use', and yet, the end-users have a multitude of other drivers required to make a wise purchasing choice, this leaves a lot of responsibility on the various people involved in purchasing to make that choice. There is also not enough evidence to suggest that all these stakeholders speak to each other. Cheng

from the WHO emphasises that all must communicate their needs in the supply chain (Cheng 2003) as echoed by the earlier guidance from supply and asset management.

Having set the context of the device market and introduced the challenges of its possible routes into the NHS, attention is now turned to the particular challenges of buying medical devices and the guidance made available to those responsible for purchasing.

2.3.2 Challenges to Purchasing Medical Technology

The focus of this research is not the purchase of all medical ‘technology’ as has been alluded to in general in previous sections, since this could also include new treatments, drugs and similar innovations. The US Congress defines ‘medical technology’ as anything from drugs, devices, surgical procedures, organisational support systems (US Congress 1982). This division does create a challenge for purchasers but even in setting the boundary of the research given how interconnected technologies actually are. For instance, the purchase price for a piece of equipment or drug, or fee paid to surgeon is not the whole cost of a treatment, this also includes operation costs, implementation costs, supervisory personnel, training, insurance, supplies, space in the hospital, and so forth (Gelijns & Halm 1991).

However, devices themselves do have particular characteristics compared to other ‘technologies’. Despite the common coupling of the term ‘drugs and devices’, both their development and purchasing strategies differ. The device industry is “younger, less concentrated, and comprises mostly smaller firms”, and there is much “greater heterogeneity of medical devices in terms of design purpose and use” (Gelijns & Halm 1991). The product life of a device usually is also much shorter than that for drugs; competitors may rapidly introduce a slightly modified version of a previous device (Gelijns & Halm 1991). An article back in 1998 highlights the poor state of medical device evaluations and the dangers of using devices without adequate information. They note that many purchasers and providers are unaware that the clinical testing and regulation of medical devices is vastly different from that for pharmaceutical products (Ramsey et al. 1998). In terms of forming evidence bases, randomized trials common in drug studies are often difficult or unrealistic to perform for medical devices (Ramsey et al. 1998).

Before establishing the boundary definition for device as will be used in this thesis, these challenges in technology assessment are addressed next.

Health Technology Assessment

“When comparing medical technologies, there is often a complex interplay of advantages and disadvantages between various drugs, devices, and medical techniques...Each alternative has a different cost, risk, application, and the desirability of each can vary widely when viewed from the patient, general population, insurance payer, legal, or governmental perspective” (Sloane 2004).

In particular, the field of Health Technology Assessment has emerged to help answer some of these complex problems. Technology Assessment is claimed to have started in the US public sector (O'Donnell et al. 2009; Banta 2003) with the launch of the Office of Technology Assessment (OTA) in 1972, which provided Congressional members and committees with comprehensive analyses of “technical issues of the 20th century” (OTA, web source). Although closed in 1995, during its establishment it served to assess the consequences of technological applications and therefore considered in determination of public policy on existing and emerging national problems. It has also been described as being increasingly devoted to more effective dissemination and implementation in order to influence administrators and clinicians (Banta 2003).

When the UK then launched their National Institute of Clinical Excellence (NICE), they generated global interest due to their transparent review process to determine real ‘value for money’ to the NHS for each new treatment (OTA, web source). After the OTA, the US has produced other bodies that provide a similar assessment service, such as Blue Cross Blue Shield Association Technology Evaluation Centre and the Emergency Care Research Institute (ECRI). Since then, however, decision support for acquiring equipment was needed, and some examples of these emerged later. One such example was a model for medical technology assessment programme, including automated technology monitoring and evaluation methods using indicators presented as a systems approach (Cram 1999). In the Netherlands, a priority setting project for general equipment acquisition was developed in 1997 (Banta et al. 1997). A review of these assessment methods in England, Wales, France, the Netherlands and Sweden was written by Oliver et al, summarising the reaction to these developments from a variety of different disciplinary and stakeholder perspectives

(political science, sociology, economics, ethics, public health, general practice, clinical medicine, patients, and the pharmaceutical industry). They conclude that despite the growth of HTA over the past two decades, its influence on policy making, and its perceived relevance for people from a broad range of different perspectives, remains marginal. (Oliver et al. 2004)

In the UK, the NIHR Health Technology Assessment forms part of the National Institute for Health Research (NIHR), and aims to produce “independent research information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS.” (NIHR, web source) But there are challenges in achieving value in purchasing decisions even in terms of care provision, let alone with instrumentation and technologies. To take some hypothetical examples, value can mean:

- Assessing performance – meaning anything from lifetime cost, training, reliability, availability
- Cost per hour (£/hr) of device capability
- Clinical effectiveness compared to a completely different treatment or technology (taking then into account all service and treatment costs at least)

It is no wonder that published literature has addressed the ‘cost-effectiveness’ of technologies (McAteer et al. 2007). These considerations are also important during the product development cycle. To cover some of these aspects, the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) was created in 2003 (Martin 2005). It aims to support the healthcare technology sector and its user communities by creating methods to assess value from concept through to mature product. For instance their work includes a spreadsheet tool to compare costs and patient benefit for new device-related procedures versus standard care with an incumbent device or other alternative (Craven et al. 2009). They have also addressed some of the challenges existing with capturing user requirements in the device design development process (Martin et al. 2008).

Once the device is in the market, these considerations must also be taken into account by the purchaser. It is yet to be shown whether these tools and assessment strategies are adopted by the healthcare community, as different parts of healthcare technologies might be purchased by different stakeholders within the healthcare community acting as

purchasers. For instance, the clinician may be purchasing a procedure or piece of equipment, the purchasing office may administer the purchase, and the pharmaceuticals associated with the technology purchased may be also arranged separately. These hospital-based divisions are addressed later in this Chapter and in the findings. The World Health Organisation and other experts make it clear that the term “health technology” must encompass all potential technical facets, including things, people, and processes (cited by (Sloane 2004)). Given such complexities and challenges, a boundary is set for focus in this study: the purchase of *medical devices* only. This is defined next.

Definition of Medical Device

According to US regulations (FDA), a medical device is defined as:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."(FDA, web source)

A Medical Device is defined in Directive (93/42/EEC) as:

“Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for the proper application, intended by the manufacturer to be used for human beings for the purpose of :

diagnosis, prevention, monitoring, treatment or alleviation of a disease, an injury or a handicap;

*investigation, replacement or modification of the anatomy or of a physiological process.
control of conception*

*and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means.*⁹

The above is a definition that is given to medical device manufacturers for the purpose of regulating. In practice, those working in the NHS may address devices by terms that are sometimes interchangeable, as noted in the exploratory observations so far: equipment, medical device, and medical products. These terms are explored below¹⁰ :

Equipment: an instrumentality needed for an undertaking or to perform a service

Device: an instrumentality invented for a particular purpose

Product: an artefact that has been created by someone or some process

Each stakeholder in the whole life-cycle of a medical device may also have a different experience and hence perspective on a device. These perspectives affect its design, its selection, and finally, its use and disposal. For instance, from the manufacturer's perspective, the classification of medical devices varies by regulatory risk standards. Both the USA and EU regulation systems classify devices according to their inherent risks and have different regulatory control mechanisms to suit these classifications, as indicated in Table 2.

⁹ The following products are excluded from the scope of the Directive:

In vitro diagnostic devices

Active implantable devices covered by Directive 90/385/EEC

Medicinal products covered by Directive 65/65/EEC

Cosmetic products covered by Directive 76/768/EEC

Personal protective equipment covered by Directive 89/686/EEC

Tissues or cells of human origin

Viable tissue or cells of animal origin

¹⁰ Definitions taken from <http://wordnet.princeton.edu/>

	Risk	Example	Controls
<i>Class I</i>	Low	Surgical bandage	General
<i>Class II</i>	Medium	Intravascular catheter	Special, 510(k) pre-market notification required
<i>Class III</i>	High (supports human life)	Prosthetic heart valve	High, Pre-market approval (PMA) required

Table 2: Classification of medical devices according to level of risk, USA regulation

The EU system differs only slightly, as seen in Table 3.

	Risk	Controls
<i>Class I</i>	Low	Manufacturers can declare conformity without notified body. If sterile, or if it has a measuring function, a notified body gives authority to manufacturer to apply its CE mark.
<i>Class IIa</i>	Medium	The design of the product and the production process will mostly be evaluated by the notified body (at production stage only for Class IIa; at design and production stage for Class IIb and III). The manufacturer may choose between various combinations of different control procedures.
<i>Class IIb</i>	Medium / High	
<i>Class III</i>	High	

Table 3: Classification of medical devices according to level of risk, EU regulation

The USA and the EU seem to differ in their intentions in setting safety standards. For the FDA, to achieve the standard the device needs to go through pre-market notification process, and achieve verification of reasonable safety and effectiveness of devices. For the EU, however, an assessment is made of the safety and performance of device according to manufacturer's intended purpose of use. Both accept a level of risk, nevertheless.

A discussion on the selection of medical devices chosen as case examples for this study is found in Section 4.3.3, based on themes that may relate risk to purchasing practice, or characteristics relevant to both risk and purchasing priorities. For now, it is simply

established that the boundary for this research is the medical device as defined similarly to the EEC Directive earlier: *any artefact designed and intended for use in a hospital setting and hence purchased by a hospital for providing clinical care*. This would therefore include all devices falling under the ‘F-class’ category as determined by PASA logistics (Table 1), but may include the pharmaceutical products if bought together with devices under ‘D-class’ category, dental and optical equipment (I-class), and diagnostic imaging and radiotherapy equipment and services (J-class). However, given the hospitals own understanding of medical device to be mainly those under category ‘F’, it can be assumed that these other categories were not taken into consideration by the respondents when providing responses.

2.3.3 The Role of Clinical Engineering

Much of the literature alludes to the role of the Clinical Engineering, or Electro-biomedical Engineering (EBME) department within a hospital, as the crucial link between purchasers and clinicians. Identifying the key decision-makers, however, remains a challenge dating back through literature.

Identifying Stakeholders in Purchasing

The literature on identifying purchasing stakeholders dates back to the 1970-80s, when the role of the clinical engineer started to be established. Many changes have taken place in both procurement policy and healthcare decision-making and these changes could be investigated further. Furthermore, the literature on the nurses’ voice in the purchasing process highlights an important potential barrier, which may be a reason for poor purchasing practice. Interestingly, however, such articles are also only found in nursing management journals, limited a wider audience to truly achieve stakeholder engagement.

Many of the roles discussed in this study are already introduced in the literature but in very limited examples:

- Discussion exists on identifying who the true decision-maker is in the purchasing process. Identifying a purchaser or the main body responsible for device purchasing has been discussed previously and may continue to be part of the questions that

continue to be addressed today.(Stafford 1978; Bauer & Clark 1975; Trafas 1980; Lewis 1979; Harju 1984)

- The role of the nurse in purchasing decisions has also been highlighted, given their central role in actually administering care using equipment (Carroll 1992; Raab 1984). But in practice, their role may also not be recognised and this also forms part of the observations collected in this study.
- The importance of teamwork in purchasing decisions appears in later literature (Fahlstrom et al. 2006), highlighting the fact that decisions for devices require knowledge that sits in different areas of the hospital.

The Clinical Engineer as the Purchaser

“Biomedical engineers are often called upon to lead a procurement decision because of their knowledge of how medical technology works, technical problems with the current technology being used, requirements to maintain technology, what products are available on the market and their existing relationship with medical technology companies.”
(Cassano Piché 2005)

The role of the EBME in device selection process has continually been highlighted since the emergence of this discipline within a hospital (Moody 1965; Burton 1996; Draper 2004; Whitworth 1979). More recently, the role of engineering and procurement in a hospital and at strategic level has been highlighted in international publications (Rothnie 2004). Their role is seen as key decision-makers in buying equipment, since they work closely with clinicians and technicians and finance, and recognise that “various features and benefits are offset with risks and limitations”(Sloane 2004).

According to guidance given specifically to the EBME community, the role of the ‘EBME manager’, whose role can be played by a senior clinical engineer, medical physicist, or clinical scientist, they are responsible also for:

1. Purchasing: *“It is the responsibility of the EBME Manager to control the documentation and inspection of purchases. It is the responsibility of the Quality*

Assurance Manager to ensure that this procedure is carried out.”(EBME, web source)

2. Stores procedures: *“It is the responsibility of the EBME Manager to ensure that a list of all equipment used is maintained in the Department in a professional manner and to ensure that the stores are controlled and handled efficiently.”(EBME, web source)*

The overlap between storage and maintenance, ‘estates’, procurement, and EBME within a hospital, is therefore significant, making collaboration and communication between these departments a crucial feature to consider in this study. This stakeholder group is an essential subject for study in this research.

Equipment management

Guidance for equipment management as a whole is mostly found in regulatory literature, rather than published journals. The FDA has put together guidance on incorporating Human Factors Engineering (HFE) into risk management of devices, including aspects of usability testing (understanding a device in user environment), explaining what HFE means, what level of effort is required in implementing its principles, and implementing general risk management processes (Crowley & Kaye 2000). All of this guidance is readily available to download online. Similar guidance is available for medical device management from the British Standards Institute (BSI 2009). The criteria for appropriate risk management include:

1. Board level responsibility for medical device management
2. Medical device group, in accordance with MDA DB 9801
3. Comprehensive organisation-wide policy on management of medical devices including deployment, monitoring and control
4. Selection and acquisition of devices acquired in accordance with the MHRA and NAO recommendations
5. Access to manufacturer’s instructions for end-users; statement signed to the effect that they have received instructions on the safe use of devices or equipment
6. All instructions supplied by the user organisation are evaluated for their adequacy
7. Acceptance checks on newly delivered medical devices

8. Devices designed for single use are not reused under any circumstances.
9. Information required to managed devices recorded on a suitable system
10. Adverse incident recording
11. Key indicators to show improvements in device management

All points highlight holistic, system-wide considerations for device purchasing and management. In particular, no. 4 points out the necessity to select devices appropriately. Details on this point state that this should include “a properly planned approach to the purchase of medical devices, taking into account the needs and preferences of professionals and end-users whilst retaining consistency and control” (BSI 2009). This includes lease, renting, in-house manufacture, refurbishment of devices and very comprehensive criteria for choice of supplier as well. These criteria also show a heavy reliance on in-house processes, controls, checks, and improvements, rather than relying on the supplier’s design of safe devices.

In academic journals, the focus is more on particular types of equipment that may highlight some of the challenges in implementing such guidelines. A small article published in an Accident and Emergency journal also gives these general guidelines to the ‘purchasers’ of equipment, aimed at management staff, within an A&E department. The same lessons are repeated: conduct regular/annual review of all equipment, maintenance contracts, service record, cost of maintenance vs. frequency of use and effectiveness. It also recommends building up good relations with charitable organisations, personal relationships with suppliers, and the importance of negotiation skills with suppliers and specialists within the particular unit (Oakland 1998). An interesting anecdote from this paper is the reference to capital funding allocations per department, speaking for their own department that the annual allocation for new and replacement equipment works like “national lottery”, given the random allocations given per budget holder. Capital and revenue funding seems to be a large divide in deciding how devices are purchased and the amount of control adhered to the purchase. In this article, the thresholds are as follows:

<£300:	Directly purchased from A&E budget
£300 - £5000:	Purchased from revenue budget
>£5000:	Purchased through business plan from capital budget

These figures are similar to those found in the Trusts in this study, and the challenges with such funding barriers are also addressed.

2.3.4 Guidance for Device Purchasers

Guidance in relation to healthcare has existed in literature for decades and literature on this can be found dating back to the 1960s. These are introduced here along with discussions of their limitations and implications for this study. These studies are published mostly by staff working in equipment management in hospitals and are therefore found in their specific care related journals (e.g. *Clinical Engineering* or *Biomedical Instrumentation*). Some are found in healthcare economics journals. In the case of device specific decision-making support, these are mostly published by either nursing staff or clinicians themselves and appear in a care-specific journal, and would not necessarily be picked up by a more generic healthcare service audience.

Standardisation & Evaluation

Representatives from the NPSA have advocated the standardisation of product models in a hospital, as a way of reducing errors (Lowe 2006), and studies have shown how standardisation in procedures and product can reduce medical errors (Paoletti & Casey 2000). These concepts are not new to those working with equipment, as publications advocating both evaluating and then standardising on new equipment purchases date back to the 1980s (Pauley 1980a; Pauley 1980b; Ratcliff 1984; Enger et al. 1987; Larson & Maciorowski 1986). More recent guidance has focussed on particular case studies and gives advice on how to conduct evaluations in practice (Seto et al. 2006; Simpkins et al. 1995; Gagnon et al. 2004). Seeing their implementation in current practice also forms part of this study.

Selection and Decision-making Tools

Early guidance also exists to give support for decision-making, but most of these are applicable to technologies at the time (Schabracq 1980; Shaffer 1978; Fecteau 1995; Hostutler 1996; Smith 1977; Simmers 1993; Jackson 1989; Donahoe 1989). In the 1990s, asset management and planning appeared in device maintenance literature, mainly highlighted the importance of forward planning and taking into account clinical needs (Cohen et al. 1995; Dickerson et al. 1992). As suppliers increased, it was also necessary to

provide guidance on how to select suppliers (Deboer & Vanderwegen 2003). More recently, specific guidance on making decisions on various models of the same device for infusion pumps is particularly useful given the large number of errors that occur to do with infusion devices (Ginsburg 2005).

Given all this available literature, it is important to question whether or not these recommendations are implemented in practice. Themes have been repeated for over 30 years, but technologies have changed and evolved. Moreover, it is not always clear which audience is being addressed with some of this guidance. One stakeholder group stands out in the literature: the clinical engineer. This may be one of the key groups for whom this guidance is applicable.

Guidance from EBME

Not only is their role identified in the literature, but also the EBME network itself is a source of guidance on purchasing decisions and is a forum for voicing the challenges they face. The literature available from the EBME website and online discussion forums are a very valuable source of informal information on how purchasing decisions are made, and provide questions on how to consider usability, safety, quality and so forth. It is a community with a lot of expertise but perhaps not enough of a voice in the rest of the healthcare sector. The discussions centre on crucial topics, such as:

- Risk quantification on different devices being evaluated
- Keeping clinicians and budget holders 'happy'
- Manuals/technical data sharing
- Controls assurance, quality standards
- Questionnaires for supplier before purchase (Pre-purchase Questionnaires)
- Obsolete equipment handling
- Specific product information

On the one hand, the site shows how rich this knowledge base is within the EBME community. On the other hand, it also shows how many of these issues exist and continue to be raised among this community.

Noting that practices vary from Trust to Trust, one EBME forum author has modelled a process showing key elements that are common throughout purchases within hospitals. This gives a clear and simple indication for purchasers that can help them design their purchasing process. The original version of the diagram originates from a website, not a particularly tried and tested method, but a straight-forward example of the purchasing process¹¹. The site states;

“In designing purchasing processes it's important to take into account both how information systems can be leveraged and where Hospital constraints and governance exist. Whilst some fundamentals e.g. originating need - communicating the need to the supplier - delivery - the payment of the supplier - may exist in most processes - how they are deployed can vary depending on the overall strategy of the Hospital and the prevalence of, and confidence in, information systems.”¹¹

According to the description given, the process follows the following model. A fairly linear model is suggested to occur, based mostly in the actual purchasing “office”:

¹¹ Taken from <http://www.ebme.co.uk/arts/procurement/>; referring to <http://www.bizbodz.com/Supply-Chain/General-Supply-chain/How-to-design-a-purchasing-process-1.asp> (Accessed 01/12/2009)

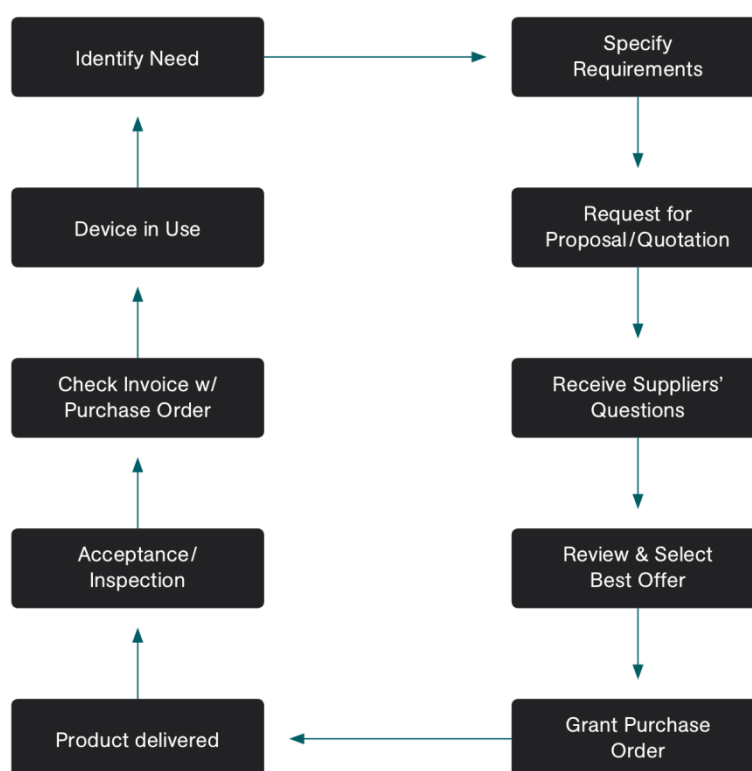


Figure 4: Purchasing administration process, from EBME sources

Many of these processes can now be automated too, and some hospitals have adopted such new technologies. But, as pointed out in the website text, an automated procurement process is usually a strategy and does not reflect reality, as NHS purchasing departments “often find themselves in a hybrid where a mixture of technology, partners and culture may be unable to accept a fully automated approach and traditional and contemporary processes co-exist.”¹¹

This may well be the reality encountered in many Trusts and is certainly that encountered in the Trusts in this study. Ultimately, while the bespoke process cannot be implemented, designing elements of good practice may be possible, allowing each Trust to use guidelines that suit its particular culture and organisational structures. According to the EBME site, the important considerations when designing a purchasing process are:

- How are the requirement identified?
- What is the authorisation process within the hospital?
- How will the organisation communicate with its supply base?

- Is a tender process required?
- How are costs managed within the process?
- Which performance indicators/measures can be applied?

These recommendations resonate with the guidelines from performance and operations management, as well highlighting the very important first step of requirements identification. Once again, it is their implementation in practice, and the ownership for these processes, that need examination.

Tools from regulation, management and human factors

The MHRA website has produced guidance on making a specific device purchase. Their recommended questions are (MHRA 2006):

Will the MD do what I want it to do, and is the usage advice included in the packaging? Is intended use covered in manufacturer instructions?

Will it fit in with what I already have available? (E.g. infusion pumps)

Are intended users trained to use it, and is additional training needed? How many need training? Do they include it in price?

What service and maintenance is needed? Or will this be in-house?

Do I have facilities to store them? What is needed? What is their shelf life?

Is it physically compatible with other devices?

Do I have components needed?

What is its life expectancy?

Will it need to be cleaned or decontaminated? Can this be done in-house?

As well as these guidelines for individual product purchase decisions, documentation exists for contextualising devices within a design, manufacturing and use life span. Within the World Health Organisation's documentation on medical device regulations and management, one chapter is dedicated to the nature of medical device safety as a risk management process that must encompass the life span of medical devices from their conception to disposal. The figure used is shown below:



Figure 5: Major phases in the life span of a medical device and associated stakeholders, adapted from (Cheng 2003)

Any of these phases can affect the safety and performance of a medical device, and this risk is shared between the manufacturer, vendor, government, user and the patient/public (Cheng 2003). Given that the purchasing stakeholders interact closely with those involved in the latter steps of this life span ('Advertising' onwards), this risk is also shared with purchasing stakeholders, and the changes of each process are inevitably linked. It also means that system changes in either arena can trigger systems changes in the other.

Not all guidelines appear from regulation and some literature from the management sciences also highlights similar principles. The concept of analytic hierarchy process is emphasised (Sloane 2004) because "in the case of a medical technology decision, there is an ethical obligation to try to honour the patient's needs and beliefs first and foremost, but other stakeholder perspectives and needs must also often be considered... Few business school researchers understand the medical field, but it has been encouraging to see how often they can quickly identify and apply their portfolio of well-documented tools and techniques once they understand a healthcare problem." (Sloane 2004)

Literature from other international sources speak about the more generic term Healthcare Technology Management (HTM) as follows (Poluta et al. 2005), described as:

Planning; Acquisition; Utilisation I (Asset Management); Utilisation II (Risk Management); Utilisation III (Maintenance)

The use of Human Factors Engineering (HFE) has also been encouraged in selecting devices, particularly for infusion devices which appear frequently in medical error published literature (Lin et al. 1998; Zhang et al. 2003; Ginsburg 2005; Gagnon et al.

2004). In Canada, such approaches have been encouraged as well. The University Health Network in Toronto, Ontario used HFE to evaluate electrosurgical units on the market. This process influenced the purchasing decision, and in the end the chosen product was the oldest on the market and had the fewest new features, but it was deemed to be the most usable and had the highest acceptance by clinical end-users (Cassano 2003). HFE was also used by the Veterans Health Administration to compare the usability of various infusion pumps in order to inform procurement decisions (Wiklund et al. 2002).

A study conducted by Johnson et al (Johnson et al. 2005) has identified what role patient safety currently plays in the medical device purchasing process. The study involved looking at three sites where purchasing of infusion pumps occurred. The observations were based more around sociological influences and disconnects within the system, but the findings were interesting as they showed consistency across the three subjects. “Serious limitations in the selection process” at each site were the main conclusions. They claim to also be in the process of producing guidelines for purchasers to look out for patient safety considerations in their future selection processes, these would be interesting to look out for in future. Various stakeholders must be taken into consideration when selecting a device. These have been identified after a study on infusion devices, as:

nurses (who program the pumps)
physicians (who write the orders)
pharmacists (who write the orders)
biomedical technicians (who repair the devices)
quality improvement staff
unit managers (who supervise the nurses)
patients
trainers for device use
administrators accounting for their costs and maintenance

The symptoms for driving change in purchasing, as exemplified by this study, are very similar to those experienced in the UK. While stakeholders usually recognise the importance of patient safety in purchasing decisions, the understanding of what this means is lacking. The size of the hospitals can reveal variances. Problems identified in Johnson’s study included:

- Sometimes not a huge range of devices is considered until problems occur with that model
- No purchasing teams included end-users
- No formal methods for assessing safety issues that could arise from design of device interface (mostly only technical safety issues)
- Bias in a ‘preferred’ pump, which then influenced the justifications made for choosing that model
- Limited HFE considerations (“ease of use”, “ease of programming”) but overall inconsistencies in that understanding of patient safety
- Inability to define or articulate those factors with a direct connection to patient safety

These social, cultural and skill-set based issues also remain at the forefront of observation for this study to see if similar issues arise.

2.4 Healthcare and Design for Patient Safety

Aim: To introduce previous knowledge on general process improvement measures and how to approach patient safety and healthcare improvements with ‘design’ and ‘systems’ concepts

2.4.1 Measurement of Safety

At least 44000 (up to 98000) people die each year in USA in hospital as result of medical error, which costs between \$17 - 29 billion per year in hospitals across the country (Kohn et al. 2000). Currently most talk of patient safety is based around describing what happens when our devices or systems in which they are used are not safe. Quantitative indicators of patient safety incidents have served the healthcare community as a straight-forward way to assess its performance. For instance;

“A breakdown of the latest figures show that in two thirds of cases - 303,016 - there was no harm to the patient, while a quarter - 122,246 result in low harm, which included minor injuries from things such as falls resulting from poor safety practices. Another

28,521 - or 6% - resulted in moderate harm and 5,717 - 1% - in death or severe harm, which is classed as permanent injury or disability” (BBC 2009).

Hence, in this school of thought the measurable criterion for assessing the extent of safety is to look at medical device errors. However, patient safety is partly affected by medical device errors which are both user errors and design errors (Lowe 2006). A combination of qualitative and quantitative data exists for research trying to ‘decrease medical device errors’ as a means to improve patient safety (Karsh & Alper 2005). The methods for understanding and analysing errors and risk are introduced here, as a background to the design and qualitative approaches adopted.

Medical error and device use

Patient safety incidents have been referred to by different terms. A few basic definitions of the terms used by different research communities are presented below:

- An error is defined as *the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)* - Institute of Medicine, USA (Kohn et al. 2000)
- An error is defined as *the failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance* - James Reason (Reason 1990)
- A patient safety incident is defined as *any unintended or unexpected event that leads to death, disability, injury, disease or suffering for one or more patients* – National Patient Safety Agency (NPSA 2003)

Medical device error analyses come in different forms. It can be measured by the extent of harm (Tan 2002), or by the presumed cause of error (Ward & Clarkson 2004), such as device-related errors or user-errors. Kletz in his book on human error bases his findings on the theme that it is difficult for engineers to change human nature, and it is therefore necessary to accept people as they are and instead remove opportunities for error by changing the work situation, either through the equipment design or by the method of working (Kletz 1991). These errors can therefore be skill-based, knowledge-based, or rule-

based depending on the intention of the user, or the inherent skills and training. Rasmussen's model of human behaviour also assumes the three types of behaviour (knowledge, rule and skill-based) (Rasmussen 1983).

Understanding error and behaviours towards devices constitute part of the knowledge that an intelligent purchaser would need, given the role of devices in patient safety incidents. This re-emphasises the importance of training and competence in device use.

Reporting and learning from incidents

Assessing the value of technological intervention versus the risk of patient harm is a challenging problem but may well constitute the role that a risk manager, or anyone responsible for introducing the equipment to a hospital, needs to play. The challenge is then to measure the success criteria for patient safety in these terms. The traditional approach is to take a look at the number of patient safety incident counts, as has been shown before and typically quoted and used by both the NPSA and the NPSF. The USA Food and Drug Administration (FDA) site pages regularly display incidents that have been reported back to them, similar to those shown on the NPSA website. Research conducted by the National Audit Office (NAO) shows that the most common incidents reported are (in this order) (NAO 2005):

Patient injury (due to falls)

Medication errors

Equipment related incidents

Record documentation error

Communication failure

It is through these reports that patient safety is currently assessed. However, several factors about this system need to be considered due to limitations in relying on reporting systems. Firstly, they do not allow for a hierarchy for urgency of addressing each error, and secondly, the records give no indication on the use of the incident reporting systems. According to a study by Barach and Small, reporting systems do not necessarily reflect the real extent of harm to the patient (Barach & Small 2000), and there exist too many instances of underreporting in most hospitals (Leape 1994). Based on the largest review of the system, the National Audit Office found little evidence of improvement in the NHS due

to complaints. They conclude that there is a lack of learning from complaints, and providers are not making clear to end-users that services are being improved as a result (NAO 2008).

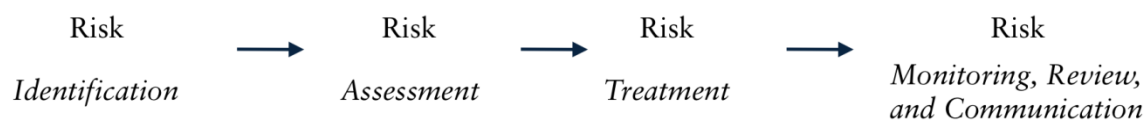
At the moment no taxonomy for reporting types of incidents has been identified, it is the World Health Organisation that is currently working on this. The Medicines and Healthcare products Regulatory Agency (MHRA) and NPSA had previously suggested a 'single-data entry point' for reporting system, but this project never took off either. In the UK, therefore, Trusts currently still have to report incidents to more than one organisation. A number of local and national systems are in place for sharing lessons learnt, but most are under-used. Research has also examined the aviation, rail and recreational diving industry for ideas on how reporting systems can be improved (NAO 2005).

Harm, Risk and Safety

One method of addressing errors is to identify their causes, as has been done in previous sections, and then be able to predict the probability that these happen, to avoid those situations in future. It is not possible to estimate those due to poor training or instructions, lack of physical or mental ability or lack of motivation. But it can be assumed that they will continue in an organisation at the same rate as in the past, unless there is evidence of change (Kletz 1991).

Formal risk management has become a requirement for a range of industries, and has affected developments both in design practice and in research in design and in the social sciences (Clarkson & Eckert 2005; p. 291). The ISO guide to risk management vocabulary defines risk management as "co-ordinated activities to direct and control an organisation with regard to risk" (ISO 2002). In practice, various industries have developed their management processes to mitigate risks according to their requirements. Early studies came from the nuclear, aerospace and construction industries where the focus was on risk to 'life and limb', while later studies developed around project and technical risk in the design of software systems, the defence and construction industries, aerospace, nuclear and medical engineering, as well as in even more uncertain industries such as flood and coastal defences and the oil and gas sector (McMahon & Busby 2005). The characteristics for each of these industries have led to the adoption of particular methodologies or frameworks for risk

management. Although they may differ, frameworks developed for risk analysis and control all contain the four key phases (McMahon & Busby 2005):



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 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 various others developed for specific contexts and purposes.¹²

In healthcare, a number of Human Reliability Analyses (HRA) has not necessarily been as well accepted as it has in other industries, though their potential has been defended (Lyons et al. 2004). Similarly, the use of FMEA and RCA has been advocated in various healthcare publications (Senders 2004). In the USA, the National Centre for Patient Safety (NCPS) adopted a prioritisation scoring method, the Safety Assessment Code Matrix. This is similar to a risk matrix in that it gives scores based on severity and probability of occurrence. The feedback methods for these are based on RCA methods that are outlined by the front line staff. In the UK, the NPSA has published Risk Assessment Guides (NPSA 2006a), which explain what risk assessment is, its importance and use in industry and healthcare, and a practical approach on how to do it. The document points out that risk is inherent in various aspects of the healthcare delivery process; namely in organisational strategy and business planning; financial planning; projects and service developments; purchasing; the design of services; and the treatment and care delivery.

The value of risk assessments, or their current method of implementation, has been subject to scrutiny, however. Nieva and Sorra (Nieva & Sorra 2003), claim that cultural changes

¹² The reader is referred to BSI standards: (BSI 2008), (BSI 1996b) and (BSI 2009) for a comprehensive understanding of medical device risk analysis guides.

are far more important given the flaws in quantitative methods, given inherent flaws in any reporting systems and retrospective analyses:

“Analytical methods such as root cause analysis (RCA) and failure mode effects analyses (FMEA) will not succeed in uncovering latent sources of error if staff, bound by an implicit “code of silence” and a fear of challenging the institutional hierarchy, are uncomfortable with exposing weaknesses in processes for which they are responsible. Even benefits from new technologies designed to improve safety, such as computerised physician order entry, may not be realised if they are not accompanied by cultural and process changes” (Nieva & Sorra 2003).

If $RISK = CONSEQUENCE \times PROBABILITY$, there is value in at least understanding either the consequence or probability in a qualitative manner. As argued by Redmill, the usefulness of such methods, he argues, is “not in the values derived but in the fact that the process forces us to think deeply about, and therefore better understand, the risks” (Redmill 2002). This resonates with the viewpoint taken for this study. Here the focus is on the consequences that can occur when good purchasing guidelines are not followed – these lead to risks in the service. It is acknowledged that even risk analyses themselves, although invaluable for mitigating potential hazards, present subjectivity in their assessment. The methods are therefore surveyed, but the study focuses on what is learnt during the process of identifying risk rather than quantifying the risks themselves.

2.4.2 Healthcare Design

“The operation of a health service depends upon a complex interaction between the patient, the environment in which care is provided and the people, equipment and facilities that deliver the care.” (Sir Liam Donaldson writing in (Rosenthal et al. 1999))

Design, human factors, and ergonomics have already been introduced to healthcare contexts. There are examples of successful uses of HFE methods in safety-critical industries, for instance the use of task analysis used in control room designs and operations (Higgins et al. 2002), and the example of St Joseph Hospital’s design for patient safety as reported by the National Patient Safety Agency – reported to have been designed with ‘patient safety’ as the key driver (NPSA 2006b). More publications are encouraging

the use of the word ‘design’, for example quality by design (Nelson et al. 2007) and safety by design. Design approaches have been demonstrated in use to improve healthcare delivery practice (Wagner et al. 1996) and ‘re-designing’ healthcare services (Smith 2001). Plsek in a publication on re-design in healthcare claimed that this is simply a ‘natural extension of the incremental improvement efforts underway in many healthcare organisations today” (Plsek 1997).

Human Factors in Purchasing

The Human Factors Informed Procurement (HFIP) Process evolved from the inclusion of human factors methods into the procurement process (Cassano Piché 2005). The paper does not specify how the HFE principles were selected, it just states that, it was seen ‘which methods most contributed to an understanding of the safety and adoption implications of each product’ to arrive at their model. The process steps include assembling a multi-disciplinary team including EBME, identifying the function needs, selecting different vendors, conducting task analyses or flow-charts of how the device would be used, consider the training, conduct clinical walk-throughs and even usability testing. All these recommendations are good in principle, but they also recommend having a human factors specialist accompany the hospital staff during this process, which is not feasible for each decision. Some decisions may also have tighter timescales.

Process of designing a purchasing process

The purchasing process forms part of the healthcare delivery system. Therefore, if the healthcare system is to be improved, the purchasing process is one potential area for improvement. Hence, the design of both sub-systems should be aligned to promoted patient safety. Similarly, both the medical device and the system in which it operates need to take patient safety into account in their design. The Design for Patient Safety (DPS) report recommends taking a systems/design-led view to improving services in NHS (Department of Health 2003) (Figure 6). Following from the discussion above, in the idealistic sense, purchasing for medical devices could also be viewed within the context of the model shown in this figure.

If the purchasing process is viewed as ‘the product to be designed’, the model corresponds in the following manner:

1. Designers of the purchasing process build a knowledge base of purchasing practice.
2. Based on this knowledge, the requirements for designing the purchasing process are defined.
3. The purchasing process is designed.
4. The system around the process is designed; iteratively with step (3), the design of the purchasing process.
5. The new purchasing process embedded into the medical system is delivered.
6. The process is evaluated (feeding back to the requirements).
7. Safe medical care is provided (further building the knowledge base).

Management of risk, engagement of advisory panel, and promotion of design for patient safety underlie all these activities (Figure 6).

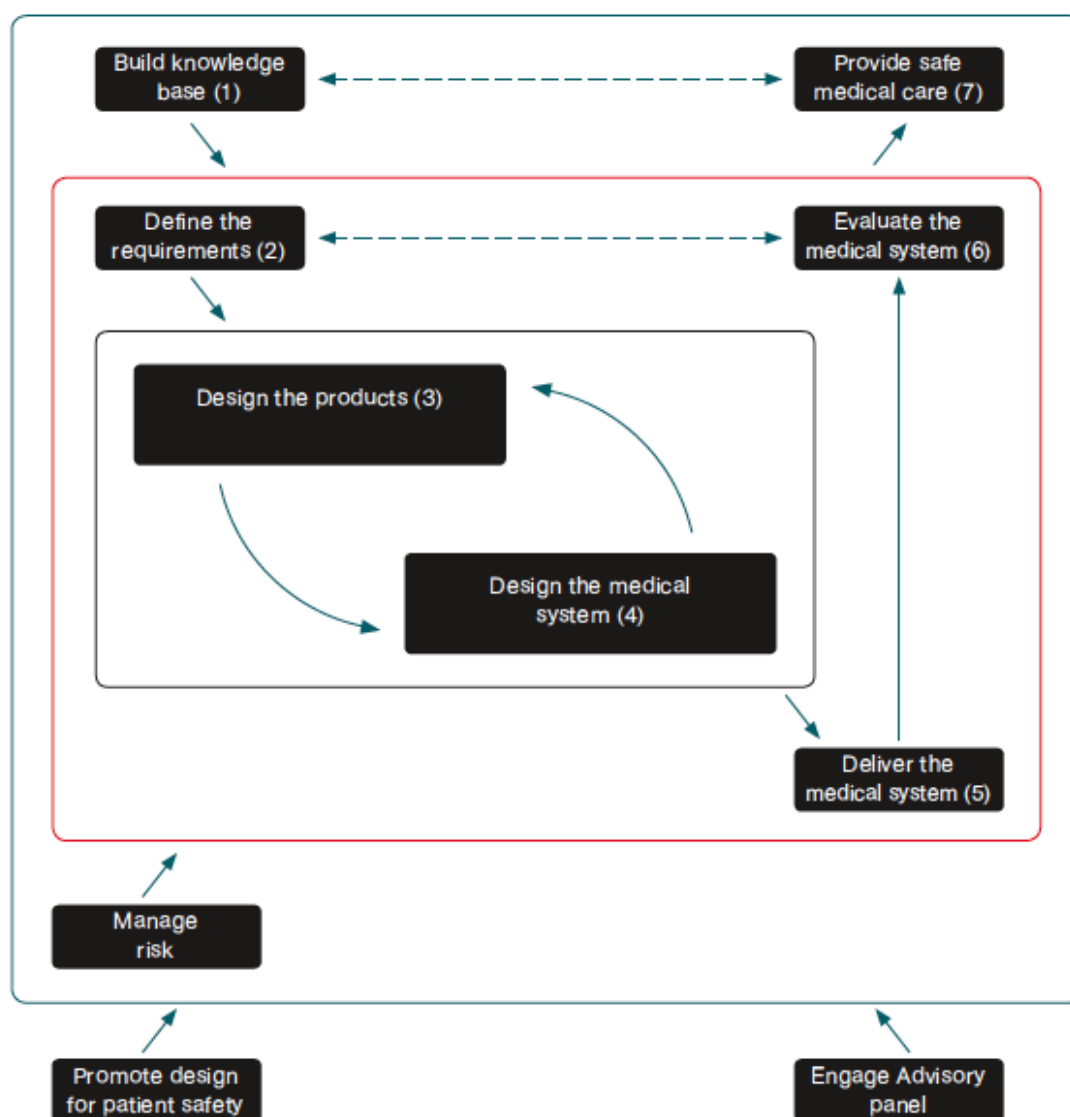


Figure 6: A model of a systems-based, user-centred approach to healthcare design, adapted from (Department of Health 2003)

The cycle is continued as further knowledge around purchasing practice and safe care is accumulated. This could be one model of an idealised design process for purchasing, when the process is to be designed from a ‘blank sheet’, as seen in Figure 7.

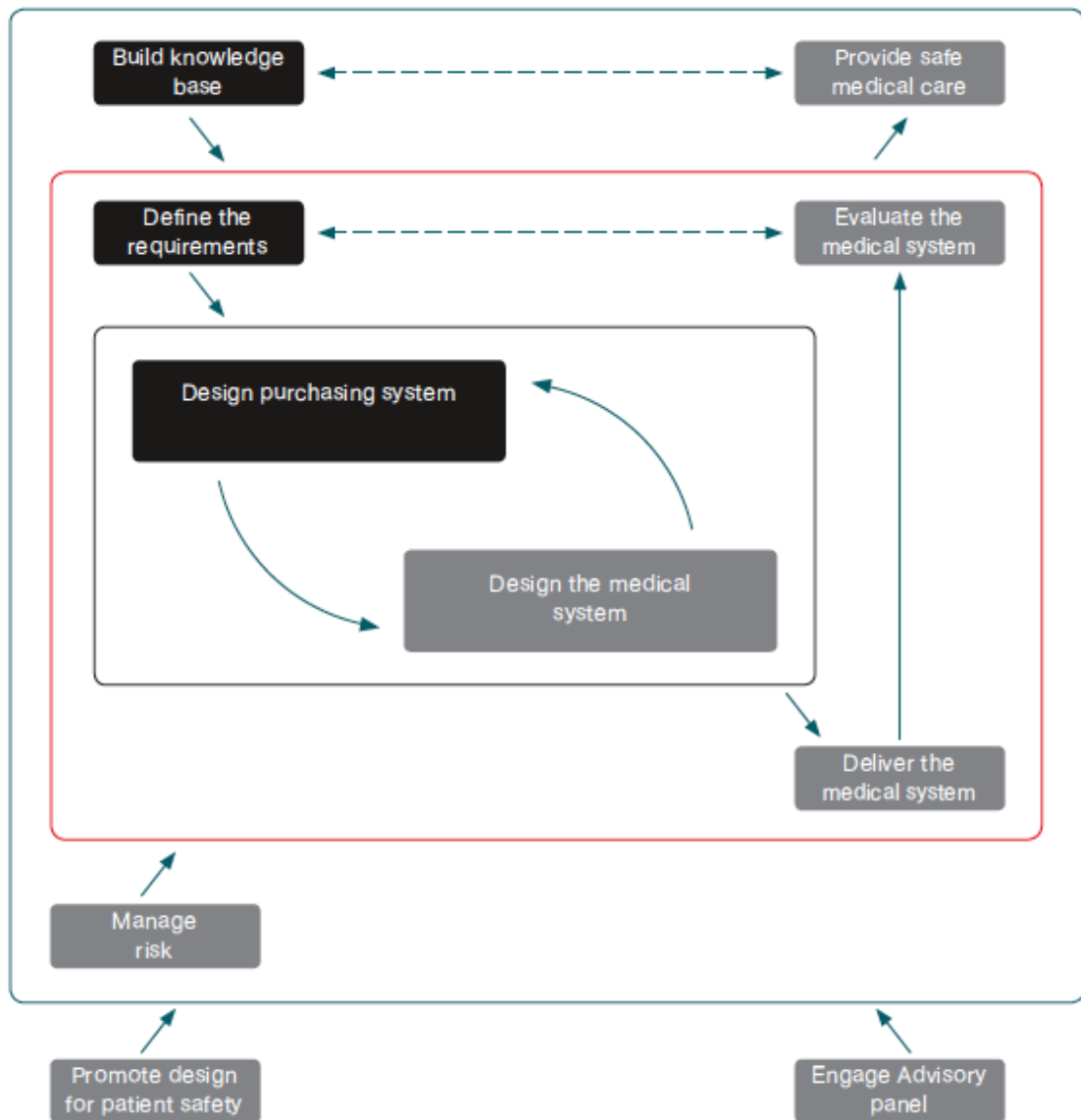


Figure 7: Suggested model of a systems-based, user-centred approach to designing a purchasing process

However, there are challenges to implementing systems-based approaches, particularly given ongoing practices in the NHS. The DPS report claims that such approaches are lacking in current practice in the NHS (Department of Health 2003). Also, a recent study in the UK showed that purchasing in the NHS does not currently respond to ergonomic principles and guidelines (Cole 2008). Unlike other safety-critical public sectors, such as defence, fragmentation is the dominant tendency in the purchasing of medical technologies (Phillips et al. 2007). Similar practice is seen in the USA. In a recent study it has been

shown that while stakeholders usually recognise the importance of patient safety in purchasing decisions, the understanding of what this means in practice is lacking (Johnson et al. 2005). They also suggest that sociological disconnects contribute to the complexity in the purchasing process.

In presenting both models in Figure 6 and Figure 7, the intention is to give an idealised view of how new ‘designs’ of processes in healthcare, and in this case purchasing, could be approached, in line with good engineering design practice. This sets a standard for the approach of the contributions made to ‘design’ sciences in this thesis. It is important to note, however, that the actual contribution is largely a ‘descriptive’ study as indicated in Figure 2 in Chapter 1. In other words, while the study begins to provide recommendations for future designers of device purchasing systems, its main contribution is in ‘building a knowledge base’ and ‘defining the requirements’ (steps in Figure 6) for future process design activities.

Validation of Purchasing Design Process

In Design Process Improvement (Clarkson & Eckert 2005), the design activity is introduced as a complex set of interactions between different stakeholders. Once a product exits the design box and enters the purchasing stage, a similar set of interactions occur – between the suppliers, the purchasing process, the people using the device and the product itself. The process of designing a purchasing process can be likened to a design process from other contexts. This would require that the process is subject to both validation and verification, as portrayed by Alexander et al. (Alexander et al. 2001). Just as a product design process is subject to these steps, here is a suggested ‘design process for a purchasing process’ version:

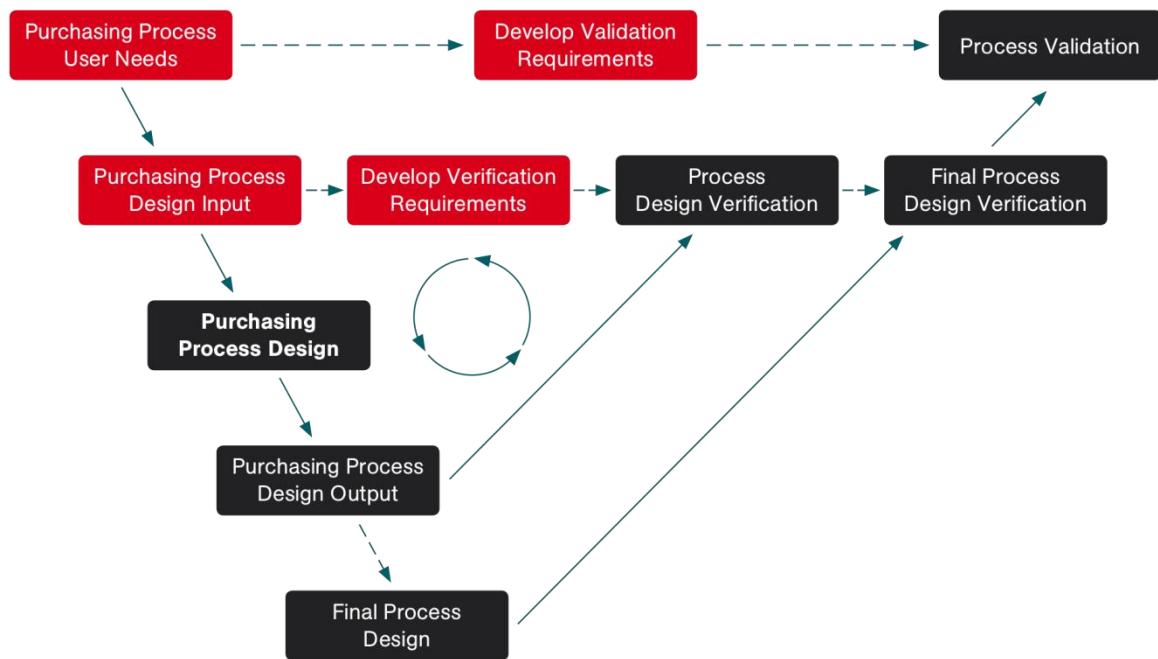


Figure 8: Activities associated with purchasing process validation, adapted from (Alexander et al. 2001)

This version is adapted from Alexander et al.'s diagram on medical device design process validation (Alexander et al. 2001). It is intended for product design process, rather than a "process design process", but the principles for designing a product and designing a process both require similar good design practice. When comparing this model back to the Design for Patient Safety model in Figure 6, these very same elements are present and theoretically can be applied to a healthcare process design. Broadly speaking, validation is ensuring one has "built the right product" and verification is ensuring one has "built the product as intended". In this case, the purchasing process is the 'product'. It is noted here again that these principles remain as standards set for future process designs.

The concepts of 'validation' and 'verification' can also be used in a different way. Just as design processes require checking at the various design phases as in Figure 8, a purchasing process requires its own checking at various purchasing stages. This would imply ensuring one has "*purchased* the right product" and "*purchased* the product as intended". In this case, the device is still the 'product' but the design activity is replaced by the purchasing activity. These ideas are returned to in the latter chapters to test both the way in which, and the extent to which, these process design concepts can be applied to a healthcare

setting and to this research. An understanding of healthcare and its context is primarily the first step before these ideas can be adopted.

2.5 Summary of Implications of literature for this study

The literature related to this thesis falls under a variety of disciplines, but serves different purposes. Lessons from purchasing theory and operations management serve to identify pointers towards good practice in these well-established disciplines, even if they mostly relate to other contexts. Turning to patient safety and healthcare improvement sources then serves to give context and understanding of the current system under study. Finally, pointers from healthcare design and process improvement literature serve to introduce the approaches that can be used to analyse these types of environments and provide tools for improvement. The main points from each of these sections are repeated below.

From Purchasing Theory, Operations Management, and Process Improvement

Simplified processes for purchasing exist in theory and can be drawn upon to compare current practice. The context of the specific purchasing environment, however, needs to be taken into account. For instance, in safety-critical industries, controls & checks, as well as expertise judgement are needed on decisions at particular touch-points in the process. According to more general guidance, the importance of a proactive and engaging purchasing manager is emphasised, who brings together end-users with sales. Appropriate risk evaluations and control of existing inventory is also important. In terms of project management, the guidance suggests to have clearly defined goals, sufficient resource allocation, control mechanisms, adequate communication channels, and troubleshooting mechanisms. Performance indicators are one way of indicating improvements, but this requires establishing what those performance measures are in the first place. Finally, continuous improvement cycles preferred to breakthrough improvement for this study.

The NHS itself also has resources online for providing guidance on what channels are available to purchasers. However, there is a lot of material to cover and not all of it is available in a cohesive form. This resonates with the earlier comments made by representatives from PASA themselves, stating that the true entry points in the NHS are

unknown to suppliers and that the real decision makers are not known. More knowledge is required of what actually is translated to local practice as opposed to national agencies. A lot of emphasis is placed on evidence-based purchasing on the local level, where appropriate risk decisions can be made and the true value of new technologies ascertained. While this is useful for making individual decisions on new technologies, this still does not address the process of purchasing itself.

From Medical Device Purchasing

It was noted that the need exists to define a medical device as separated from general medical technology. There is complexity associated even in making this distinction due to interconnectedness of drugs, devices, consumables, technologies, and procedures. The way PASA classifies their devices (with its changes along the supply chain) by the time the local purchasing decision is reached, the criteria for these classifications have changed, resulting in the device not really differentiated from the rest of the purchases in a hospital.

Guidance exists for purchasers and other EBME departments. Some are outdated, but the sources for these are within a limited community. Elements of good practice from these sources include: standardisation, evaluation, integrating nurses into decisions. What can also be ascertained from literature is the focus on EBME and the large role they play in connecting expertise.

From Patient Safety & Healthcare Design

Measurement of device error is one good way of assessing patient safety but this in itself also requires subjectivity when speaking about harm or consequence. Design approaches bring together many of these concepts - from the qualitative, quantitative, organisational methods -to a healthcare context. Examples include service design, process quality, user-centred design, and experienced-based design. Safety is also examined in design sciences in the context of quality.

Summary of main topics

Much of the operations and management literature speaks about stakeholders and their engagement. These concepts can be explored further, given that there are so many

references to its importance. Both process knowledge and literature suggest that understanding the stakeholders in an organisation is key to progress. This can be taken further by also examining their drivers and barriers and resources used to make decisions. If performance indicators are to be used, it is important to establish what those indicators entail. Process improvement and validation/verification both have control mechanisms, understand the complexity factors, and perhaps connect these to some of the cultural and attitudes that are specific to a healthcare community. These emergent themes presented here as ‘topics to explore’ which lead to assumptions about current practice that are to be explored further.

	<i>Factors to explore</i>
<i>Stakeholders</i>	<i>Stakeholder definition</i>
	<i>Device knowledge & competence</i>
	<i>Process knowledge</i>
	<i>Stakeholder engagement</i>
	<i>Resources for decisions</i>
	<i>Drivers for decisions</i>
	<i>Culture and mindsets</i>
<i>Process</i>	<i>Process description</i>
	<i>Control measures</i>
	<i>Reporting and feedback</i>
	<i>Pressures on process</i>
	<i>Inventory management</i>
	<i>Goal alignment</i>

Table 4: Factors to explore in research, following literature analysis

It is in the context of these parameters or themes that the study is conducted; to continuously allude to good practice and theory. The study is not limited to these themes, however, as an open-ended approach is conducted especially in the Exploratory Studies. The exact methods employed, and approach taken, is discussed in the methods chapter next.

Chapter 3

RESEARCH PROCESS:

Approach and Methodology

The term ‘research process’ here refers to the totality of the chosen steps within the execution of research. This chapter describes the approach taken following an introduction to the challenges faced in this research project.

3.1 Overview of Research Process

A framework for a research process has been suggested by Sim and Wright in their book on healthcare-specific research (Sim & Wright 2002). This has been used as the framework for the description of the research process described in this chapter, as diagrammed in Figure 9:

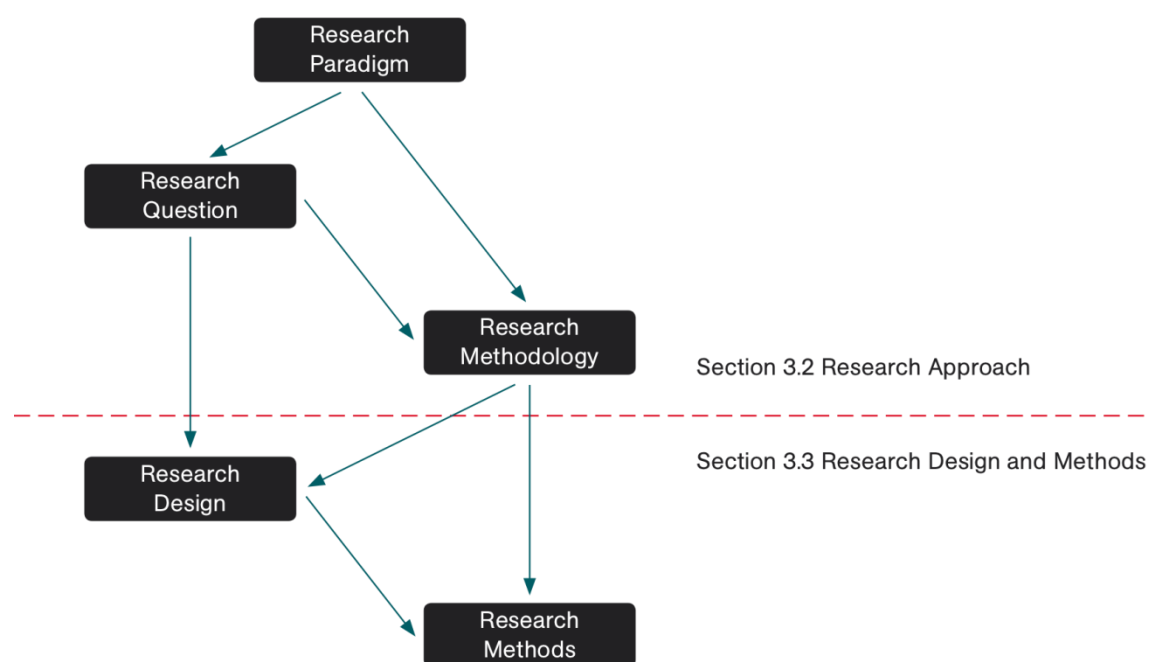


Figure 9: Components of a research process, adapted from (Sim & C. Wright 2002)

Section 3.2 describes the theoretical starting points with respect to the research. This can be equated to Hay's framework for decomposing a research process into individual building blocks dealing with different aspects of a scientific enquiry (Hay 2002): the theoretical starting point is the 'paradigm' for the research (understanding what 'knowledge' is out there to be acquired for this research). The research questions and methodology are based on this paradigm. Section 3.3 then gives the details of the design of the research and the particular methods employed. Both these sections are preceded by a discussion of the challenges particular to this research project, to provide the context upon which the latter discussions are based.

3.1.2 Research Challenges

Research in a healthcare context is subject to unique challenges with regards to methodology. Allusions to 'design' approaches in healthcare by previous researchers have already highlighted some of these challenges and warn against some of the pre-conceived ideas of research and systems approaches in the healthcare community:

Methods in the healthcare published community

Leape, Berwick et al question traditionally used formal evidence methods in healthcare that place heavy emphasis on data from randomised control trials (RCTs) (Leape et al. 2002). They claim that achieving safer care has three agendas, all of which are necessary: “identifying what works (efficacy), ensuring that the patient receives it (appropriate use), and delivering it flawlessly (no errors)”. But in order to identify what ‘works’ they state that formal scientific proof according to evidence “lacks validity” and is neither necessary nor sufficient for recommending new safer practices in this particular context. “Reducing the types of intravenous infusion pumps used in a hospital from 7 to 1 or 2, for example, reduces errors. [It] has not been in a randomised controlled trial” (Leape et al. 2002). The use of other measures and improvement processes, such as the PDSA cycle introduced earlier, are encouraged, given that “healthcare processes do not need a pre-existing hypothesis to be tested, nor randomisation, power calculations, and large samples. We need just enough information to take a next step in learning” (Berwick 1996). However, it is still important to create rigour in these other methods and produce evidence of improvements to the healthcare community through other means. The challenges for published qualitative findings in medical journals has been highlighted (Greenhalgh & Taylor 1997), and while the culture may be changing, it is important to retain rigour in qualitative research to compete with many of the more quantitative studies.

Application of improvement methods from other safety-critical industries

Some studies have stated that healthcare differs in practice to other industries, and particular sensitivity is required in application of any models to this context (Olsen et al. 2005). Firstly, it is pointed out that in many studies the focus is on the workers’ safety, rather than the product (Flin et al. 2000). It could be argued, therefore, that healthcare provides an extra layer of complexity as the ‘product’ of its service or process is also a person (the patient). In general, the healthcare service is considered more personnel-centred than other industries (Spath 2004). A recent article in the British Medical Journal also suggests that mistakes in healthcare are on a different scale from the level of error tolerated in other industries (Elwyn & Corrigan 2005), suggesting that they cannot be assessed by the same methods for risk analysis. Reports from the Department of Health and quotes from the Chief Medical Officer suggest that healthcare can still learn from these industries,

“Although it is a rare occurrence, pilots regularly rehearse engine failure in simulators. So when faced with a real situation habit takes over. Simulation enables people to train for rare events that do not occur often, in real life.” – Chief Medical Officer (Donaldson 2009)

Systems, Design, and Complexity in healthcare studies

Design in healthcare services is not a new concept, but may have varying definitions of use and applicability. It is of course recognised that design activities already occur in healthcare service planning, but the terminology employed in the community may be different to that of design research. Plsek comments on current design activity:

“The usual approach to design in healthcare is often at too high a level, it is assumed that the people involved will work out the details as they go along, little consideration of what might go wrong is involved, and little provision is made for the inevitable stresses that workload and urgency will place on the process” (Plsek 1997).

Complexity and systems are also used in healthcare already. One of the ways in which the term ‘complexity’ is used is in reference to the patients themselves; e.g. a ‘complex patient’ would be one with extra needs and multidisciplinary clinical needs and social care needs. Organisations often seek to address problems of coordination by increased standardization with checklists, algorithms, or detailed information packets (Young et al. 1998). Problems in integrating such services and stakeholders arise when unremunerated hours are spent coordinating care activities, such as referrals and mental health issues (Antonelli & Antonelli 2004).

A more in-depth complexity perspective is adopted by Capra, who suggests that understanding the patterns or informal networks within the system is equally important, and that successful improvement requires integration and change in all three layers of a system: structure, process and outcome (Capra 2002). Traditionally studies have focussed mainly on layering the structures (physical or administrative) and the re-design of processes. Such an approach requires both qualitative and quantitative investigations, with a focus on ‘failures’ to understand complex systems (Matlow et al. 2006). Giving the example of a child undergoing a tomography scan, complexity science offers methods to create coordination of patient care from the healthcare service through to social care, but

studies are needed to actually understand the subtle complexities of care by way of ethnographic or similar qualitative studies. Flowcharts are also good ways to document current practice, but Plsek warns that “simply constructing a flowchart is no guarantee that the (re)design process will be much different from past processes” (Plsek 1997). The support for approaches advocated in design research and systems theory is present but what this means in practice still requires communication with the healthcare community.

Access to Data

Obtaining access to data in healthcare can be a huge challenge to researchers. In many cases, ethical clearance is needed and the design of the study must be stated upfront. For access at the Trusts, ethical clearance was waived due to the limitations of the scope of the study (at the time of application). Although mostly qualitative social science methods are used, this research was not aimed to result in an ethnographic study of the people involved in the interviews. Therefore all interviews, observations and input elicited from NHS staff were used as data to inform the ‘as is’ situation within the purchasing process. Since this study is confined to medical device purchasing, the NHS staff involved included: EBME, nurses and clinicians who interact with the devices, risk managers for procurement decision-making, and procurement staff.

Establishing stakeholder sample

While the obvious stakeholder base for this study are the ‘purchasers’ administering the orders for medical devices, both the Literature and the Exploratory Studies have shown that they form only part of a larger stakeholder base. This adds not only to the complexity of the process itself, but presents challenges in obtaining a valid data sample in researching the process.

Achieving stakeholder engagement

Having established a stakeholder base, achieving engagement with them provided a further obstacle to the research. The flexibility and open engagement in Trust A was a sharp contrast to the limited engagement in Trusts B, C, D and E, mainly due to the limited time available to develop a trustworthy and honest relationship with the collaborators.

Data validity

The data was obtained in partial data sets, obtained from each Trust as shown in the T-shaped diagram in Figure 1, Chapter 1. Therefore, to truly achieve generalisability and validity, it was necessary to triangulate observations from any one collaborator with insights from other Trusts.

No pre-existing methodological research framework

As established earlier, there was no pre-existing methodological framework for such a study. The subject itself lies in a multitude of disciplines and could have been addressed from either an economical, operational, or clinical standpoint. Taking a systems or design-led approach provided a means by which various perspectives could be considered while still making a valuable contribution to design research in healthcare.

The specific way in which some of these challenges were addressed in implementing the research is addressed in design and methods in Section 3.2.3. The next section introduces the general research approach.

3.2 Research Approach

For this project, the scientific inquiry consists of capturing views, perceptions, and elements of current practice of different stakeholders in relation to purchasing medical devices. This largely involves social issues and stakeholders' views on their world and system. Therefore, although the approach and framework of the research is to examine the field of study as a 'system', which is arguably a technical approach, the approach to the inquiry itself tends towards the social sciences. The theories behind such social science approaches therefore require some explanation and are introduced in these sections. The approach to the research consists of three sections: establishing the paradigm of research, to then lead to the creation of appropriate research questions and methodology, as introduced earlier in Figure 9.

3.2.1 Research Paradigm

With reference to Thomas Kuhn’s use of the word ‘paradigm’ (Kuhn 1962) in his work, Guba later defined a research paradigm as “the starting points or givens that determine what inquiry is and how it is to be practiced”, whilst warning that these are ‘human constructions’ and, therefore, “subject to all the errors and foibles that inevitably accompany human endeavours”. (Guba 1990)

Adopting a particular research paradigm fundamentally influences later decisions in the research process. These may differ greatly, and dictate different ontological, epistemological and methodological lines of thought and action in research. Generally speaking, the ontology refers to our ideas about what exists, whether there is truth ‘out there’ waiting to be discovered and explained. Epistemology relates to the philosophic inquiry in the nature and grounds of knowledge – understanding how it is that we know what we know. Finally, the methodology refers to the conceptual and logical elements of the research process. These four paradigms, taking Guba’s classification, are summarised below:

	<i>Ontology</i>	<i>Epistemology</i>	<i>Methodology</i>
<i>Positivism</i>	Realism	Objectivism	Experimental / manipulative
<i>Post-positivism</i>	Critical realism	Modified objectivism	Modified experimental / manipulative
<i>Critical theory</i>	Critical realism	Subjectivism	Dialogic, transformative
<i>Constructivism</i>	Relativism	Subjectivism	Hermeneutic, dialectic

Table 5: Research paradigm characteristics, adapted from (Guba 1990)

Generally speaking, the first paradigm, positivism, is based on a belief of ‘how things really are’. As Guba described, the nature of science is to “discover the ‘true’ nature of reality and how it ‘truly’ works” (Guba 1990). Generally speaking, classical sciences fall under such categories. Post-positivism is a modified version of the positivist stance, with an

understanding that although there is a reality ‘out there’, given human frailty, the conclusions made about such realities will be flawed. Critical theory and constructivism stray further from this approach to a more subjective approach, which, in the extreme case, assumes that all our perception of knowledge is relative to the way we understand it and that our sense of ‘reality’ can change according to this understanding.

At first glance, the research paradigm for this research sits closer to the less objective paradigms: post-positivist, critical theory, or constructivism. The ontological stance taken is close to that of ‘critical realism’, where one can acknowledge the existence of a reality but at the same time take into account the extrinsic influences present in the individuals’ perceptions and cognitions, and hence their responses (Bryman 2001). Given that the study is largely based on respondents’ views on the process, and an inquiry into the need for future improvement, a positivist view is not the dominant view taken. However, while the aim is limited to assessing findings based on the stakeholders’ accounts of current practice; the study still aims to formulate a picture of current practice relating to the collective truth of what happens in practice. As noted by Robson, within the social sciences relativistic approaches are distinguished from the positivistic traditions (Robson 2002). These include ‘constructivist’, ‘naturalistic’ or ‘interpretive’ – all of which reject the view that ‘truths’ about the social world can be established by using natural science methods. An extreme adherence to relativism may therefore imply a complete disassociation from natural science. As a potential solution, Robson introduces the term ‘realism’ in a different way to Guba’s definition above. He claims that ‘realism’ can “provide a model of scientific explanation which avoids both positivism and relativism” (Robson 2002), quoting various studies where the potential for its utility has been shown in economics, criminology, international studies, geography, medical education, nursing, organisational analysis, political science and sociology, among others. Realism in this definition has been seen as particularly appropriate for research in practice- and value- based professions such as social work. For realists, in Robson’s terms, there are social objects, which can be studied scientifically, but the methods chosen must fit the subject matter (Robson 2002). Generally speaking, a realist approach integrates both the subjectivist and objectivist approaches in social theory. This means that “social structure is at the same time the relatively enduring product, and also the medium, of motivated human action... Social structures such as language are both reproduced and transformed by action, but they also pre-exist for individuals” (Robson 2002).

In summary, for this study the ontological stance is closest to that of a realist (in Robson's terms), and the epistemology tends towards modified objectivist, since there are no pre-determined values on 'how healthcare should be conducted' being assigned to the enquiry. Similarly, the ideas behind systems engineering principles and approaches, although tested elsewhere, are also not claimed to be the 'true' and only way of addressing the issues faced in healthcare purchasing; they are simply one method for putting forth the problems raised and discussing their potential for creating improvements.

The next section describes how the literature review created a starting point for 'viewing the world' of purchasing practice in healthcare. The preliminary conclusions drawn at this stage served to draw up research questions.

3.2.2 Research Questions

The question that is investigated at the highest level in this study is repeated here:

What are the characteristics of a medical device purchasing process that effectively focus attention on patient safety?

A set of questions derived from this question is needed to facilitate the data collection process. Based on preliminary evidence gathered from the literature and direction described in the first chapter, two very general statements can be inferred from the literature, in light of some general topics or factors that influence current practice:

- 1. Challenges to current practice in medical device purchasing exist, because of wide range in stakeholders' knowledge and skills, cultural differences, and external structural influences and pressures on the process.*
- 2. Medical device forms an integral part of a larger equipment management and healthcare delivery service and can therefore affect the efficiency of, and add risks to, this service.*

Each of these statements leads to a particular set of research questions. The first refers to a general examination of current practice with a particular focus on different stakeholders

within the system. The system boundary or focus here is the purchasing process itself and the decision-making that occurs within that process. The second statement also involves examination of the current system, but with a deeper focus on the internal decision-making processes of purchasing, with the specific aim of finding potential inefficiencies in the process. Therefore, the purchasing process is also viewed as a sub-system of the general device management system within a hospital. This itself is a sub-system of the healthcare delivery service. The focus of these two statements in relation to their associated systems is diagrammed in Figure 10. The boxes and colour relate to the original Design for Patient Safety Framework shown in Figure 6, and act to put this particularly study into a larger context of healthcare system design.

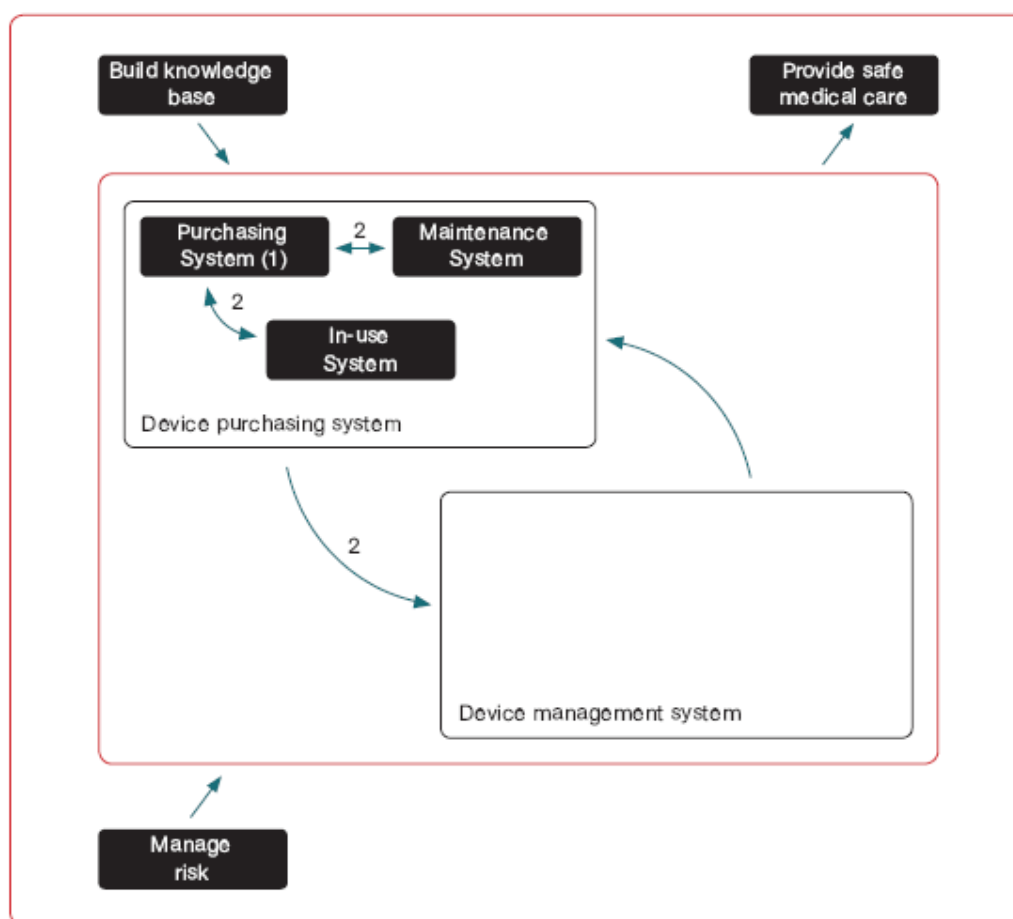


Figure 10: Device Management system elements and relation to healthcare delivery system

Due to the different focus required by each statement, three separate sets of research sub-questions were designed. The first (indicated as 1 in Figure 10) addresses the general workings of current practice in medical device purchasing in the NHS. The second (shown as 2 in Figure 10) consists of linking current practice to the identification of potential risks to the healthcare delivery service. This second statement is addressed firstly by re-visiting the factors that influence current practice through evidence of inefficiencies within the purchasing process and device management; and secondly through an investigation of the types of impact that the purchasing process can have on the healthcare delivery service. Finally, though not indicated above, an analysis of how such factors could be managed to improve on current practice is conducted in the third research question. In the context of the diagram above, these questions address the internal constituents of the purchasing sub-system, the interaction between the purchasing sub-system and its device management system, and finally its influence on the healthcare super-system. These general questions are listed in Table 6.

MAIN RESEARCH QUESTION	
What are the characteristics of a medical device purchasing process that effectively focus attention on patient safety?	
STATEMENTS TO EXPLORE	RESEARCH QUESTIONS
<p><i>Challenges to current practice in medical device purchasing exist, because of wide range in stakeholders' knowledge and skills, cultural differences, and external structural influences</i></p> <p><i>Medical device forms an integral part of a larger equipment management and healthcare delivery service and can therefore affect the efficiency of, and add risks to, this service.</i></p>	<ol style="list-style-type: none"> 1. What is current practice in medical device purchasing? 2. (How) does current practice present risks to healthcare delivery services? 3. Where are areas for improvement on current practice?

Table 6: Research Questions relating to statements to explore main research question

The first question is constructed such that they will lead to general basic learning of current practice. The insights gathered during collection of data for this question, however, that may elicit further insights that provide the basis for analysis that leads to the wider question of purchasing implications in healthcare practice, which leads to a more direct

philosophical contribution of the research taken in the second and third questions. Therefore, Questions 2 and 3, although alluded to in the evidence gathered, require some inductive analysis, to produce answers that are generated through discussion. The specific research questions, therefore, are as follows:

<p>Main Research Question</p> <hr/> <p><i>What are the characteristics of a medical device purchasing process that effectively focus attention on patient safety?</i></p> <p>Research Sub-Questions</p> <hr/> <p>1. What is current practice in medical device purchasing?</p> <p>Who are the stakeholders and what are their roles in purchasing? What type of knowledge and competence do these stakeholders have? What are the resources and drivers for purchasing decisions? What other factors influence current practice?</p> <p>2. (How) does current practice present risks to healthcare delivery services?</p> <p>What challenges and risks are present in current practice? How are the factors of current practice different from good practice? How do these factors impact the healthcare service?</p> <p>3. Where are areas for improvement on current practice?</p> <p>How do the stakeholders themselves view improved practice? How can factors in current practice be managed towards improvement?</p>

Given that a general direction of research has already been established through the statements concluded earlier, which were the real influence on the research questions, it must be made clear here that the research is not intended to be completely open-ended. Current practice is assessed, but in light of particular parameters that guide the research (though not limited to these parameters). These parameters or ‘factors to explore’ were listed by the end of the literature review in Table 4 in Chapter 3, but are now listed as an empty table, which is populated through each new set of results, shown here in Table 7.

	1	2	3
<i>Factors considered</i>	<i>Current Practice</i>	<i>Risks to Healthcare</i>	<i>Improvement Areas</i>
<i>Stakeholders</i>	<i>Stakeholder definition</i>		
	<i>Device knowledge & competence</i>		
	<i>Process knowledge</i>		
	<i>Stakeholder engagement</i>		
	<i>Resources for decisions</i>		
	<i>Drivers for decisions</i>		
	<i>Culture and mindsets</i>		
<i>Process</i>	<i>Process description</i>		
	<i>Control measures</i>		
	<i>Reporting and feedback</i>		
	<i>Pressures on process</i>		
	<i>Inventory management</i>		
	<i>Goal alignment</i>		

Table 7: Factors considered to answer Research Questions (initial empty template)

This table template is filled through each new set of results in Chapters 5, 6, and 7 to indicate which data sources (Literature, Exploratory Studies, etc) have contributed to learning in those particular areas.

3.2.3 Research Methodology

Methodology refers to the general principles of investigation that guide a study, based on its underlying theoretical and philosophical assumptions (Sim & Wright 2002). Ultimately, research aims to provide a new contribution to knowledge, usually referring to a field of interest. In this case, the field of interest is the purchasing of medical devices, using the context of the NHS. The research strategy describes the approach taken in order to reach its conclusions.

Two different strategies are commonly used: deductive and inductive. The deductive approach starts with a hypothesis; a preliminary theory that is then tested for validity in

the course of the research process. Popper argued that a hypothesis is only considered to be true until it is proved be false (Popper 1959). In a real world scenario it is far more complicated to provide a controlled environment in which to test a hypothesis rigorously (Eisenhardt 1989). Inductive strategies do not start with a hypothesis; but rather generate a theoretical framework of understanding where none previously existed (Sim & Wright 2002).

No explicit theory for purchasing in healthcare is adopted in this study. Certainly guidance is available on how to manage the process and pointers gathered in the literature, but not an overarching theory as such. Given this gap, a more inductive strategy was used. However, the findings constitute a very first glimpse and description of current practice and, due to limitations of access to healthcare settings, would also not claim to provide grounds for proving nor providing new theory in terms of purchasing and supply of devices in the NHS. However, what they do provide is an understanding of current practice, an analysis of the possible reasons for such behaviour according to external drivers and regulations on their practice as well as their present conditions. All of this provides a framework to raise awareness about current practice and give the foundation of future work in making improvements. In line with good design practice, this work also forms another example of how design practice works in researching one particular healthcare setting or system. Chapter 7 introduces feedback from participants as part of validation of the results presented, with their perspectives of how such findings can make an impact to future practice.

Despite a lack of a specific theoretical standpoint on purchasing in healthcare per se, it is important to recognise the existence of any biases that affect this study. As pointed out by Bowling:

“Values are inherent in natural and social sciences from the inception of an idea to its development as a viable research project, to the choice of research method and the synthesis of the whole research process and results, as well as from the decision of a funding body to sponsor it to the decision of journal editors to publish it.” (Bowling 2002).

In an attempt to make these ‘values’ in this research explicit, the underlying assumptions that have guided the approach to the inquiry are introduced next, including the use of

systems theory, and the view of purchasing practice as a cultural phenomena; views which then guide the research design.

Systems Theory

Although earlier allusions to more holistic approaches to problem-solving, i.e. systems approaches, may have appeared in earlier philosophies and thinking, one of the more modern founders of systems theory was the biologist Ludwig von Bertalanffy (Von Bertalanffy 1973). As he points out in a survey of these approaches, these problems are “a contemporary expression of perennial problems which have been recognised for centuries and discussed in the language available at the time”. By recognising the interconnectedness of single parts and their processes in biological systems, von Bertalanffy called for the “systems theory of the organism”, which was then taken on to apply also to organised entities such as social groups, personalities, or technological devices (Von Bertalanffy 1973).

In one comprehensive survey of systems theory and methods, Ropohl defines systems from different perspectives. From a structural point of view, a system includes a set of elements and a set of relations between these elements (Ropohl 1999). Functionally, a system can be considered an entity, sometimes called black box, which transforms inputs into outputs, depending on specific internal states; the kind of transformation is called a function (in the descriptive meaning of the word). The hierarchical conceptualisation of systems is that one regards the different elements as subsystems, and the original system is in itself a subsystem of a larger super system. From these very basic definitions it is possible to view the healthcare delivery process as a system. For the purposes of this study, however, the purchasing process is our system and the delivery of care its super system as seen previously in Figure 10.

What is comprehensive about Ropohl’s paper is his reference to polarities of systems theory. He argues that systems theory provides a form of “unity beyond specialisation”. This is particularly useful for solving problems as it is able to cope with the confusion between different expert languages, for instance in its use of graphic representations which “illustrate complexity much better than uni-linear verbal language” (Ropohl 1999). This is particularly helpful in a healthcare setting, where the types of stakeholders involved are making decisions for the same purpose, but may have different backgrounds, training and

even agendas in their particular line of daily work. Such a unifying perspective is almost indispensable. From a pure science or clinician perspective, where some research and practice is conducted in a specialised way by isolating elements for deeper studies, this might seem an attempt to over generalise issues and therefore lose the focus on particular problems. However, systems theory is not introduced to abolish such approaches, but to provide direction and context to see the connections between these independent parts. In systems approaches in healthcare, one may also be faced with the criticism that models do not capture the full complexity and complete picture of the task, process, or service in question. While no argument is provided here to support or disprove this notion, the pragmatic modelism approach is taken, with the idea that while systems might be largely human-made models, “in reality there do exist objective entities to which the models correspond” (Ropohl 1999).

Application of Systems Theory to Purchasing

If purchasing is defined as the simple act of buying and selling, the boundaries of a purchasing system could be placed in a very narrow context. However, as seen from Exploratory Studies, they encompass much more than just the administrative task of ordering a device in one department. Two other systems terms are defined here in establishing the scope and boundary of this study: stakeholder and domain.

Stakeholder: The underlying stakeholder theory concerns stakeholders’ roles and actions with respect to the entity they have a stake in (Friedman & Miles 2006). Stakeholder theory has developed significantly but the definition of a ‘stakeholder’ as first described by Freeman is largely maintained by the published community (Friedman & Miles 2006) as “any group or individual who can affect and is affected by the achievement of the organisation objectives” (Freeman 1984). In this study, therefore, such stakeholders had to be found, which formed the first purpose of the Exploratory Studies. All those affecting or affected by the purchase of medical devices in the hospital were considered, even if not all used to the same degree in the data collected. The literature helped point out the role of EBME as a stakeholder group, along with those in purchasing departments, clinicians and nurses.

Domain: In systems theory, domains are used to refer to groupings based on higher-level abstractions. The ‘healthcare provision’ domain, for instance, can refer to a single ward, or the totality of healthcare services.

In his book on environment-behaviour research, Zeisel, subtly acknowledges the need for a more holistic view of systems and organisations by providing tools for collaboration between designers and social scientists, and hence increase collaborations for other groups with similar varying backgrounds (Zeisel 1984). In what he calls mass design, designers (be it of products or services) have two clients: those who pay for what is built and those who use it. The user client, he claims, has no choice and no control, which is true for the healthcare setting, since the patient has no overall control of the process they enter. Zeisel’s model describes a relationship between clients, designers and users in architecture. In the medical device purchasing scenario the system boundary is a little different: The paying client is the budget holder, but funded by a higher finance body, and the user client is the operator who originally requisitioned the device.

An adaptation of the model leads to the abstraction chosen to depict the stakeholders’ interactions in this research as shown in Figure 11. Wittner adapted this model to show interactions between stakeholders, device design, and medical device purchasing (Wittner 2009):

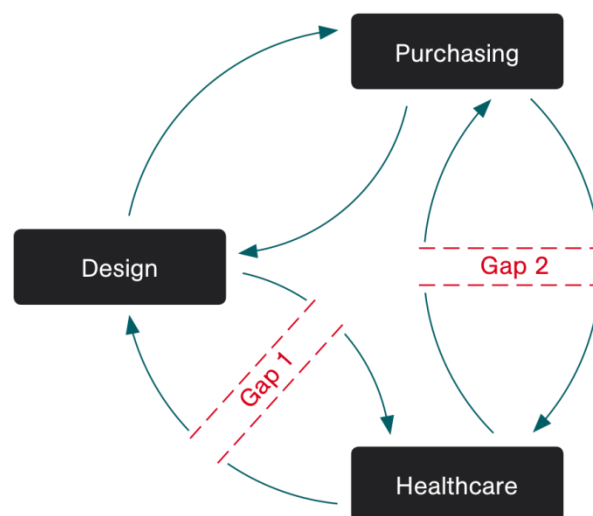


Figure 11: Interaction gaps between stakeholders, adapted from (Wittner 2009)

The remoteness of healthcare professionals and designers is known to be a major cause of usability problems when it comes to medical devices, as pointed out by Ward and Clarkson (Ward & Clarkson 2004). This is shown as Gap 1 in Figure 11, which was the focus of other studies on device design, and much of the focus on HFE principles in the design of medical devices. The focus of this study, however, is the gap between purchasing and healthcare users (Gap 2 show above). The insights provided in this research may also provide information on the influence of device design or healthcare provision design on healthcare services, but the focus here is to understand the other side of the supply chain, and recognise that purchasing is an important, yet poorly understood, contributor to safer patient care.

Purchasing Practice as a Culture

Many comments made during Exploratory Studies suggest that cultural barriers impede collaborative practice in purchasing. This section explores approaches that address these barriers.

The definition of organisational culture is given as “a complex framework of national, organisational, and professional attitudes and values within which groups and individuals function” (Helmreich & Merritt 1998). According to Nieva and Sorra, who have done a study on the different ways to measure organisational improvement, adopting a safety culture is more useful in eventual effective improvement. They conclude as follows,

“While a variety of levers – clinical training and guidelines, information technology, organisational structures and industry regulations – are being pushed in healthcare organisations to improve patient safety, the belief is growing that an institution’s ability to avoid harm will be realised only when it is able to create a culture of safety among its staff” (Nieva & Sorra 2003).

This may well include practice during purchasing decisions, especially given its multidisciplinary nature. Part of what was realised in the Exploratory Studies is the cross-functional nature of purchasing decisions in healthcare. In particular, respondents pointed out the need for managers and financial decision-makers to be aware of the complexities of medical device purchasing. Lonsdale and Watson present a model supplemented by a real-life case that shows how it applies in practice and can help managers interpret their

environment: *“It was shown... [that] whilst the fragmentation of [our hospital’s] demand for pathology equipment emerged for a number of reasons, some technical and organisational in nature, politics and power significantly amplified the problem”*. They conclude that *“organisational power has been shown to be critical to the decision-making process”*(Lonsdale & Watson 2005).

A look at cultures in the healthcare profession cuts across perspectives from the delivery at point of care, right through to management of hospitals. Foucault in his philosophical account of the clinical hospital development challenged the way we view the medical profession by questioning its empirical nature:

“The clinic - constantly praised for its empiricism, the modesty of its attention, and the care with which it silently lets things surface to the observing gaze without disturbing them with discourse - owes its real importance to the fact that it is a reorganization in depth, not only of medical discourse, but of the very possibility of a discourse about disease”(Foucault 2003).

In modern publications we are encouraged to understand the progression of healthcare delivery from a more holistic diagnosis, to what has now become a division of ‘objective’, clinical medicine, and ‘alternative’ therapies (Seale et al. 2001). Such divisions in practice from clinician to nurse, to allied health professionals, to divisions in engineering and the ‘technical staff’ that maintain equipment cannot be ignored in the context of making improvements. These greatly affect the culture, if not at least the mindset, of those making purchasing decisions. If one were to provide recommendations following this study, this could also be a tool that increases cultural awareness, or in this case, the importance of good purchasing practice awareness. For instance, in the case of the MAPSAF (introduced in Section 2.2.4), some anecdotes relating the use of the tool comment on the validity of a tool that, at a minimum, raises cultural awareness (Ashcroft et al. 2005).

Cultural aspects, however, can also be combined with systems theory. As pointed out in a commentary on US healthcare systems, creating a culture of safety might be important, but creating a ‘culture of systems’ is “a more fundamental challenge... The greatest barrier to patient safety and safety culture is the inherent fragmentation of the US system of care. Safety will improve when the underlying system of care improves”(Shortell & Singer 2008).

Cultural and structural factors are therefore both considered in the ‘systems approaches’ here, both in the analysis of current practice itself and in providing tools and recommendations for future. The final state of a system may be reached from different initial conditions and in different ways. An organisation with a particular set of cultural attributes may be successful in achieving patient safety, while another organisation with a different set of cultural attributes can also potentially achieve the same levels of success (Nieva & Sorra 2003).

3.3 Research Design and Methods

Having established a general approach to the research and drawn up research questions on which to focus the study, this section addresses the research design and methods to implement the research.

3.3.1 Research Design

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. 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 (Sim & Wright 2002). Such criteria are also applicable to research if it is to create the same rigour to other healthcare-based research. Before the design and methods are introduced, a mention is made of how the particular research challenges faced in this study were addressed.

Addressing Research Challenges

Taking an approach by Sim and Wright as a simple list to describe the research methods employed, the general design is summarised as followed:

Design to employ →

Non-experimental

Variables to study →

Qualitative

Setting →	<i>Naturalistic (not controlled)</i>
From whom or what →	<i>Group study (partly comparative)</i>
At what time points to collect data →	<i>Cross sectional</i>

The research methods depend on questions asked, as continually reinforced by Robson (Robson 2002; p.80). The value of using qualitative methods has been identified in particular in relation to research on healthcare technologies:

“One of the major strengths of qualitative research lies in its emphasis upon understanding the phenomenon of interest holistically. Whereas many quantitative researchers aim to isolate causal relationship from the context in which they occur, qualitative researchers avoid such context stripping and place complexity at the centre of their research. Such attention to context is particularly relevant to Health Technology Assessments insofar as it offers a bridge between the discoveries that participating patient, clinical and/or organisations management strategies are effective under experimental conditions, and the efficient implementation of such findings in clinical settings”. (Leape et al. 2002) and quoted in (Nieva & Sorra 2003)

A few pointers to note during this study, given its adoption of rigorous qualitative methods, are discussed below.

Data sources

Given the more exploratory nature of this project, opportunities for access were obtained to ensure a broad understanding of practice. Three collaborations emerged by making enquiries with relevant contacts:

PASA project ‘Purchasing for Safety’ on infusion device purchasing practices for a generic broader view of purchasing practice (Three NHS Trusts B, C and D).

Honorary research contract with one Trust (referred to as Trust A here) to examine in-depth practices for general medical device purchasing

Invitation to a Scottish NHS Trust for examination of their procedures to evaluate infusion pumps (Trust E), used as a case study.

Flexible and fixed research design

Robson refers to two general approaches to the research methods employed: fixed and flexible designs (Robson 2002). With the above-mentioned three specific opportunities, the methods adopted required avoidance of bias and pre-conceived expectations on current issues in medical device purchasing. In particular, it was important to first gain an understanding of where the general issues in purchasing lay, for all Trusts. Therefore, a set of Exploratory Research studies were conducted at the start, where open-ended questions were used and ‘blank-sheet’ brainstorming methods undertaken (Chapter 4). This indicates that a more flexible approach was taken. Furthermore, to allow for cultural and subtle contextual drivers within current practice alluded to earlier, the use of semi-structured interviews was preferred, rather than fixed surveys.

Sampling

Sampling can largely influence the bias in the research and the method should be questioned appropriately. Of the available methods (theoretical, probabilistic, non-random, and opportunistic), considerations were given to the research questions (Stake 1994; Robson 2002). The questions are not testing a theory but aim to gather a true picture of current practice at grass-roots level. It was learned during the Exploratory Studies that each Trust operates in a specific way and displays its particular culture. A random sample of Trusts would not necessarily shed light on all current practice in the NHS. Furthermore, a large study encompassing many Trusts would limit the time and depth required to create true understanding of current practice. The types of sampling methods adopted are therefore ‘opportunistic’; since an opportunity to enter and work with a Trust is a necessary requirement for access to healthcare as discussed earlier; and ‘within case study sampling’, where opportunities within each case are used to sample data further (Hammersley & Atkinson 2007). While remaining opportunistic, a systematic approach is still adopted within the study to retain the rigour in the research and results triangulated by comparing data across the Trusts and across stakeholders from different departments.

Validity

The term validity can refer to any feature of the inquiry that ensures ‘trustworthiness’ of the results. Robson points out that this can include accuracy of the description of the

study, valid interpretation of the phenomena, or not considering alternative theories to explain the results (Robson 2002).

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 (Lewis 1998). Robson recommends using negative case analysis but these methods were not employed in this research as the observations made were not cases that needed to be ‘tested’ but rather described. Such concerns were also avoided by ensuring that results were presented back in various forms to stakeholders both separately in the same Trust, and across other organisations (Chapter 7).

Dependability

Also referred to as reliability in more positivist circles, dependability refers to the stability of results over time. One recommendation is to use audit trails to at least demonstrate the conditions under which these particular observations were made. Clear context of the situations under which the data was gathered are therefore noted in each results chapter.

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 Trust A 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. For this purpose, as seen in the Exploratory Studies, transcript excerpts are also included as quotes from respondents (Miles & Huberman 1994).

Generalisability

Generalisability or transferability refers to how well the findings could be applied to other settings. The intention was not to provide results that are generalisable across all hospitals or NHS Trusts, but that with the models provided and frameworks derived, a working model to both describe and improve current practice is designed. The response to these models, together with the conditions under which such models work, by showing the context where they were developed, provide the background to allow critics to assess its applicability to their own setting.

This particular study may be subject to criticisms as to its generalisability, as it has already been observed that purchasing practice can vary from Trust to Trust. However, gleanings from the Exploratory Studies already suggest that stakeholders do feel some dissatisfaction with current practice, and that some of the factors that influence current practice are embedded within the cultural context of the NHS as an organisation. The study therefore can only claim to paint a picture of current practice, within the current political climate existing in the healthcare system. However, some of the common factors emerging from the samples can be compared to other studies and their learning in global settings.

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 humans” (Kimmel 1988).

For the purposes of this study, the exact scope of the study was presented to the Research Ethics Committee for each Trust 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 (Sim & Wright 2002):

Informed consent

Privacy and confidentiality

Anonymity

Deception

Risk of harm

Exploitation

All participants in the study approached voluntarily, following the establishment of a research contract with Trust A. For the studies at Trusts B, C, and D, the participants had already given consent to the study as part of the PASA project. Trust E was initiated by invitation, and participation of the eventual participants themselves was also voluntary. All personal details were kept confidential and are anonymised in this thesis. The aim of the study was stated clearly at the start of each interaction to avoid deception. Although the ultimate real effect on healthcare practice, or 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.

3.3.2 Methods for Data Collection

The following are a description of all the methods employed to collect the data and conduct analyses.

Systems Analysis

A publication on systems analysis in healthcare describes how to apply systems theory in practice and execute systems analysis in healthcare. They propose a method “to analyse a system so that system wide problems can be uncovered and solutions implemented” (Karsh & Alper 2005).

Step 1: Decide on system boundary for analysis (e.g. entire medication system or nurse communication system). In this case, this would be the purchasing process, which currently means the purchasing of all medical devices in the NHS, but as applied to a particular Trust as a case study (Trust A).

Step 2: Produce a preliminary system map. This is similar to a workflow diagram, including decision points, and identification of people, processes, policies, and other factors involved.

Step 3: Use preliminary system map to identify human resources required to carry out analysis (ensuring end-users, policy-makers, and experts are all represented).

Step 4: Use team to produce an initial scan of the system and identify missing information. This involves engaging stakeholders in interviews to verify the scan and then turn to external factors that may be influencing the system.

Step 5: Put boundaries on system under study and ensure it is well representative of factors needed (e.g. bounding the medication process to include only the day shift may not capture differences between shifts)

Step 6: Determine performance expectations for each step in the system. This can serve to define failure, risks involved, weaknesses, and hazards.

Step 7: Begin formal data collection to revise and collect the system maps. Use time studies, administrative databases, maintenance records, structured observations of the process, and interviews of stakeholders involved.

Step 8: Analyse collected data to (a) identify weaknesses, variances, and any series of events that can cause the system to fail, and (b) prioritise the identified problems for re-design

Step 9: Develop control strategies to address hazards identified above. A hazard control matrix could be developed as exemplified in the original text.

Step 10: Conduct system analysis on the re-design of the hazard-control ideas that the team develops. Only then can pilot testing and implementation begin. By separating system boundaries, identifying all stakeholders involved in a process, and then following the people, products, and process pathways, one is then in a position to identify where potential hazards lie. Such a distinction allows them to be correctly analysed and reviewed for avoidance in future.

Trust A provides the context in which to try these steps given the open access to the relevant stakeholders. A version of this process was followed in the process-map exercise with Trust A leading to an analysis of risks in the process, described in detail in Chapter 6.

Case Study Research

The purpose of case studies can be to describe a problem, to solve it, to interpret critically, or build theory (Yin 1993). Case studies are found frequently in design research literature, as they are empirical studies that investigate contemporary phenomena with multiple sources of evidence, where the boundary between phenomena and context is unclear. Yin suggests that in order to produce valid results, case studies need to include project objectives, field procedures, case-study questions, and report guidelines (Yin 1993). Given the small sample size for this whole research project (five Trusts in total), the whole study may be considered a 'case' in itself, adhering to the guidelines indicated by Yin. The specific examples illustrated in Chapter 6 are therefore not called Case Studies but rather Case Examples as they do not have rigorous research methods and serve rather as examples that illustrate evidence previously formed in the field work shown in Chapters 4 and 5.

Workshops

In the Exploratory Studies, various methods were used in a workshop setting, briefly explained below:

- **Brainstorming:** used with open ended questions on essential themes to be addressed in the research
- **'Blue-sky thinking':** used to note down each participants' belief in the ideal scenario, untainted by any previous conceptions
- **MAPSAF exercise:** used to test the usability of a maturity grid as a form of assessment

Such methods were appropriate in the initial stages of the study given the lack of specific direction of the research. They helped understand the main issues among participants and allowed for reflection on what research questions could feasibly be pursued.

Questionnaire and Surveys

As a way of confirming some of the first findings, and the conclusions made in the Exploratory Studies, a questionnaire was designed pointing out these very same issues.

These have taken into account some guidance on how tools and questionnaires and surveys should be developed.

A review by Nieva and Sorra gave some pointers about how to design tools, pointing out that “more evidence is needed about the validity of safety culture assessment tools; how to use assessment data to initiative and sustain safety culture change, and how it must be combined with other patients safety information in making decisions about ways to improve patient safety” (Nieva & Sorra 2003). Requirements for selection are that the following criteria for suitability of the tool must be taken into account:

- the domains of culture that are assessed (in this case, purchasing)
- the types of staff who are expected to complete the tool (perhaps purchasing)
- the setting for which the tool was developed
- the availability of reliability and validity evidence about the tool

The questionnaire designed for this study incorporated some of the questions from the NPSA infusion device purchasing toolkit; a list of questions that guide infusion device decisions. The questionnaire used in its final version is included in Appendix II.

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, interviews were chosen as the main method for data collection. Robson distinguishes between structured and unstructured interviews as the former having more rigid questions and direction and the latter more open-ended, leaving the interviewer with little control of the process (Robson 2002).

Given the combined use of questionnaires and diagramming tools, the methods used here are semi-structured interviews. Although there is a general structure and guideline used (e.g. the questionnaire in one instance, and the use of diagrams to initiate discussion in the other), the interviewer is left free to modify the questions according to the responses given. This allows for in-depth and rich data to arise from the interaction, while keeping the aim of the meeting focussed.

Diagramming and Mapping Methods

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 challenged in an attempt to improve the process. (Slack et al. 2007; p. 105). Crilly et al suggest the use of diagrams as a graphic elicitation tool, or as interview stimuli (Crilly et al. 2006), a method employed for this study. However, the choice of diagram and modelling method is also vast. A study focussing solely on the applicability of modelling techniques to a healthcare setting (Jun 2007) noted the importance of using the correct process model for the right context to be investigated. In this study, flowcharts 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. For this reason, the usability of the tool was more important than its ability to accurately depict the situation. Simple flowcharts, developed over time into process maps, were therefore chosen in favour of the many more sophisticated and complex models available.¹³

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.

¹³ Examples of mapping methods found online include (accessed 01/12/2009):
<http://www.medmosaic.co.uk>
<http://www.smartdraw.com>
<http://www.scenarioplus.org.uk>
<http://www.brass-bullet.co.uk>
<http://processmapping.com>
<http://processmaps.com>
<http://www.pms.ac.uk/mashnet>

Coding and Analysis

The problem with qualitative data analysis is that it is done with words or text, and not with numbers, making it more difficult to “move around and work with” (Miles & Huberman 1994). The purpose of coding in this case is to be able to classify and synthesise data for analysis, so that one is able to ‘move it around’ and also allow for the process of data “selecting, focusing, simplifying and abstracting” (Miles & Huberman 1994). The process of coding, however, can also be viewed as part of analysis and theory-building. In a pure grounded theory approach, for instance, a completely blank empty code list is the starting point for research, and the research process itself allows for codes to emerge from the data and steer the direction of the research (Glaser & Strauss 1967).

The approach taken here is more closely related to an approach suggested by Bryman and Burgess, where instead of using an empty code list, a limited number of preliminary codes are drawn up (Bryman & Burgess 1994). Following the literature review and Exploratory Studies, such a code list did emerge from the data and this 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.

In this study, comments were collected around the research questions asked. 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 research questions. These original 167 quotes and comments made by the participants that shaped the conclusions in this study were selected to then design the final framework noting the important aspects of purchasing practice. The issues/codes were then assigned a stage in the life-cycle of a medical device within a hospital, also based on data that was collected during the process mapping. These exact developments are explained in more detail in Chapter 7, but an overview of how this coding was conducted is shown in Figure 12:

	Original quote / Raw data	Code / Category	Life-cycle stage (1-6)	Stakeholders involved	
1					...
2					...
					...
					...
167					...

Figure 12: First stage in development of framework from original data

Once the issues were clustered according to each life-cycle stage, these were listed under their respective headings, without the original quotes (i.e. using only the Code/Category tab above), as seen in Figure 13:

WHEN?	1. Identify need	2. Choose device	3. Determine funding	4. Purchase	5. Install & Train	6. Use & Maintain
WHO?						
stakeholder1	yes/no			
stakeholder2	...					
stakeholder3						
...						
WHAT?	Issue 1.1	Issue 2.1	Issue
	Issue 1.2	Issue 2.2
	Issue 1.3

Figure 13: Second stage in development of framework

Finally, when reviewing each life-cycle stage, some of the further insights and observations drawn from the study were added to each column for completeness.

3.3.3 Data Collection

The Sources of Data came from the following collaborations:

Trust A: Collaboration with a Trust (Trust A) that provided most of the detail in the data and deeper understanding of the healthcare context.

This collaboration allowed for complete freedom of engagement with relevant stakeholders in medical device purchasing. A combination of open-ended interviews, semi-structured interviews, and participatory research methods were used.

Trusts B, C, and D: Collaboration with a PASA project on Purchasing for Safety, examining the safe purchase of infusion systems.

Initial engagement of participants was organised entirely by PASA, and the study was limited to infusion systems (drugs and devices). Three workshops were held to elicit main issues regarding only device purchasing (included as Exploratory Studies) and the same participants were subsequently used for telephone interviews in Summary of Current Practice I.

Trust E: Invitation to a Scottish NHS Trust to examine the process of evaluation of new infusion pumps for the Trust for standardisation on a model.

The Trust was in the process of standardising its patient-controlled analgesia pumps for a particular area of the Trust and was in the process of conducting evaluations involving four medical device suppliers. The same questionnaires were used as the basis of semi-structured face interviews and subsequent telephone interviews.

A comparison of the five Trusts studied is shown in Table 8:

	<i>Trust Identifier</i>				
	A	B	C	D	E
<i>Type</i>	Foundation Trust	NHS Trust, non-Foundation	Foundation Trust	Foundation Trust	Scottish NHS
<i>Notes</i>	University teaching hospital	Merger of three former acute hospitals	Five specialist hospitals	University teaching hospital	Combination of specialist, teaching and community care
<i>Catchment population</i>	500 000	700000	600000 (estimate)	600000	800000
<i>Staff</i>	7000	7800	8000	7000	28000

Table 8: Comparison of Trusts used for data collection

The graphical overview of the research process (with approximate time lines) is shown in Figure 14 and the full list of data together with the methods used to collect the data is listed in detail in Table 9. As described in that section, the first set of data (Set 1) was a result of a more continuous and independent collaboration with Trust A. Set 2, however, was initiated through the collaboration with the PASA project did not allow for as much flexibility as Trust A. The methods used, therefore, were mostly opportunistic and most appropriate given the time constraints of the participants. Set 3 took place at Trust A and was also an opportunity taken to meet medical devices sales representatives visiting the Trust. Finally, Sets 4-9 collectively contributed to the analysis and are described in their relevant chapter stages as shown in Table 9.

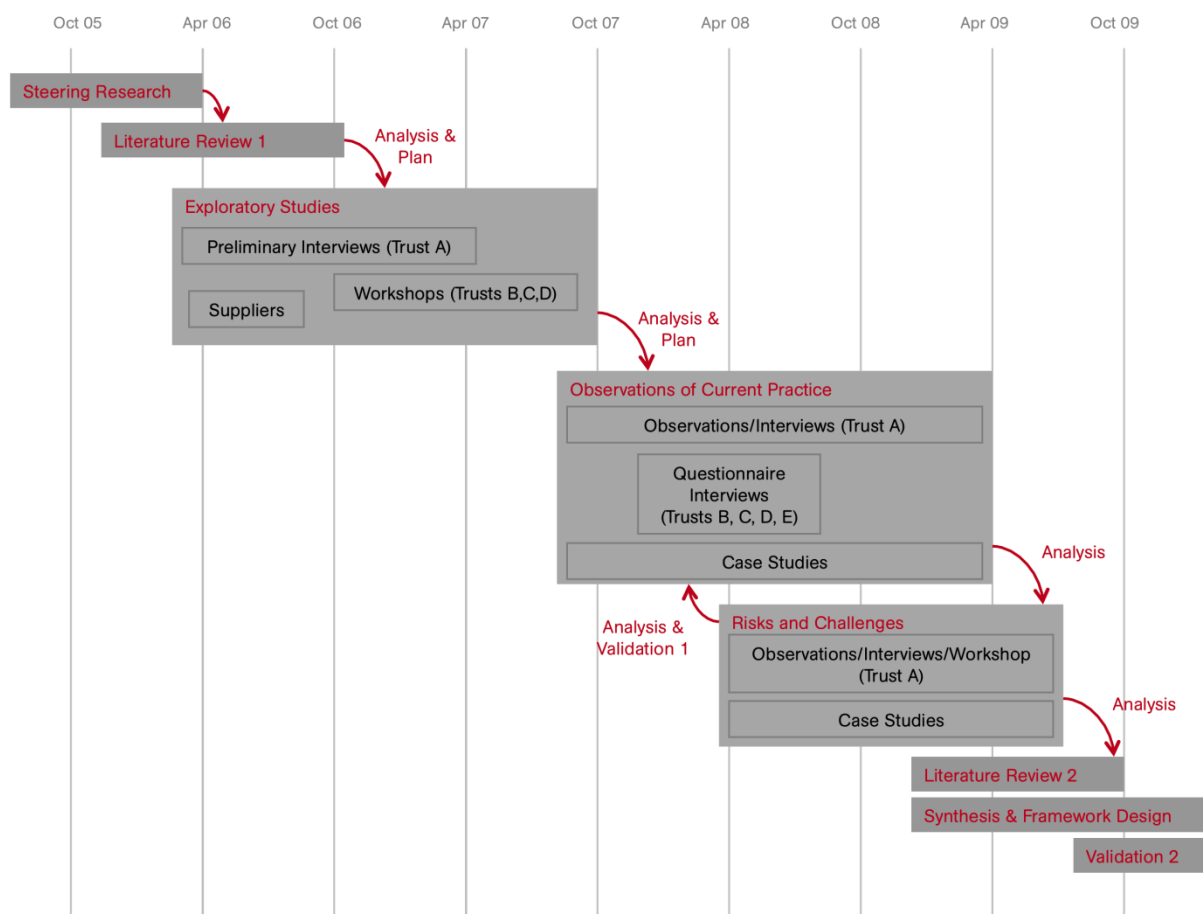


Figure 14: Graphical overview of research process

Location	Person(s)	Setting	Tool used	Method(s)	Source in thesis	
Set 0: Steering the direction of the research						
1	PASA	NPSA, PASA, EDC, Surrey	Steering meeting*	None	Open-ended questions, Brainstorming	Chapter 1
2	EDC	NPSA, PASA, EDC, Surrey	Steering meeting*	None	Open-ended questions, Brainstorming	
3	ABHI	ABHI Head	Telephone interview*	Research overview	Graphic elicitation	
4	Private	Researcher	Face-to-face interview*	None	Open-ended questions	
5	CRISPS	CRISPS Head	Face-to-face interview*	Research overview	Open-ended questions	
Set 1: Exploratory studies (local trust)						
6	Trust A	Clinical Engineer (CE)	Face-to-face interview	Process Map	Free drawing	Chapter 4
7	Trust A	Procurement (Pr)	Face-to-face interview	Process Map	Graphic elicitation	
8	Trust A	Medical Electronics (ME)	Face-to-face interview	None	Free drawing	
9	Trust A	Equipment library (EL)	Face-to-face interview	Process Map	Free drawing, Open-ended questions	
10	Trust A	Device training (DT)	Face-to-face interview	None	Open-ended questions	
11	Trust A	Medical Physics (MP)	Face-to-face interview	Process Map	Graphic elicitation	
12	Trust A	Procurement committee ² (N=5)	Monthly meeting	None	Observation, Ideas evaluation	
Set 2: Exploratory studies (PASA project and local trust)						
13	Trust B	Various ¹ (N=4)	Workshop	None	Open-ended questions, Brainstorming	Chapter 4
14	Trust C	Various ¹ (N=3)	Workshop	None	Open-ended questions, Brainstorming	
15	Trust D	Various ¹ (N=6)	Workshop	None	Open-ended questions, Brainstorming	
16	Trust A	Procurement committee ² (N=5)	Monthly meeting	Process map	Observation, Ideas evaluation	
Set 3: Exploratory studies (Medical device supplier perspective and products analysis)						
17	Trust A	Device sales reps (N=7)	Face-to-face interview	None	Open-ended questions	Chapter 4
18	Trust E	Device sales reps (N=2)	Face-to-face interview	None	Semi-structured interview	
Set 4: Observations of current practice (3 English NHS Trusts + 1 Scottish NHS Trust)						
19	Trust B	Various ¹ (N=3)	Telephone interview	Questionnaire	Semi-structured interview	Chapter 5
20	Trust C	Various ¹ (N=4)	Telephone interview	Questionnaire	Semi-structured interview	
21	Trust D	Various ¹ (N=5)	Telephone interview	Questionnaire	Semi-structured interview	
22	Trust E	Various ³ (N=5)	Face-to-face interview	Questionnaire	Semi-structured interview	
23	Trust E	Various ³ (N=7)	Telephone interview	Questionnaire	Semi-structured interview	
Set 5: Risks and challenges (Local trust + 1 Scottish NHS Trust)						
24	Trust E	Various ³ + Device sales reps	Device sales meeting	None	Observations, Note taking	Chapter 5
25	Trust A	Clinical Eng. Research	Face-to-face interview	None	Open-ended questions	
26	Trust A	Renal dialysis technical	Face-to-face interview	None	Open-ended questions	
27	Trust A	Equipment library	Face-to-face interview	None	Open-ended questions	
Set 6: Risks and challenges (Local trust)						
28	Trust A	Clinical Eng. Research	Face-to-face interview	Process Map	Graphic elicitation	Chapter 6
29	Trust A	Renal dialysis technical	Face-to-face interview	Process Map	Graphic elicitation	
30	Trust A	Equipment library	Face-to-face interview	Process Map	Graphic elicitation	
Set 7: Risks and challenges (Local trust)						
31	Trust A	Procurement committee ² (N=3)	Meeting	Process map	Risk identification	Chapter 6
32	Trust A	Clinical Engineer (CE)	Face-to-face interview	Process Map	Risk identification	
33	Trust A	Procurement (Pr)	Face-to-face interview	Process Map	Risk identification	
34	Trust A	Medical Physics (MP)	Face-to-face interview	Process Map	Risk identification	
35	Trust A	Finance (Fi)	Face-to-face interview	Process Map	Risk identification	
36	Trust A	Procurement committee ² (N=8)	Workshop	Process map, Risk matrix	Open-ended questions, Risk analysis	
Set 8: Validation of ideas I (Local trust)						
37	Trust A	Clinical Engineer (CE)	Face-to-face interview	Process Map	Member validation	Chapter 7
38	Trust A	Procurement (Pr)	Face-to-face interview	Process Map	Member validation	
39	Trust A	Medical Physics (MP)	Face-to-face interview	Process Map	Member validation	
40	Trust A	Finance (Fi)	Face-to-face interview	Process Map	Member validation	
41	Trust A	Procurement committee ² (N=6)	Workshop	Process map, Risk matrix	Open-ended questions, Brainstorming	
Set 9: Validation of ideas II						
42	Trust A	Procurement committee ² (N=6)	Workshop	Results framework	Graphic elicitation	Chapter 7
43	Trust D	Device Training	E-mail Questions	Results framework	Graphic elicitation	
44	Trust A	Finance (Fi)	Telephone interview	Results framework	Graphic elicitation	
45	Trust E	Clinical Engineer (CE)	Telephone interview	Results framework	Graphic elicitation	
46	Trust A	Clinical Engineer (CE)	Telephone interview	Results framework	Graphic elicitation	
47	Trust A	Clinical Eng. Research	E-mail Questions	Results framework	Graphic elicitation	
48	Trust A	Renal dialysis technical	E-mail Questions	Results framework	Graphic elicitation	
49	Trust A	Clinical Eng. Administration	E-mail Questions	Results framework	Graphic elicitation	

* Not counted as data

1: Participants represented from CE, MP, Risk, Pharmacy, DT

2: Medical Equipment Committee Procurement sub-group includes Fi, Pr, CE, and occasional Clinician

3: Scottish NHS Trust, with participants from CE, MP, Pharmacy, Nursing

Total No. of Face-to-face interviews:	36	(Sample N = 25)
Total No. of Telephone interviews:	22	(Sample N = 19)
Total No. of Workshops:	6	
Total No. of meetings observed:	>15	
Total No. Steering Meetings/interviews:	5	

Table 9: Full list of data and methods used for study

3.4 Summary of Research Process

The overall research paradigm adopted here is a realist approach, in the absence of an overarching theory for medical device purchasing processes. The study also adopts systems theory as a way of approaching the subject, choosing the purchasing process as the system and the delivery of care its super system. In a healthcare setting, where stakeholders come from many backgrounds and may differ in culture from one organisation to another, such a unifying systems approach helps paint a common picture to illustrate the process.

The methodology follows an inductive strategy to provide a description of current practice and, due to limitations of access to healthcare settings, would also not claim to provide grounds for proving new theory in terms of purchasing and supply of devices in the NHS. However, what they do provide is an understanding of current practice, an analysis of the possible reasons for such behaviour according to external drivers and regulations on their practice as well as their present conditions. The methods chosen take into account potential bias and the importance of a systematic approach within opportunistic sampling.

Furthermore, in line with good design practice as forms the basis for the approach to this research, the work forms another example of how design practice works in researching one particular healthcare setting or system. This is demonstrated not only through the overarching framework already presented in Chapter 1, but by the mapping methods employed to conduct the research process.

Chapter 4

RESULTS I:

Exploratory Studies

Given the lack of substantial literature to describe current practice in purchasing, coupled with the lack of appropriate guidance from the Department of Health on suitable purchasing practice at the local level, this study had to begin by firstly exploring the need for new practice at all. Therefore, a set of Exploratory Studies was conducted before formal data collection to inquire, on a very general level, how medical device purchasing is practiced, and whether or not there is the need for improvement on current practice, and what, in theory, this improved practice would look like. A more open-ended approach was adopted at this phase, to elicit findings that could then be confirmed through other methods in Chapters 5 and 6.

This chapter is divided into three parts:

1. An overview and starting point, where an initial conceptual vision for purchasing medical devices was shared with key stakeholders
2. Description of methods and results from initial observations at Trust A, along with experiences of involvement with initial stages of PASA project at Trusts B, C, and D

3. Description of methods and results from initial studies of medical devices issues, from workshops and dialogue with medical device sales representatives

4.1 Overview of Exploratory Studies

The research questions introduced in Chapter 3 are now repeated as a reminder of the aim of the overall study.

Research Sub-Questions
1. What is current practice in medical device purchasing?
Who are the stakeholders and what are their roles in purchasing? What type of knowledge and competence do these stakeholders have? What are the resources and drivers for purchasing decisions? What other factors influence current practice?
2. (How) does current practice present risks to healthcare delivery services?
What challenges and risks are present in current practice? How are the factors of current practice different from good practice? How do these factors impact the healthcare service?
3. Where are areas for improvement on current practice?
How do the stakeholders themselves view improved practice? How can factors in current practice be managed towards improvement?

Despite keeping these questions in mind, however, this Exploratory Studies expanded beyond the focus of these questions. The shaded area remains the focus, but elements of other questions, shown in grey, were also drawn. This was done to ensure that contextual factors in the wider system for purchasing were kept into account before more focussed studies were conducted in subsequent chapters. Sections 4.1, 4.2 and 4.3 therefore address their own sets of generic questions around purchasing practice, but they keep in mind the key pointers identified in the literature. These pointers are shown again in Table 10, with added data to show the evidence gathered and shown in this chapter and in the literature.

	1	2	3	
<i>Factors considered</i>	<i>Current Practice</i>	<i>Risks to Healthcare</i>	<i>Improvement Areas</i>	
<i>Stakeholders</i>	<i>Stakeholder definition</i>	✓		
	<i>Device knowledge & competence</i>	✓	✓	
	<i>Process knowledge</i>	✓		✓✓
	<i>Stakeholder engagement</i>	✓		✓✓
	<i>Resources for decisions</i>		✓	✓
	<i>Drivers for decisions</i>	✓		✓
	<i>Culture and mindsets</i>	✓		✓
<i>Process</i>	<i>Process description</i>	✓		✓✓
	<i>Control measures</i>	✓	✓	✓✓
	<i>Reporting and feedback</i>	✓		✓✓
	<i>Pressures on process</i>	✓	✓	✓✓
	<i>Inventory management</i>	✓	✓	✓✓
	<i>Goal alignment</i>	✓		✓✓

Key to Data Sources: ✓ : From Literature (Chapter 2)
✓ : From Results I (Chapter 4)

Table 10: Data gathered from Literature and Results I (Exploratory Studies)

4.1.1 Starting point for Exploratory Studies

The unknowns in the study at this point were as follows:

- The exact roles and names of the stakeholders who are involved in the purchasing of medical devices in any given Trust, other than the contacts initiated through the EBME Team and Procurement manager at Trust A

- Any standard set of processes or procedures followed in any given Trust
- The scale of the asset base in any given Trust
- Variations in practice between Trusts
- An appropriate detailed interview approach and a sample on which to focus

What was known, were those pointers from the literature and theory pointing to some of the elements of good practice in general purchasing scenarios, as well as theoretical ideas for how a holistic approach to purchasing could be practiced in a manner that is safe for healthcare users. Furthermore, following the literature review, conversations with key stakeholders were held to gauge where research could be initiated. Described in the next section are the results of such conversations.

4.2.1 Guidance prior to Exploratory Studies

In order to initiate the conversations, a theoretical model was presented to these stakeholders resulting from analysis of the literature and the ‘vision’ for the research direction, as shown in Figure 15. This shows a vision of the recommendations gathered in policy, advocated in this research: a virtuous circle with appropriate communication pathways between stakeholders in the medical device supply chain. The diagram was developed following conversations with stakeholders in the initial steering of the research, namely from Association of British Healthcare Industries (ABHI), PASA, NPSA, CRiSPS, and previous researchers looking at purchasing in the NHS. A similar model is presented in earlier work by Zeisel on design communication (Zeisel 1984) as presented in Chapter 3.

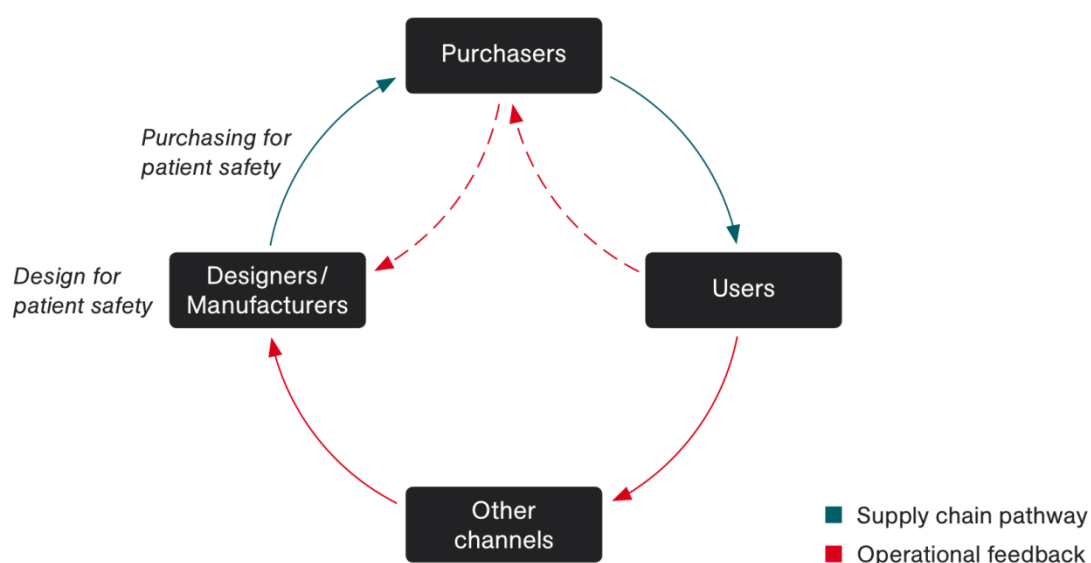


Figure 15: Conceptual framework of a virtuous circle for medical device purchasing

Figure 15 was presented at conferences at the start of the research and published in an article aimed at medical device sales companies (Ward & Hinrichs 2006), which was received by one respondent as “an article that people will empathise with”, Delta Consultants. The sympathetic feedback received gave confidence that the direction of the research and the conceptual vision would address existing problems. Figure 15 served to elicit comments that shed light on some of the research questions, but initially helped guide a focus for the research sample. As a result of the guidance given by these individuals, the chosen research focus is centred on the following stakeholder groups:

- purchasers (which may include other people involved in purchasing and device management),
- end-users of devices,
- interactions between these stakeholders, and
- device sales representatives

The ‘other channels’ diagrammed in Figure 17 refers to any general routes for feedback either through national agencies of the NHS and informal feedback gathered from manufacturers from users. These were not addressed in detail in this study as most of the data was gathered within the Trusts to show current practice at grass-roots level.

The details of the comments gathered from these stakeholders are presented next; but an overview of what they demonstrate can be summarised in the following main points:

- ⇒ *That the purchasing of medical devices does present some challenges*
- ⇒ *That improvement measures for medical device purchasing could be adopted*
- ⇒ *That complexities in both the device industry itself and the purchasing process may welcome a more holistic, systems approach*

On the challenges to current practice in device purchasing

Part of the challenges to current practice are the changes in policy that have affected the culture of NHS purchasing, as well as the increasing demand for new technologies in medical practice. As commented by PASA themselves, many changes were occurring within their organisations at the time;

There are a lot of changes going on in purchasing, telling you about PASA is not going to be useful necessarily

PASA

Purchasers have also changed in the way they are viewed within a hospital, given that end-users would have a degree of purchasing authority on their own,

In the old days purchasers were out the loop because end-users would specify directly and have a degree of purchasing authority on their own, and purchasers were just paper pushers effectively.

ABHI

To a degree, this culture might still exist in practice and this is something to investigate in this study. With the advances in technology, it has meant that all purchasing stakeholders are faced with more choice and intelligent purchasing is required;

I think the medical device industry seems to be going into the stereo of the 80s - how many buttons can we get onto the box? (Graph equalisers, etc.) In the private sector everyone understands that – iPod, iTunes, you have 4 user buttons for an

incredibly complex bit of kit - whereas 10 yrs ago with computer, that was a complete barrier.

NPSA

Intelligent purchasing also implies making patient safety explicit in decision-making;

Patient Safety should be implicit in everything. But it has to be explicit before it can become implicit... When we show nurses two infusion devices with keyboards going down the different ways, they never even thought about it. They're stunned, literally... No incident [report] will go back and say "part of the error was that I thought the '1' was a '7'".

NPSA

However, the ABHI is also keen to maintain open innovation within the medical device industry and not create further blocks through purchasing; commenting how they could potentially act as 'drags' on the system;

There's casebooks of examples where products, customers first approach is "I don't need this, I don't need this". Most products face that initially. The whole system has a high degree of inertia involved. So the salesman's first job is to say there is a need for it. Then the adoption process is generally very long and slow. And at the end of that process if you ask the end-user, would you go back and use what you were using before? And the answer is 'God, no!' And so the system is in a steady state but requires inertia.

ABHI

On potential improvement measures

While little comments were made about the process of purchasing, the ABHI representative commented vastly on the purchasing stakeholders themselves. There is a sense of the necessity for empowerment and training within the purchasers as a way towards intelligent purchasing;

...I think that is a good idea so that the incentive is evolution, and big cultural evolution, because the [advanced] buyer is a different one to the [less advanced]

buyer... the [advanced] buyer is somebody who has sophisticated capabilities, he is able to interact with clinicians and manages in a way that adds to the value.

ABHI

In terms of a process that represents 'best practice', direction was sought from CRiSPS, but the feedback gained was that this is usually only relevant in context. Strategic purchasing guidance mainly exists on an operations level;

There are no real 'must reads' on purchasing, none that are very good anyway. Nor template maps of purchasing in the NHS. Though you may be able to get things for operations level.

CRISPS

It was also recommended to follow the developments that are more localised, such as the Centres for Evidence-based Purchasing (CEPs)

They are the key for addressing 'value' in purchasing decisions. I would say it is useful to keep an eye on them and on their progress... they might be able to answer or at least clarify how current drivers are being asked during the purchasing process.

CRISPS

On the value of a systems approach

In general, the comments made from these key stakeholders while introducing the above framework were sympathetic towards a more holistic, systems approach to purchasing;

The whole systems approach is needed because they [purchasers] are disconnected from the end-users...I think that line between purchasing and end-users is weak.

ABHI

It was suggested to tackle specific cases within the system for deeper insight;

The medical device industry is so vast. How can you go from pacemaker to catheters, and have the same risk factors? – Because of the nature of the field, it is advisable to choose a set of case studies to focus on.

Natasha Browne (author of (Browne et al. 2004))

At the moment there are about 17 different subsystems for procurement, plus collaborative procurement hubs, DoH directorates, and Trusts themselves. It's very complicated. There is no point in really trying to get to grips with it all as there is so much politics involved too. What is more realistic is to follow one device through, use it as a case study, in one clinical area.

CRISPS

The NPSA stakeholder was keen to see developments that would aid decision-making;

What I would like to see in the end product of this project are answers to the following questions:

What info is needed when making purchasing decision?

What is the vehicle for delivering that information to the purchaser?

How is the vehicle populated, updated, and vetted?

NPSA

Having taken this guidance and direction, the rest of the Exploratory Studies focussed on the contacts made within the Trusts themselves. These results are presented next; first the studies at the people and processes NHS Trusts themselves, and then a set of workshops and observations focussed on devices.

4.2 Studies at NHS Trusts

While bearing the potential challenges, complexities and potential improvement measures in mind, these early interactions at the NHS Trusts continued to expand on the themes pertinent to device purchasing. The methods are described first, followed by the learning gathered throughout the studies.

4.2.1 Overview of Methods

Studies at Trust A

Trust A was the first contact made for which an honorary research contract was set up. This meant that there was full access to members of the Trust involved in the purchasing, training, and selection of devices throughout the Trust, except for clinical staff. This Trust helped answer the overall questions of how equipment is managed in the hospital from the moment its need is identified to purchase to use.

Given such flexibility and full access, the method used for this Trust was a series of interviews used to develop maps of the purchasing process. The developments of these maps are included in Appendix III. It was through the use of these diagrams that other issues were captured and participants were given the context to comment on their process and eventually identify risks, control measures, and potential improvements to the process. This development is captured in Section 6.1 of the results.

Studies at Trusts B, C, and D

The aim of this section was to explore the issues raised through the literature, to gain an understanding of how different Trusts approach their purchasing processes and what challenges they face. Given the limited access available to these Trusts, and the fact that it was conducted in the wider context of the PASA project itself, the method used for this stage was a three-part workshop involving stakeholders from various segments involved in infusion systems purchasing. Representatives from the local Collaborative Procurement Hubs were also invited to participate given their interest in the PASA project.

These first workshops were divided up into three parts:

1. Understanding the stakeholder groups involved in purchasing infusion device systems and their communication paths for decision-making
2. Sky-blue thinking: establishing an ideal purchasing for safety scenario
3. Trial of tool for improving current practice (Based on MAPSAF, maturity model described in Chapter 2).

The workshops were advertised by PASA aimed at those involved with purchasing of any part of the infusion system. The stakeholders targeted included:

EBME staff

Pharmacy (management role, purchasing function)

Risk Management/link to Clinical Governance

Medical device training

Medical device technical services

The details of the workshops will be described together with the findings. During all of these exercises, a number of codes emerged that dictated future research questions. These were based on comments made on the participants not in direct response to any of the questions asked, but gave an indication of the characteristics of the stakeholders involved in purchasing. A discussion on the findings and emerging themes follows.

4.2.2 Current Practice: Purchasing Stakeholders

Involvement with the above Trusts solved the very first step required for this research – establishing who the purchasers are, and what general processes are undergone. The research question generally addressed in this section is the first one:

1. What is current practice in medical device purchasing?

Who are the stakeholders and what are their roles in purchasing?
What type of knowledge and competence do these stakeholders have?
What are the resources and drivers for purchasing decisions?
What other factors influence current practice?

Identifying the purchasers (Stakeholder definition)

It became clear in early conversations with the Trusts that those ‘purchasing clerks’ ordering equipment were not the sole stakeholders responsible for the whole purchasing process. When using the term ‘purchaser’, hospital staff usually mean those who conduct the actual administrative act of buying equipment – usually belonging to the ‘logistics’,

‘procurement’, or ‘supplies’ department within the Trust. Other observations made at this stage included:

- Other groups involved with equipment purchase are those responsible for maintaining them; these fall into ‘Medical Physics and Clinical Engineering’. They also include those running the equipment library and, in some cases, a person or group running training for devices (usually infusion pumps)
- Training programme structures differ in hospitals. Some are incorporated into the Clinical Skills department, which is exclusively for clinician’s training. They usually fall within the clinical governance/risk remit, which are also responsible for dealing with incident reports and links to the NPSA.
- Some Trusts have appointed ‘medical device coordinators’ for coordinating equipment use on the wards, and ‘medical device technical services’ staff, who are responsible for specific equipment within a ward/unit

All these roles vary in terms of organisational hierarchy within a Trust, and as far as could be deduced at this stage, this is not consistent across Trusts. The full list of stakeholders and roles identified are listed below:








	ENG.snr = Senior position within Clinical Engineering
	ENG.tec = Technical services based at ward level, managed by either Ward or Clinical Engineering
	ENG.clin = Technical services based at Clinical Engineering workshop
	ENG.med = Medical Physics and Clinical Engineering management
	LIB = Medical equipment library
	CLIN.doc = Medical doctor
	CLIN.nurs = Chief nurse, specialist nurse, ward nurse
	PHA = Pharmacy staff
	TRAIN.cl = Managed by Clinical Skills training or nursing staff training
	TRAIN.tec = Training on medical devices
	RISK = Risk Management department
	FIN.snr = Senior level finance
	FIN.proc = Procurement/logistics department

Table 11: Key to stakeholder identifiers throughout the research (with colour codes)

The establishment of this list meant that for the rest of the exploratory phases, participants were chosen from among these roles; which served to identify the main issues to be investigated further in this study. Further findings on characterising these various stakeholders are described next.

Knowledge and skills (Device knowledge & competence)

One of the first observations made in this study was the different skills base present among all potential purchasing stakeholders, which is not surprising given that ‘to purchase’ is not within their background (clinical or otherwise) training. But these varying levels of IT, and device-use competence can affect both the process of purchasing as well as the processes of using these devices safely.

Not all staff are IT skilled. Remember we did a survey on our staff about IT skills?

They are really not ready...

TRAIN.clin_C

Medical device training is separate from clinical skills in other hospitals - purely for medical students...What I do is primarily for nurses, not the clinical school, but Trust staff...Clinical students should [be trained on devices used here] but because it's not actually their job to do it, it's not one of those things.

TRAIN.tec_A

The simulation suite - it is primarily for doctors, although nurses occasionally get to use bits of it I think but not as well as the doctors do I don't think.

TRAIN.tec_A

Furthermore, the knowledge base about particular device features for a purpose sits within different parts of the larger organisation. Is a medical device a consumable or equipment, and what kind of knowledge is required to purchase it? Not only are these questions answered differently by each stakeholder group, but whether they are asked at all is also a varying factor.

[There is] often confusion by requisitioner of what is consumable and what is device

ENG.snr_A

Our 'buyers' are 'purchase order clerks' really... Procurement operational staff (4 members in this team) are not interested in what the product is, to be honest, they may have some products that have been standardised though ...We in procurement do not have the technical knowledge to understand what the equipment needs or what the equipment gives the organisation, or safety mechanisms, we rely on engineering

FIN.proc_A

Drivers for purchasing decisions

Given the varying knowledge and skills base among stakeholder, along with the fact that they reside in different parts of a hospital, the expectations and drivers for making decisions are also varying factors. For instance, when it comes to actual devices, the training provided by suppliers is a large factor in their expectations, but these expectations are met differently by suppliers:

Training for 'pharma' is different....If pharmaceutical preparation had difficult technique or involved manipulations that were difficult, you do not have pharmaceutical industry to train you ...It does depend. Some companies do do training. But as you say it's the exception rather than rule.

PHA_D

The expectations of how a device operates, and its associated manuals, were also factors mentioned:

Ideally, I want a syringe pump with an ON simple button, don't want mode executive standby, I want it to go through self test in English and tell me what's happening, with a self-test failure code I can look up, a good clear setup so I can wipe any information, etc...

TRAIN.tec_A

People say do you train on the [Brand Name] pump? I say 'Which one? We've got six.' They say the pale blue one. I say 'They're all pale blue!'

TRAIN.tec_A

I got asked 'that is a nice cable but it's not long enough to reach patient'. I thought, 'it doesn't need to reach the patient'!

TRAIN.cl_C

Culture and mindsets

The participants also pointed out characteristics of their particular Trust's culture, and the culture of individuals within the organisation due to varying backgrounds. This can have implications on the way the organisation operates and adopts new measures:

An Australian nurse comes over and somebody tells her to do something, she'll quite happily turn around and say 'Why? Why am I supposed to do that? I haven't been trained to do that, what's the rationale for doing that? With the [Asian nurses] if somebody told them to do something and it was the boss they would do it, regardless of whether they were safe doing it and they didn't actually see it as being a problem for them if they got it wrong.

TRAIN.tec_A

Putting the infrastructure into place is pretty hard because you are dealing with cultures. Now hospitals have cultures, all large organisations have a culture which basically means we've done this way and this is the way we'll do it to the day we die and you have to change the culture in order to make that type of system work, because the culture does not support that type of thinking because the Trust, and I'm sure it's not just ours, they work like silos so each department works separately from the rest, instead of them pulling together as a team they are in self-preservation.

LIB_A

With the inception of incident reporting, some organisations have struggled to be open to admitting to incidents. Varying comments were also made on 'blame culture' in the nursing sector:

No I don't necessarily think that pharmacy has the same blame culture that nursing has generally. It's been more tolerant of that and still supportive.

PHA1_D

Staff generally feel safe reporting incident...There is an open culture...

RISK_C

There is emphasis on reporting incidents, nobody's fault. But they still get blamed. And there are a number of times when I haven't reported an incident simply cos I know what will happen to the member of staff that is involved.

PHA_D

Finally, a point was made about the value of individual initiative:

Paediatrics - one of the reasons they've got standardisation is they got people in their area doing this and who talk to the companies asking what deals they can do. ... Partly because the funds are available to Paediatrics, partly because of her attitude and assertiveness I think she [the manager] can get better things.

TRAIN.tec_A

Summary of findings on the stakeholders

To collect the overall knowledge base for each stakeholder group interviewed in Trust A, a summary of the types of questions asked by each group during purchasing decisions was collected from the interview transcripts, as sampled by the quotations above. These sample questions asked by the different stakeholders are depicted in Table 12.

It can be seen from the list that these questions focus on very different aspects of decision-making for device purchases. EBME in particular seems to maintain a more holistic process knowledge, while the end-user does not focus on the whole process but rather its intended use.

Directorate	Stakeholder	Sample of questions asked during decision-making
"End-user"/ Ward level	Requisitioner	<i>Product needs replacing</i> <i>Product no longer works</i>
	Budget holder	<i>We have/do not have funding for this</i>
Numerous	Approver	<i>We have/do not have a standard model for this product</i>
		<i>If capital, should we standardise?</i>
		<i>Is this device managed centrally?</i>
		<i>Is this order over 5k?</i>
		<i>Is this Capital/Revenue purchase?</i>
		<i>Has device been on market for over 2 yrs?</i>
		<i>What is the length of support supplier offers</i>
		<i>Can we maintain/acceptance test this? If not, can they do acceptance test on site?</i>
		<i>Do we already have relationship with supplier?</i>
		<i>Does the library already have such a device?</i>
Clinical Engineering/ Medical Physics Team	ENG.snr	<i>If new device on market, user trial and technical trial?</i>
		<i>Is it a complex equipment, do we need user trial?</i>
		<i>Will the device be maintained centrally or not?</i>
		<i>Check cost centre/expense coding/authorised/preferred or suggested supplier/price?</i>
Procurement	FIN.proc	<i>Is the requisition form filled in properly?</i>
		<i>Does it have a Pre-Purchase Questionnaire?</i>

Table 12: Variety of questions asked by different stakeholder groups involved in the purchasing process, Trust A

The key findings from studying and characterising the purchasers themselves are listed below:

<i>Current practice (from Exploratory Studies)</i>	<i>Topic</i>
1 A purchaser usually refers to the person who places the order, but in practice incorporates roles in Engineering (Maintenance), front line staff (User) and clinical governance (Training).	<i>Stakeholder definition</i>
2 There is not one purchasing team for a hospital, depends on device	
3 Purchasing ‘clerks’ have little knowledge of device use/safety.	<i>Knowledge base</i>
4 IT and device working skills vary among clinicians and nurses.	
5 Ward level practitioners display different routes for decision-making	<i>Drivers for decisions</i>
6 Multiple input reasons for entering purchasing process pathway exist (i.e. different reasons for purchase).	
7 Variations in process depend on product characteristics	
8 Acknowledgement of the difference between policy and practice	<i>Culture and mindsets</i>
9 Feelings of dissatisfaction arose: fragmented, compartmentalised, no risk component, feedback was ignored.	
10 In theory, roles are clear-cut, but in practice, due to some habits, culture and non-holistic awareness of process, these roles are not known to all and can change.	
11 There are deeper cultural issues within the NHS that affect practice, and the implementation of policies.	
12 Allusions to ‘blame culture’ mentioned	
13 Feelings of trust in their systems mentioned: “we have the right people in place”, “our servicing history is very accurate”, “we seldom go query the request”, “we are good at training people”, “medical device quality is on the whole ‘good’”	
14 Culture/habits difficult to change in large organisation	

4.2.3 Current Practice: Purchasing Process

The research question generally addressed in this section is also to do with current practice, but with a focus on the purchasing process. As a means of introducing the participants and obtaining an overview of the purchasing process, workshops were held at Trusts B, C, and D, which required participants to name their role and indicate in which part of that process they were involved. They were also invited to comment on current

practice and their attitudes towards purchasing in their Trust. These findings were based on the results of these workshops and compared to observations made at Trust A.

Description of the process (Process Knowledge)

By combining the process maps developed with Trust A, shown further in Appendix III, and confirming these with a few stakeholders at the other Trust, meta-level steps or processes were also formed from these studies:

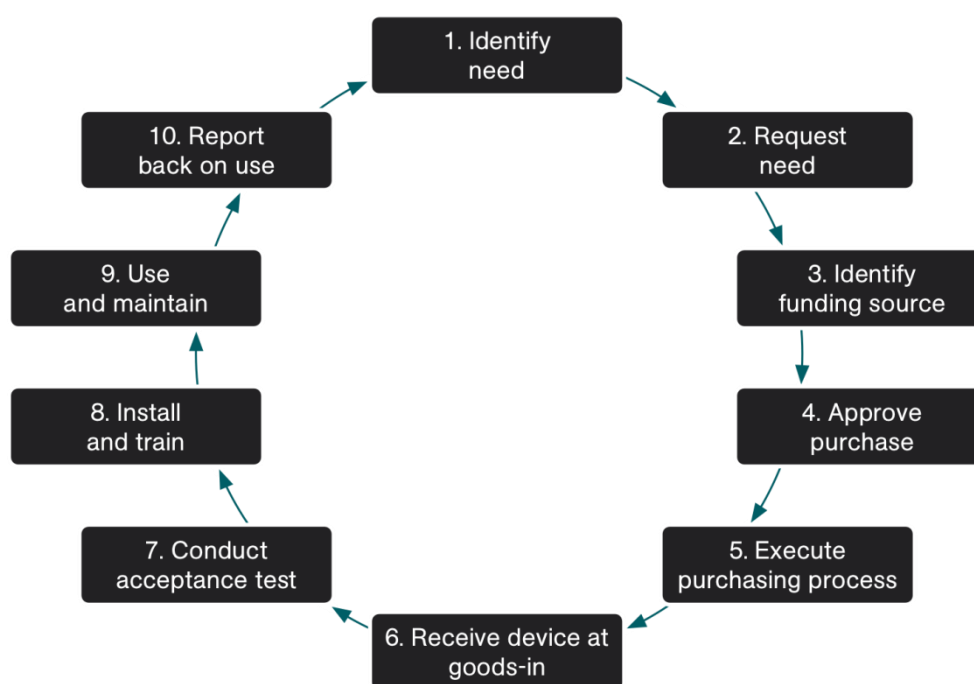


Figure 16: Overview of the main sub-processes that form part of medical device purchasing

The development of these diagrams are described further in Chapter 6 as it is these process maps created with Trust A that led to an eventual risk analysis workshop to elicit potential risks in the whole purchasing process. Figure 16 is simply one example of how the various stages of the process can be clustered. The justification for including these particular steps form part of later analysis as described in Chapter 6.

While collecting the data needed to create the above diagram, various observations were made about the process knowledge scattered throughout the organisation. The first

observation was that there seems to be a variety of process knowledge among the different stakeholders, mainly relating to their particular role or place in the system. This is especially true of the end-users who initiate the purchase:

The end user or requisitioner will not know if its capital or revenue, nor if it's something that's been ordered before - no way to capture this information/knowledge base due to changing staff too.

ENG.snr_A

Departments with more experience and those that have been through process before know that device is capital/revenue and know of the process

FIN.proc_A

In particular, all stakeholders that held a role in EBME claimed to have a holistic overview of the process. They also claimed that they hold most of the knowledge base of the whole medical device purchasing process. Roles such as budget holder and requisitioner also were mentioned as those played by end-users, as identified earlier:

Knowledge base of how all this works lies mostly with us, a handover would be required if we left.

ENG_A

Budget holder can be: service delivery manager, budget holder - they check a) kit appropriate for their dept and b) can they afford it.

FIN.proc_A

Tiered stakeholder base for purchasing includes requisitioner, budget holder, and approver.

ENG_A

We don't have systems in place that are structured in committee terms or so all those areas are involved with me.

ENG_C

*At Procurement we check cost centre, expense coding, if authorised, the value of the order, preferred supplier or suggested supplier, price, check price with supplier
FIN.proc_A*

Another observation was the different understandings of the elements of equipment management processes present in the hospital. For instance, the presence of an equipment library, as an alternative to acquire particular types of equipment, is not known to all. In one Trust this knowledge seems to have simply evolved over time:

When the library was first started there was no formal agreement as to what the library's obligation was and what the wards' obligation was, so over the last three years there's been somewhat confusion and people... they're not quite sure what's going on so they develop their own rules, as a result equipment that leaves the library doesn't necessarily get put into the collection point... you might find equipment that's sitting in cupboards or obscure places which doesn't end up being circulated... eventually it turns up in medical electronics...sometimes a year later.

LIB_A

If you ask anyone in a Trust do we have a library they would say "no". But actually yes we do!

PHA2_D

It is not a surprise, therefore, that some participants see the need for understanding their own systems:

We just need to map our communication systems.

RISK_C

Communication routes (Stakeholder engagement)

Most of the Trusts showed that the roles for the various stages of the purchasing process can vary, but essentially narrow down to:

- The end-users at ward level (those who requisition for the device)

- The approvers of the requisition (which may have two hierarchies: the budget holder and, in some cases, another ‘final approver’)
- The EBME team (involved if a new framework or standard purchase is to be implemented; though in some Trusts they are always the ‘final approver’ as above)
- The procurement department (handling the administrative task or ordering the device from the supplier or completing the tender process)
- Goods receiver (this may be a separate bay part of the estates department or, in some cases, a medical-device specific bay dedicated to EBME)
- The electronics lab (usually part of EBME, in charge of asset testing the device and registering it before its use, as well as subsequently maintaining the device).

The stakeholders involved in purchasing come from different directorates within the hospital, and therefore are likely to have a different knowledge base and skills base, well as different managerial and clinical imperatives. Yet, in a given hospital, various roles can take on the role of ‘requisitioner’, ‘budget holder’ and ‘approver’ depending on their organisational hierarchy within the hospital.

Furthermore, during these initial interviews participants offered information about whom they communicated with, particularly while describing their particular process steps. Although not all relevant communication routes were explicitly sought out during these interviews, certain routes were indicated as being those used regularly. Such responses gave the impression that those responsible for ultimately maintaining the equipment and then training the end user to use it safely, may not necessarily be the ones involved in every decision. The following are attempts to diagram the communication routes as depicted in Trust A between the various stakeholders:

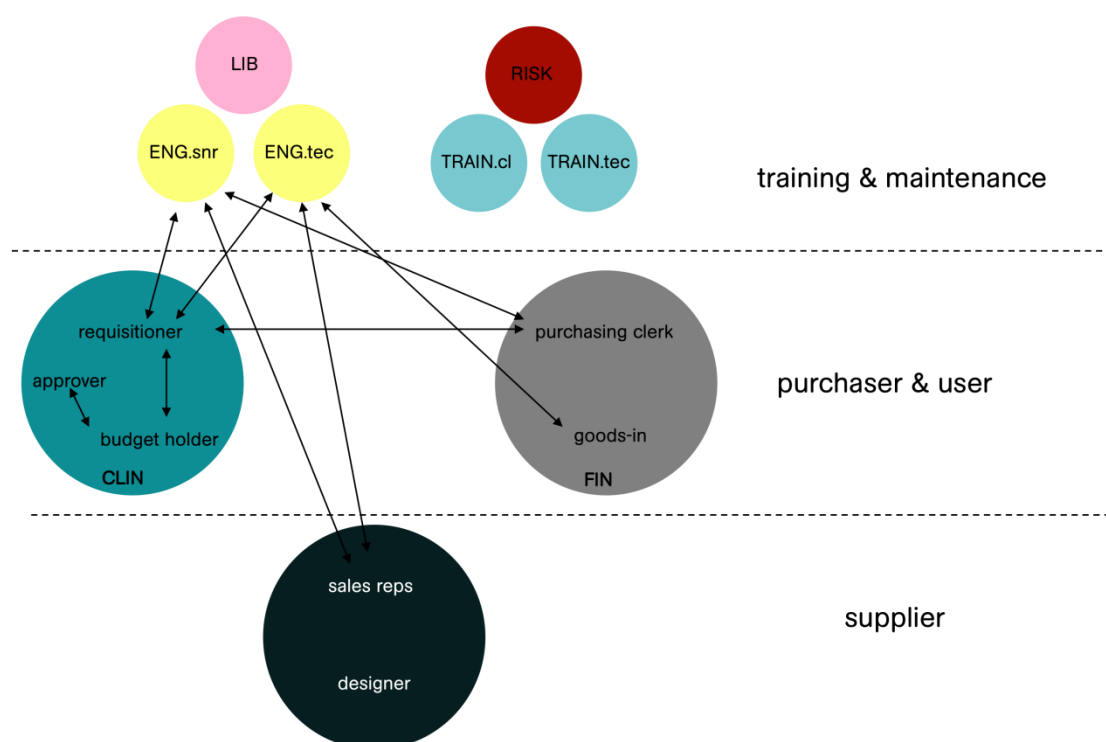


Figure 17: Major communication routes mentioned by respondents during Exploratory Studies for Trust A

Particularly in Trust A, major disconnects in communication and stakeholder engagement were expressed. These disconnects exist in other Trusts when buying devices that have pharmaceuticals as their consumables and yet follow a different purchasing route:

‘Goods-in’ have no contact with original order/requisitioners...Once goods come in, our involvement ends, we only know of lost equipment cos user will query it.
 FIN.proc_A

This is why we are taking this [the project] forward.. They [end-users] don’t know what risk is. Risks they don’t know in buying stuff.
 RISK_D

I standardise in purchasing process if its delivery of pumps or giving sets; I don't really deal with drugs. But sometimes it's part of the device or package.

TRAIN.cl_C

Issues of compatibility with pumps and drugs, is not thought through properly.

ENG_C

I don't know who makes decisions on what to buy and why they do not consult us.

ENG.clin_A

I was 'ish' involved in trial in the fact that I was aware of it but it was Procurement who would drive the tendering thing and Engineering might device criteria for the pump, not in consultation with training as such, no.

TRAIN.tec_A

Control Measures

Shown next are some sample quotes of how the process works and currently used controls, or the lack thereof. This is related not only to the lack of compliance with control measures, but to the absence of an overall process owner for purchasing, given that the responsibility resides within various stakeholder bases.

I don't know if it's about patient safety or about control procedures...they're loose enough for people to work around things.

RISK_C

There is no procurement subgroup because there is already a procurement process well-established in place. (Q: Who is in charge of it?) Who is in charge of it?... it is a process. So... you have to make a bid using that process. If you don't make a bid using that process you don't get your money... I don't think there is a single person responsible. The Medical Device Committee is chaired by the Medical Director

TRAIN.tec_B

If you can make sure they don't order things you don't want them to...You want to make it mandatory...People purchase "outside the process".

ENG.snr_C

(Someone) can still go out and buy something else... pharmacy is a bit like that...

TRAIN.clin_C

I think people order stuff by mistake.

RISK_D

Yes but there are some rogue behaviours on the sidelines.

TRAIN.clin_C

Even if controls are placed within the hospital, some comments suggest that suppliers also have a role to play in acting outside this system:

In the past reps have come in and tried to sell something.

TRAIN.tec_A

Pressures on process

A major challenge is the vast amount of demands on equipment management services:

The library exists because the demand for services varies from ward to ward. And this can vary at different times of year too.

LIB_A

There's not enough people to do all the repairs ... in [two mentioned Trusts] they had similar asset base to us and their medical electronic department had 14 people working (we have 7), plus 10 in anaesthetics (we have 3).

ENG.clin_A

Up until recently we've probably got about 800 requests in the last 6 months that we haven't been able to supply.

LIB_A

Where are we pharmaceutical purchasing-wise?... well, there is a lot of fire-fighting!

PHA_D

We handle 1000s of purchase orders in general.

FIN.proc_A

Inventory management

Another major challenge for most Trusts is the auditing of all their equipment, shown by sample comments:

Our data is not complete - we would have to know every time a piece of equipment is used on a patient and then transferred to another patient and we're not capturing that information, all we're capturing is information on requests that are put into the system and whether we can supply or not, but we don't have the actual usage on the devices because, as I said, the pickup area on the wards, they put the equipment there, but they can take it away from there as well and use it on another patient, so I've got no idea of the duration of each loan.

LIB_A

We did an observational audit of all critical care units.... and on all of our Trust's network. And 85% had problems. That was in 2005.

PHA_D

There is a loose control for purchasing infusion devices that goes into the community.

ENG.snr_C

So this device [pointing to database screen] went to Main Theatres in 2005 and has yet to be returned... so we've got a piece of equipment that's been up in medical electronics for 11 months.

LIB_A

Goal alignment

The respondents also displayed some dissatisfaction on how different groups in the decision-making process have different priorities, especially in terms of managing budgets:

A lot of the time we cannot do what we want cos the budget is not there, but that might be changing as people focus on clinical quality.

RISK_C

Lots of potential cost benefit analysis could benefit legislation... but that doesn't take place.

TRAIN.tec_A

I put in a request to get that equipment purchased but unfortunately the Trust is not forthright with giving us money. It's been relieved as we've got an injection of £350000 to buy equipment... but that is to replace items that were faulty and retired, but there's no funding to replace faulty items that can't be re-used, so stock is depleting...

LIB_A

4.2.4 Potential Risk and Areas for Improvement

This last sub-section served to question firstly the need for improvement, and to also discuss ways in which the stakeholders themselves viewed a better purchasing scenario for medical devices.

Vignettes of inefficient purchasing decisions

The first set of comments included here highlight further pointers and issues arising with purchasing decisions directly from respondent's comments:

We have a fluid chart, there's supposed to be a standard fluid and people are supposed to have observations done hourly on fluids, so if they're having an infusion either through a pump or under gravity, you're supposed to have observations of it, but what happens is that people will just write how much is in the bag and then put an arrow down to when it's supposed to go through, not

actually looking at how much has gone through each hour....no one ever uses the volume display because there's no requirement, it's not written into procedure for them to actually use the volume infused display!

TRAIN.tec_A

I've sometimes waited around a whole day for supplier to deliver at certain time.

ENG.snr_A

Approval of PPQ can take weeks if sitting on somebody's desk.

ENG.snr_A

Lots of delays, days to weeks varying on resources in my team and that of requisitioning department, lots of backwards and forwards. We also question requisitioner or engineering checking if PPQ available or question supplier who direct us back to engineering.

FIN.proc_A

This was what we purchased, we only purchase that type cos our syringe pumps go down when calibrated... The ones that aren't calibrated the end-users have... they don't know what rate to set for delivery. For some strange reason when they run out of them, they substituted for that syringe. We only found out when end-users made errors. Not cos they didn't know how to use it, not cos it didn't fit... But cos when they tried to fill it, the middle bit came out. Our end-users couldn't even fill the syringe. They didn't get to use them.

ENG.snr_C

There was a case recently where somebody was taking blood pressures and all the readings were low, it was a dodgy machine, either the cuff was broken or something else, but rather than query it or check it manually or highlight it to the nurse in charge she just wrote down the numbers and moved on to the next patient, so all these patients had low blood pressure according to the machine and it was kind of this trust of writing it down that actually questioning it...

TRAIN.tec_A

There are also examples of good practice in specific ward areas:

[Trust A] has a Point of Care Testing (which includes blood glucose measuring and arterial blood gas measurement) devices are managed by Biochemistry. The blood gas machines have been set so that a valid identification number is required to be able to login and use the machine and the staff ID badge number will be used for the purpose. Validation of the number requires attendance at initial training and then update training each year or so and I believe there is the option of refusing access if training has not been attended and recorded in time.

TRAIN.clin_A

A similar system has been introduced as part of the blood tracking system that has been introduced recently. Staff with barcodes on their ID badges have attended training in the BARS blood system and are able to scan documentation, gain access to the blood fridges and scan the units themselves. Absence of a barcode precludes following the correct procedure for removal of blood from the blood fridges and alarms will be triggered if the emergency procedure is followed.

TRAIN.clin_A

Identifying an ‘ideal case scenario’

Participants were asked to write down three criteria for the ideal ‘purchasing for safety’ scenario on post-it notes. During the next exercise, the workshop facilitators clustered these responses into categories for a new maturity grid or purchasing for safety framework.

Using the categories emerged from the clustering exercise resulting from post-it notes, a blank maturity grid was put up for discussion. Rationales for levels of maturity were discussed. This included a codification of suggested practices (using framework building on literature, anecdotes, and summary), and feedback was asked for the development of model for a purchasing perspective.

Participants were asked to prioritise 4 sets of practices into a 4 x 4 grid, along with rationale for maturity level. The results of establishing an ‘ideal’ purchasing for safety scenario, or the benchmark towards which Trusts can aspire to; is shown and summarised

in the following two diagrams: Firstly, a simple high level sketch of the steps needed for ensuring safe equipment in hospitals; and secondly, what resources are required locally and nationally in order to maintain such steps.

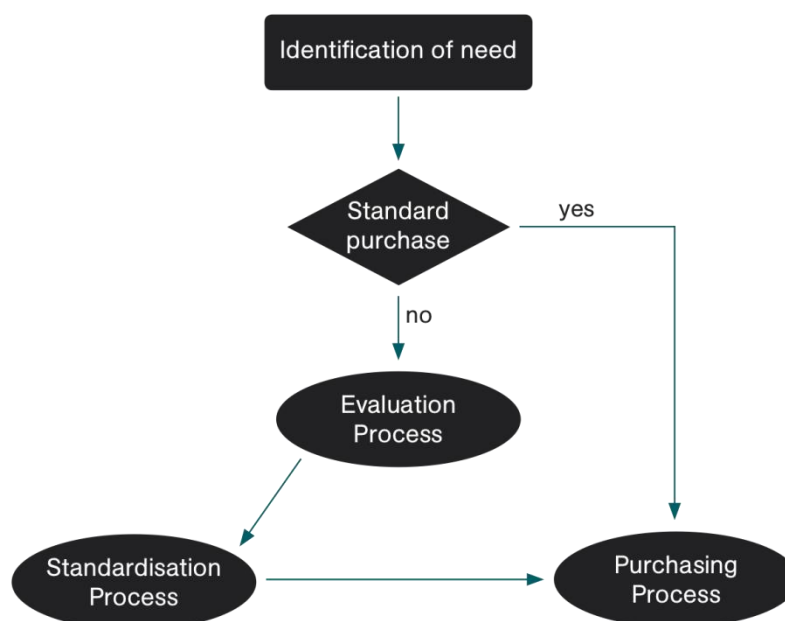


Figure 18: Stakeholder-developed diagram of ‘ideal’ route for purchasing medical devices

This basic diagram shown in Figure 18 shows how an ideal route should look like according to the participants. Both Standardisation and Evaluation refer to terms used widely by the NPSA (Lowe 2006) and adopted by the healthcare community (Pauley 1980a; Pauley 1980b). To standardise is to decide on a particular device model for use within a ward or throughout the hospital. A device evaluation process usually precedes this standardisation (in an ideal scenario) and refers to the process of testing out a selected number of device models before its selection. Evaluations can take on various forms in hospitals – from a single ‘show and tell’ day where end-users (mainly nurses and clinicians) are invited to attend and assess the suppliers’ devices, or it can incorporate a trial for a set period of time when the suppliers provide the hospital with their device for use. These various forms and their challenges were investigated further in both Trust A and E and described in Chapter 6.

However, a selection of comments were collected that related solely to the characteristics of an ideal process, along with its potential challenges.

Ideally, equipment library should manage all revenue devices, but doesn't.

ENG.snr_A

Hopefully in future we will have a catalogue to deal with requests.

FIN.proc_A

The utopian would be a customer service point for all the wards, the wards would not necessarily, they would have equipment that would be on their wards, ...so if anyone wanted to know about any equipment or anything like that they'd use us as a first point of contact and we would act as a bit of a buffer zone for medical electronics. But that would depend on all the three elements, us, medical electronics, and the ward working towards a common goal - and at the moment we don't.

LIB_A

When the Trusts merged, we had to re-standardise.

ENG.snr_C

You need flexibility but within any standardisation.... When we standardise, it must be hand in hand with training programme. Our staff move between clinical areas.

PHA1_D

The problem with standardisation is how do you achieve it? Let's say 1000 beds and we want 500 pumps, each costs between £1500 and £4500 depending on version... but they don't officially exist on capital asset register cos it costs less than £5000. But to standardise you need £100,000 all at once and that money doesn't actually officially exist. But cos total cost is over £30,000 it still goes out to tender - which means trial at least 3 devices before we can do it.

TRAIN.tec_A

We ended up telling wards that if you are buying a syringe pump you must buy this one.. .which actually made things worse for me because now I had to teach three pumps on a daily basis rather than just two as we're still using them... But, standardisation is a good idea - makes my job easier!

TRAIN.tec_A

Although standardisation is welcomed and its concepts understood among the purchasing community, the challenges mainly refer to the allocation of appropriate funding for standardising. The challenge faced is that much equipment that could be standardised does not fall into capital expenditure threshold, and yet the amounts needed to secure these contracts would require sums within capital ranges. The engagement of Board Level and Management for such decisions are required, but this means even more importance on defining the requirements for the new device type and developing a case for its clinical benefit and value.

While speaking of the ideal case scenario, common themes among the three Trusts emerged for individual, collective and national support, which would encourage good practice such as standardisation and evaluation. The main common areas for support needed were identified as those in Figure 19:

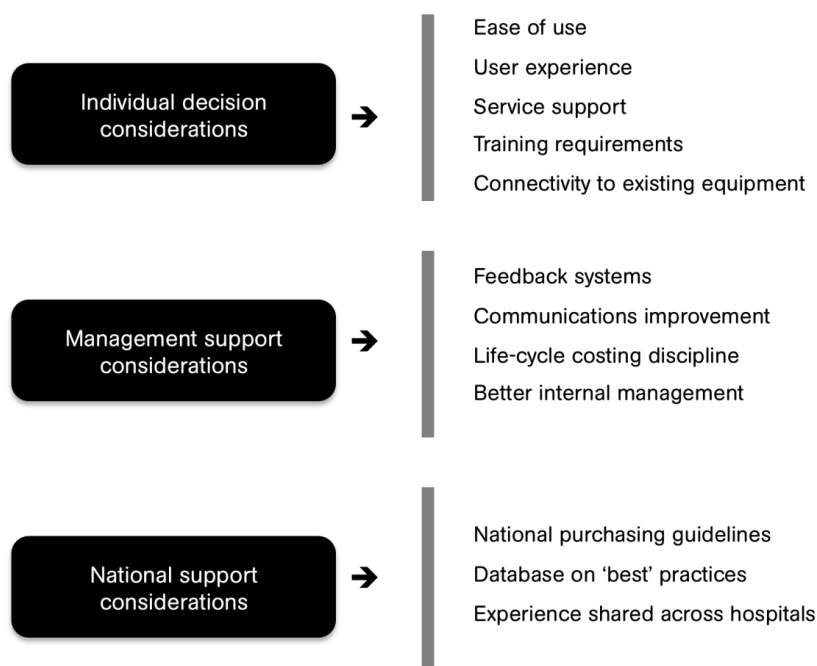


Figure 19: Stakeholder-developed list of considerations needed to improve purchasing practice

Although very theoretical and sketched out within the space of an hour in these workshops, the thoughts brought forward resonate with some of the recommendations for good practice suggested in the literature. Although national support is not within the remit of this research, the individual and management support will be areas considered for improvement measures in later discussions (Chapter 6 and 7).

Adopting improvement measures: Trial of MAPSAF tool

This final exercise in the workshops involved the use of Manchester Patient Safety Assessment Framework (MAPSAF) to elicit cultural issues and attitudes towards achieving purchasing for safety. As emphasised in the description for MAPSAF, this is not a benchmarking tool but is mainly used as a means of self-assessment. The matrix used is available in Appendix I.

This exercise was conducted in a slightly modified manner to the standard or intended procedure. The participants in the workshops were asked to imagine themselves as a ‘purchasing team’ to gain the ‘purchasing perspective’ on their maturity with regards to patient safety practices in their daily work. They also were asked, if possible, to give an assessment of what they felt their management organisation would score on the same matrix. A few reflections on the process of conducting this exercise are as follows:

- Trust B was the only one that had previously conducted a MAPSAF assessment on their own and so the results of this exercise could be compared to those results. Trust C only managed to assess itself as a purchasing team, and Trust D completed both an organisational and purchasing assessment.
- Participants expressed difficulty in imagining themselves as a purchasing team as required to complete the exercise. As noted earlier, while there may be a suggested regular set of stakeholders involved in purchasing decision-making, they still belong to different directorates within the hospital, hence would not necessarily consider themselves a team.
- The format of the maturity grid in the original MAPSAF (see Appendix I) involves descriptions of various stages in the maturity scale rather than the use of a Likert Scale. Participants expressed preference for a Likert Scale.

- Furthermore, MAPSAF was not known to all participants, even if their Trust had already completed one previously.

Some of these sample quotes are shown below:

Well, different groups will allocate differently. I mean risk management group will say we are D, but... in pharmacy or procurement we may think we are C or D...but in actual fact as an organisation we might be much lower.

TRAIN.clin_D

I think actually that some parts of Trust are running at D when it comes to purchasing, I would say, there is more, sort of D-ish behaviour than A or B if we are talking about the team.

RISK_C

I think it might be B then. We don't have a risk based procurement training programme.

PHA1_D

Overall, the main difficulties in using this tool in this quick exercise were the absence of a true purchasing 'team' that is responsible for assessing maturity with regards to purchasing, and the difficulty in applying some of the wording to a purchasing for safety context. However, the exercise itself, that is to say, the process of assigning a level of maturity or competence to a task or a set of criteria, was easily followed. The potential for a future design of a capability or maturity tool was recognised, but this involves the initial stages of assessing its requirements as completed in the rest of this study.

4.3 Study of Medical Devices

Having examined over the stakeholders' views in the last two sections, these next third set of findings summarised here relate only to medical devices themselves, and their handling within the purchasing process. In this section of the Exploratory Studies, the potentially different views of stakeholders involved in the device supply chain were explored. The

experience of each stakeholder with the device, the factors that affect its design, its selection, and finally, its use, all form part of the underlying context for this study.

4.3.1 Observations from Devices Sales Representatives

A showcase was held at Trust A to compare different competing suppliers of patient monitors. This is one example of an ‘evaluation’ that can take place in a hospital, before the actual trial takes place between selected models. Clinical staff as well as technicians from the EBME department were invited to visit each stall throughout the day; and submit an evaluation form with their opinions on the various devices viewed.

Although mostly clinical staff were invited, the event was poorly attended. A few senior clinicians were present (those with a personal interest in the devices they were to use), as well as the nurses who regularly used them. EBME expressed their disappointment with the turnout. The evaluation forms served as a guideline for questioning, but participants largely asked their own set of subjective questions – drawing on their experience with errors with devices and usability issues. Whether or not these had been reported or entered a record in their internal systems was almost irrelevant.

The suppliers themselves were very enthusiastic, energetic and were keen to point out especially the following features:

The type of applications for their monitors (mobile/transport, recovery)

Features such as mobility and transportability

Battery life and backup

Robustness (“Watch the way I drop it to the floor and it doesn’t break”)

This particular part of the supply chain is an interesting group to examine; why they point out what they point out, and whether or not this is what the purchasers need to hear – and, ultimately, whether this leads to better, safer, devices being bought – are questions to be answered. It seems there are some similarities but not entire cohesion between the expectations of purchasers and the comments made by suppliers. Some sample comments are listed below:

For new device expect it on market for at least 2 yrs.

ENG.snr_A

We had problems with [Brand name] pumps.... But that is more about how people tried to use it. Unless you have something inherently designed in the product that makes it flawed, it's more about how it's used and not designed.

RISK_C

CE process approval doesn't mean anything...

ENG.snr_A

Given some of these differences in expectations, in the next set of data collection (Results II, Chapter 5), stakeholders are asked what their drivers are for individual purchasing decisions, in line with the first set of research questions. Some of the above aspects such as usability and CE marking are covered in the questionnaire, introduced in Section 5.2.

4.3.2 Preliminary Analysis with Engineering Design Researchers

In order to reflect on some of the concepts gathered so far in relation to medical devices, a workshop was held with researchers from the Engineering Design Centre on exploring different features of products that may affect purchasing decisions. Participants at the brainstorming session were asked:

- What are manufacturers' drivers and incentives for designing for Patient Safety?
- Who is responsible for patient safety?
- What are the drivers for designing for safety in different stakeholder groups?

The workshops did not provide final answers to the questions, but they did lead to questions that needed answering before those above could be answered:

Who is responsible, the manufacturer/designer, purchaser, or end-user? If this is a collective effort, do we act as if it is a collective responsibility?

To what extent should/can a patient understand risk? Does this depend on the patient's education, or on the type of device/area of clinical practice?

The main discussion, therefore, centred around stakeholders, from the suppliers, to purchasers, to end-users and patients. This was an attempt to brainstorm ideas on the responsibilities that each of them have in the supply chain. The participants collectively helped draw Figure 20 below for discussion, based roughly on the original diagram presented in Figure 15:

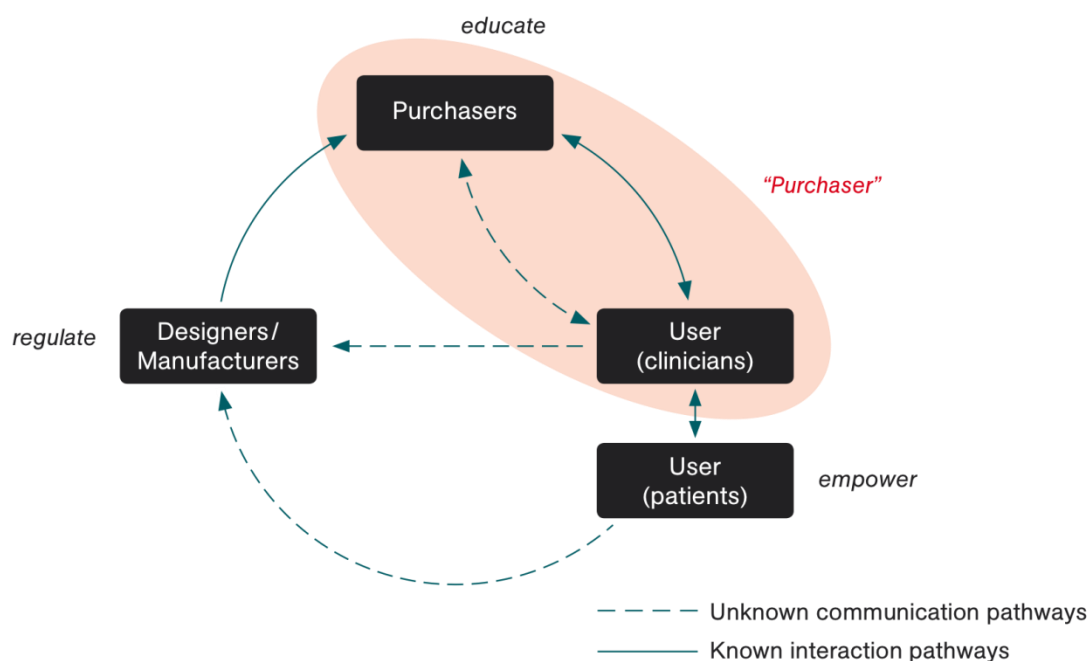


Figure 20: Adaptation of original device supply chain to discuss roles of various stakeholders

The drawing started with three main stakeholder groups: purchasers, suppliers and end-users (defined as clinicians and operators of devices). Those receiving the service, i.e. patients, were then added, and it was noted that ‘purchasers’ actually include clinicians as well as purchasing administrators. This workshop highlighted the potential role that end-users (operators) and care receivers (patients) play, and it was noted that they might also play a part if they are empowered to take ownership of medical device selection processes. This may of course apply more to operators unless we refer to home-use devices or patient-specific devices such as dialysis/infusion devices. In these cases it is the patient that has some say in the type of device they feel comfortable using.

It was also pointed out that the main drivers for suppliers are the regulations placed upon the device design, with a suggestion that this is even more influential than hospitals purchasing power. It was agreed that in general, this pressure works well and ensures certain safe design constraints are adhered to. Those who purchase, however, may require further education drivers to recognise features in device that transcend these regulations. Potential research questions were therefore established:

- What do purchasers need to look out of beyond regulatory ‘safety’ marks?
- How can purchasers be both facilitated and educated to note such features?
- How can end-users (operators) of devices be empowered to contribute to purchasing decision-making?

Some of these considerations were taken into account in further interviews and elaborated in the discussions in latter chapters. What follows is a discussion on the devices chosen for this study, and the research and analysis that took place to make these choices.

4.3.3 Choice of Devices for Study

Given the variations in products and in device features, the choice of devices to focus on for this study required some thought. One way of selecting the device is to look at those with the most mention in terms of device error; i.e. those that have received ‘device alerts’ from the MHRA. The MHRA has provided alerts for the following (MHRA):

2002a In vitro diagnostic devices (does not come into contact with patients but if used incorrectly, the misdiagnosis can have harmful implications)

2002b IVD at point of care

2002c Decontamination of endoscopes (has shown infection before, though hard to detect back to endoscope, “highest risk” of serious clinical infection)

2002d Benchtop Steam Sterilizers

2003 Infusion Systems

2003 (05) General

2003 (06) Community equipment loan stores

2005 Reporting incidents, importance of.

Staff engaged so far in the Exploratory Studies have also provided some guidance about the types of devices that would require most investigation in reference to purchasing and safety. These various classification methods are explored below:

Device complexity

It was suggested to study equipment with varying levels of complexity – internal workings complexity, since this is one major differentiating factor when it comes to servicing and repairing in-house. An ECG machine, for instance, is considered complex and varies in design if it is for home use or for hospital use. Patient monitors are not too complex but used everywhere and present different problems.

Unit cost: capital or revenue-funded

Another major observation for this stage was the different routes each device can take even in the same hospital. In particular, members of Trust A pointed out these various product routes, depending on the device cost, where it is used, where its funding comes from, and so forth.

The general practice with revenue devices is that orders are ad-hoc, standardisation occurs with capital expenditures/devices that are managed by us/ have central management/library too.

ENG.snr_A

MEC/Capital are where larger issues lie. Revenue seems fairly straight-forward except for Goods-in issue.

FIN.proc_A

Capital items we get to see mostly, but revenue ones sometimes we wonder why they purchased that?

ENG.clin_A

Only capital programmes are managed by device committees.

ENG.snr_C

But not all capital equipment is approved through MEC - and I've never understood why certain capital expenditure goes through MEC for approval and some don't.

FIN.proc_A

Procurement strategy [is] dependent on value of the order

ENG.snr_A

These divisions were expressed as obstacles to obtaining funding for much-needed new purchases, similar to the thoughts presented while discussion standardisation of devices under the capital threshold.

Consumables

Consumables are usually provided in a contract with the devices, but may also be a completely separate set of purchases initiated and controlled by individual wards. Issues with connectivity arise if these are not coordinated, as expressed by some participants:

But when it comes to consumables that come with devices we cannot make a decision on them cos it comes with the contract.. It is very clever of them.

TRAIN.clin_C

Consumables get managed by individual wards

LIB_A

Some hardware comes with consumables but wards don't necessarily stock them

LIB_A

There needs to be a better link between pharmacy and purchasing which seems to be missing.

TRAIN.clin_C

Mapping device routes varying in funding routes and consumables requirements would therefore constitute interesting variations.

Some of these features were collected and also presented to workshop participants at the EDC. Firstly, the participants were asked to come up with a list of features that potentially could contribute to ‘unsafe’ devices, which ended up as:

Unreliable

Unpredictable

Sterilisation difficulties

Confusing user interface

Wrong dosing

Electrocution/burning

Lifecycle issues

Interaction with the environment

Tangling/strangulation

Cross contamination

Redundancy

Distracting features

The group was also given the following list of features that may be considered in relation to purchasing and patient safety. Those in red were the ones that the majority ticked as ‘relevant to consider to the purchasing of devices in terms of patient safety’. The initial list was put together through a brainstorm session with fewer EDC members, but this final selection was a majority vote at the workshop.

Cost	Unit cost Cost incurred annually
Purchasing process	Type of contract Time to purchase Frequency of purchase Consumables/unit purchase
Clinical	Clinical criticality Distribution in hospital Accessibility to patient User group
Usage	Frequency of use Risk (regulatory guidelines) Complexity of use Connectivity to other equipment Mobility
Maintenance	Incident reports Training required
Glamorous' features	Number of device alerts Novelty Brand/image Whizzy features Aesthetic appeal
Design/Supply	Complexity of design Suppliers available Home use

Table 13: Features most relevant to medical device specifications for purchasing (in red)

This provided a good starting point for the future questions:

Are such features considered? If so, in what format and with what degree of importance?

If some of the other features are considered, for what reason, what are the motivations for choosing some characteristics to be more important than others?

It was clearly an area for further investigation and therefore chosen as part of the analysis in the interviews. It also helped decide which devices to take as case studies. Combining

the observations so far, it was therefore decided to choose devices using the following criteria:

- Representation from devices which are funded from capital and revenue streams (this would affect ‘cost incurred’, and ‘type of contract’ as above)
- Devices that are both distributed around the hospital (i.e. purchased for the hospital in bulk), and limited to one particular ward/clinical specialty (this would include ‘type of contract’ and potentially ‘suppliers available’)
- Devices with varying degrees of complexity (this would incorporate different ‘training required’ and potentially the degree of risk)

The final choice of devices used in the examples presented in the results in Chapter 6 were:

Thermometers

Infusion devices

Renal dialysis

The choice for these was partly opportunistic, but also took into account the diversity of features introduced in this section. The following table elaborates on the way these three devices vary, using parameters arising from the above discussions that were possible to obtain within the study.

	<i>Thermometer</i>	<i>Infusion pump</i>	<i>Dialysis machine</i>
<i>Costing model/contract</i>	Consumables charged, device 'free' (usually £285)	Over £400	Various (over £5k threshold)
<i>Capital/Revenue funded</i>	Revenue	Revenue	Capital
<i>Consumables & extra equipment</i>	Applicators, wipes	Syring driver, giving set, pharmaceuticals	Chair, table, infusions/pharmaceuticals
<i>Usage & lifetime</i>	4-5 per day per patient	Various (varies per ward)	About 90 patients/year, running full-time
<i>Distribution in hospital</i>	High (all wards)	Medium/High	Low (specialised unit)
<i>Risk (regulatory class)</i>	Class I/II	Class II	Class III
<i>Training required</i>	Low	Medium/High	High
<i>Suppliers available</i>	Various	Various	Specialised

Table 14: Comparison of features for selected device case examples

4.4 Analysis of Learning from Exploratory Studies

These Exploratory Studies help identify and expand on the main factors influencing current practice in medical device purchasing, especially those that may be responsible for inefficiencies in the process. It is therefore hypothesized, at this point, that due to some anecdotal evidence from the Exploratory studies and findings from literature, that these factors can also influence the healthcare delivery service. Furthermore, it was established that further research is needed in understanding the current communication and interaction pathways among purchasing stakeholders.

4.4.1 Factors influencing Current Practice

The factors influencing current practice are discussed in light of anticipated research questions to be constructed for the rest of the study.

Stakeholder definition, Stakeholder engagement

During these preliminary findings, a more holistic understanding has been established of who the purchasers are. The other stakeholders involved were also introduced from the maintenance and training staff. This gives some guidance as to the stakeholder domain that can form the boundary for this research.

Device knowledge & competence, Drivers & Resources for decisions, Process knowledge

However, the process knowledge for each person can vary from holistic process knowledge to a more specific view. The stakeholders also vary in skill, competence, habits, language and understanding of the different components of the purchasing process. All these could be investigated further to gain a deeper understanding of what may be motivating the decision-making process regarding devices.

Pressures on process, Inventory management, Goal alignment

Although a very generic perspective on the process itself for each hospital has been diagrammed, each one varies when examined in detail. Mapping of processes has already brought up challenges in the current system, including the auditing of equipment, the large demands on training and maintenance and lack of system controls. Appropriate stakeholder engagement in all parts of the process may also be lacking which can lead to poor adequate planning for equipment resources, and little support from management level stakeholders.

Control measures

General ownership and control of the process has been suggested to be lacking. The results also seem to show that there are variations in current practice due to unknown factors; these factors are to be investigated. They may be due to the product variations or the people involved in decision-making. External factors, such as policy drivers and the influence of the supply side are also part of the considerations that could be made.

Culture and mindsets

Lastly, while recommendations could be made for a more ideal process, challenges exist to reach such ideals that largely include the cultural barriers that need to be overcome with regards to both equipment ownership on behalf of the end-user, and management on those with more holistic process knowledge.

4.4.2 Factors considered for Improvement

A second set of observations relates firstly to suggestions arising from the stakeholders on how to improve current practice, the suggestions of which resonate with policy and guidance found in literature. Their appearance in this list is a testimony to the participants' perception that such measures are missing in current practice. By way of eliciting how participants may respond to improving on those measures, the MAPSAF tool was used as a way of assessing current practice in purchasing 'teams'.

Despite some consensus of how to improve current practice, challenges to improve the system exist:

- A degree of flexibility to standardise on device models is needed depending on ward needs
- The capital/revenue funding divisions creates barriers to achieving standardization
- Device trials or evaluations are usually needed with key individuals needed to drive process.

4.5 Summary of Conclusions from Exploratory Studies

The factors that influence current practice from both the literature and these Exploratory Studies were found to include some of those identified in the literature as seen at the beginning of this chapter, in Table 10.

It can be established from these initial gleanings on purchasing practice that challenges exist and are acknowledged by all stakeholders. The exact nature of these challenges are to be investigated in further detail, as it cannot at this stage be ascertained how these challenges relate to or affect the safe delivery of patient care.

The next three chapters each serve individual purposes:

Chapter 5 – Results II: Observations of Current Practice

This is closely linked to this chapter, where the very same concepts and topics explored here are now investigated but with more focus. The methods employed are therefore more structured (semi-structured interviews and questionnaire).

Chapter 6 – Results III: Case Examples

Serving as examples of current practice, this chapter highlights particular instances where purchasing practice has had an influence on healthcare delivery or has displayed elements of poor practice.

Chapter 7 – Synthesis and Framework for Improvements

Drawing on the elements of good practice, this chapter suggests measures that could be used to improve on current practice and proposes a framework for implementing these improvements.

As described in Chapter 3, each of these subsequent chapters refer more specifically to the research questions.

Chapter 5

RESULTS II:

Observations of Current Practice

This second set of results corresponds to the first research questions, with the aim of obtaining more empirical evidence of current practice in device purchasing. These results correspond largely to the results from the questionnaire developed following the Exploratory Studies, as well as additional interviews gathered while at Trust A. The Exploratory Studies have already established who the stakeholders are; but these stakeholders' roles, their resources used in decision-making, and adopted control measures were investigated in more detail in this section. The results presented in Results II answer general questions on current practice, followed by an analysis to decipher whether such practice can lead to risks to the service and whether it is inefficient.

The addressed research questions are repeated below. It was mainly intended to find those shaded in grey, but some responses contributing to the other questions boxed in grey were gathered as well.

Research Sub-Questions

1. What is current practice in medical device purchasing?

Who are the stakeholders and what are their roles in purchasing?
What type of knowledge and competence do these stakeholders have?
What are the resources and drivers for purchasing decisions?
What other factors influence current practice?

2. (How) does current practice present risks to healthcare delivery services?

What challenges and risks are present in current practice?
How are the factors of current practice different from good practice?
How do these factors impact the healthcare service?

3. Where are areas for improvement on current practice?

How do the stakeholders themselves view improved practice?
How can factors in current practice be managed towards improvement?

The results presented in this chapter mainly answer the questions in Research Question 1 above. However, given some of the inductive analysis that takes place in the later discussions, parts of the arguments that help answer question sets 2 and 3 are also addressed. An overview of the factors noted in this study of Current Practice is presented first, followed by the methods for obtaining these results. The details of the results themselves are then presented, culminating in an analysis of these results that lead to the second set of results in Chapter 6.

5.1 Overview of Current Practice

Table 15 gives an overview of the factors that are considered in this section of the analysis:

<i>Factors considered</i>		1	2	3
		<i>Current Practice</i>	<i>Risks to Healthcare</i>	<i>Improvement Areas</i>
<i>Stakeholders</i>	<i>Stakeholder definition</i>	✓		
	<i>Device knowledge & competence</i>	✓	✓✓	
	<i>Process knowledge</i>	✓✓		✓✓
	<i>Stakeholder engagement</i>	✓✓	✓	✓✓
	<i>Resources for decisions</i>	✓	✓✓	✓
	<i>Drivers for decisions</i>	✓✓	✓	✓
	<i>Culture and mindsets</i>	✓✓	✓	✓
<i>Process</i>	<i>Process description</i>	✓✓	✓	✓✓
	<i>Control measures</i>	✓✓	✓✓	✓✓
	<i>Reporting and feedback</i>	✓✓	✓	✓✓
	<i>Pressures on process</i>	✓	✓	✓✓
	<i>Inventory management</i>	✓✓	✓✓	✓✓
	<i>Goal alignment</i>	✓✓	✓	✓✓
<p><i>Key to Data Sources:</i> ✓: From Literature (Chapter 2) ✓: From Results I (Chapter 4) ✓: From Results II (Chapter 5)</p>				

Table 15: Data gathered from Results II (Observations of Current Practice)

5.2 Methods for Results II

From the main set of methods described in Chapter 4, the specific methods used in this set of results, Results II, were:

- Telephone Questionnaires (at Trusts B, C, D, E). See Appendix II for copy of questionnaire.
- Triangulation with previous semi-structure interviews and continued observations at Trust A

The exact source of the set of data for the telephone questionnaires and the original stakeholders observed in all Trusts is shown in Table 16. Each respondent has been grouped into four categories, which correspond back to the original stakeholders identified in the Exploratory Studies: Engineering, Clinical, Training or Risk. The table shows the four categories into which each respondent was grouped.

Location	Person(s)	KEY
Trust A	Head of Clinical Engineering	ENG.snr_A
	Head of Procurement	FIN.proc_A
	Medical Electronics Services Manager	ENG.tec_A
	Equipment Library Services Manager	LIB_A
	Device trainer, Clinical Skills	TRAIN.cl_A
	Head of Medical Physics and Clinical Engineering	ENG.med_A
Trust B	Patient Safety and Risk Manager	RISK_B
	Medical Device Training Coordinator	TRAIN.tec_B
	Chief Pharmacist (medicines management and pharmaceutical services)	CLIN.pha_B
Trust C	Clinical Risk Manager	RISK_C
	Chief Pharmacist for Trust	PHA_C
	Consultant Clinical Scientist, Head of Clinical Engineering	ENG.snr_C1
	Clinical Scientist, Deputy Head of Clinical Engineering	ENG.snr_C2
Trust D	Medical Device Coordinator, Standardisation and Training	TRAIN.tec_D
	Chief Technician for Critical Care and Theatres/Technical Services Manager	ENG.tec_D
	Directorate Pharmacist for Critical Care and Anaesthetics	PHA_D1
	Senior Clinical Pharmacist (ICU and Theatres)	PHA_D2
	Associate Director of Clinical Governance, Risk Dept Manager	RISK_D
Trust E	(Clinical) Trainer, Clinical Skills	TRAIN.cl_E1
	Consultant Cardiac Anaesthetis	CLIN.doc_E
	Servicing Manager	ENG.tec_E1
	Clinical Nurse Specialist (Acute pain)	CLIN.nurs_E1
	Management Nurse Specialist (Acute, Oncology, Palliative Care)	CLIN.nurs_E2
	Clinical Manager (nursing background)	CLIN.nurs_E3
	Clinical Specialist	CLIN.nurs_E4
	Clinical Nurse Specialist (Acute pain)	CLIN.nurs_E5
	Education Coordinator	TRAIN.cl_E
	Medical Physics Technician	ENG.snr_E
	Senior Practitioner, Clinical Skills Coordinator	TRAIN.cl_E2
Head of Clinical Engineering	ENG.snr_E	

Table 16: Source of data for Results II (Observations of Current Practice)

It must be reiterated here that all these respondents were chosen as part of the PASA project in the case for Trusts B, D, and C; and a separate evaluation project at Trust E. This implies that most of them were selected due to their involvement in the Purchasing for Safety project whose focus was on infusion systems purchasing. However, their answers to the questions were chosen only when respondents referred to 'general medical device purchasing'. For this reason, the results are presented not as direct responses to the questions asked, but as responses clustered under particular topics, which correspond to

the research questions. The questionnaires served as a guide for interviews, but the method was strictly semi-structured; the respondents were given the freedom to comment around the subject. Furthermore, in order to present the results as more generic indication of medical device purchasing, as opposed to specific infusion device purchasing, the data was analysed in conjunction with previously collected data at Trust A in the Exploratory Studies.

5.3 Factors affecting Purchasing Practice

The findings are divided into the three categories as addressed in Table 15, and are discussed in their groupings: stakeholders, decision-making factors, and other elements of the purchasing process.

5.3.1 Stakeholders

Less emphasis was placed on characterising stakeholder in this part of the study due to the data already existing from the initial Exploratory Studies to characterise stakeholders. This section mainly comprises of the roles of the stakeholders in the purchasing process, and hence their engagement in the process.

Stakeholder Roles in Purchasing Process

These results correspond to the responses to the very first section in the questionnaire (see Appendix II). Interviewees were asked to indicate the particular steps in which they took part in the purchasing process. As a frame of reference, an initial role assignment table was drawn up based on the observations made previously at Trust A. This original list is shown in Table 17:

Roles in the purchasing process	Key to Stakeholders	
<ul style="list-style-type: none"> ■ Monitoring pumps administering injectable medicines ■ Identifying that injectable medicine is missing from unit or ward ■ Identifying that pump or syringe drive is missing from unit or ward ■ Filling in a requisition form ■ Signing off requisition form 	} <i>Ward level clinicians or nurses</i>	
■ Choosing which device to purchase		} <i>Department of Clinical Engineering</i>
■ Trialling of new products		
■ Authorising or signing the PPQ for trust		} <i>Finance/Procurement</i>
■ Obtaining terms of contract from supplier		
■ Placing the order with suppliers		
■ Picking up the orders from goods in	} <i>Department of Clinical Engineering</i>	
■ Conducting acceptance tests on new devices		
■ Entering devices into a maintenance/clinical engineering asset register	} <i>Finance/Procurement</i>	
■ Entering devices into a financial asset register		
■ Delivering injectable medicines or devices to the unit or ward requesting it	} <i>Training staff</i>	
■ Training for staff on device use		
□ Coordination of medical device purchase and use	} <i>General process steps, shared across stakeholder groups</i>	
□ Strategic contract planning and monitoring		
□ Purchasing pumps and devices		
□ Purchasing of syringe sets or consumables		
□ Purchasing pharmaceuticals		

Table 17: Responsibilities of different stakeholders in the purchasing process steps at Trust A

This was then used as a baseline to compare with other Trusts, as seen in Table 18. For Trusts B, C, and D, the study was limited to infusion systems, the clinical input was limited to pharmaceutical staff. For Trust E, most clinical staff were nursing staff.

Given the low number of respondents (not statistically significant) and the sampling strategy imposed (respondents were selected by the Trusts), the data serve as indicators of the conclusions made. Instead of providing numbers of those involved in the various parts of the purchasing process, the data is diagrammed and a pattern is displayed instead.

Roles in the purchasing process	Trust Code																									
	E	E	E	E	E	E	D	C	B	D	C	C	D	E	E	E	E	E	D	B	E	C	B	D	A	
Monitoring pumps administering injectable medicines	■	■	■		■				■																	■
Identifying that injectable medicine is missing from unit or ward			■				■	■	■	■																■
Identifying that pump or syringe drive is missing from unit or ward	■				■	■		■	■					■												■
Filling in a requisition form						■		■		■				■												■
Signing off requisition form				■			■			■	■		■													■
Choosing which device to purchase	■	■	■	■	■	■			■	■			■	■	■					■	■	■	■			■
Trialling of new products	■	■	■	■	■	■		■	■			■	■	■	■	■				■	■	■	■			■
Authorising or signing the PPQ for trust													■								■	■	■	■		■
Obtaining terms of contract from supplier							■						■	■	■						■					■
Placing the order with suppliers							■					■	■	■	■							■				■
Picking up the orders from goods in				■									■	■	■	■						■				■
Conducting acceptance tests on new devices														■	■	■	■									■
Entering devices into a maintenance/clinical engineering asset register														■	■	■	■									■
Entering devices into a financial asset register														■	■	■										■
Delivering injectable medicines or devices to the unit or ward requesting it						■	■							■	■											■
Training for staff on device use		■	■		■	■								■	■						■	■	■	■		■
Coordination of medical device purchase and use	■	■		■	■	■							■	■	■	■						■				■
Strategic contract planning and monitoring														■	■											
Purchasing pumps and devices		■		■						■				■								■				
Purchasing of syringe sets or consumables				■						■												■				
Purchasing pharmaceuticals				■			■		■																	

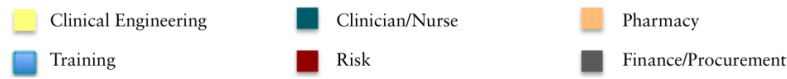


Table 18: Involvement of stakeholders in each step of the purchasing process for Trusts B, C, D and E, and their comparison to expected involvement as compared to Trust A (rightmost column)

The key observations pertaining to the stakeholders' roles were as follows:

- Involvement in the purchasing process, or the roles played in the purchasing process varies across Trusts.
- For some Trusts, those involved in training staff on devices used are already involved at purchasing devices selection stage, but not in all Trusts and not for all devices.
- In one instance, the training coordinator for skills in using devices has no say at all in purchasing decisions
- Despite an interest in device alerts and incidents, stakeholders from the Risk management department of Trusts are not involved throughout the process.
- Trust A displayed evidence of back and forth communication between their maintenance ('Engineering') and purchasing ('Procurement') departments

For the steps: *Picking up the orders from goods in, Conducting acceptance tests on new devices, Entering devices into a maintenance/EBME asset register, Entering devices into a financial asset register, and Delivering injectable medicines or devices to the unit or ward requesting it*; these were confined to Engineering staff as expected. In the case of consumables, the pharmacy stakeholders may be involved in delivering these to relevant ward.

Results suggest that there may not have been a common interpretation of the process steps involved. 'Entering devices into financial asset register' is clearly a task for the finance department but was ticked by respondents from Engineering and Technical services.

The interviewees made the distinction, however, that they would only be involved in purchasing decisions if the device related to their pharmaceutical/clinical product. It was also noted that this involvement varies a little according to the Trust.

Only Engineering respondents admit to being involved in pumps and devices, and perhaps a slight involvement for purchase of the syringe set or consumable (depending on the

supplier model), and strictly only pharmacy staff are involved in choosing the pharmaceutical medicines. It can also be pointed out that many of the other stakeholders did not state that they were involved in any of the above processes, despite having a similar role to their equivalents in other Trusts. Again this brings to mind the understanding of the word 'to purchase', which seems to have a different meaning to different people. In many cases, it is understood to be strictly an administrative process, administered by the 'procurement' or 'logistics' department, whereas some respondents displayed a more holistic understanding of purchasing.

What emerged during this study was the importance of the roles of medical device coordinators. This is not commonly defined for every Trust, but it roughly describes a person who is involved in either trialling of new products or training staff in a new model.

Stakeholder engagement

Respondents were asked to scale their view on current practice in involving the following stakeholders in the purchasing of infusion devices only (as this is what they had most experience with): patients, nurses, clinicians, a national agency (e.g. Collaborative Procurement Hub/ PASA for England, and Frameworks/ National Procurement for Scotland).

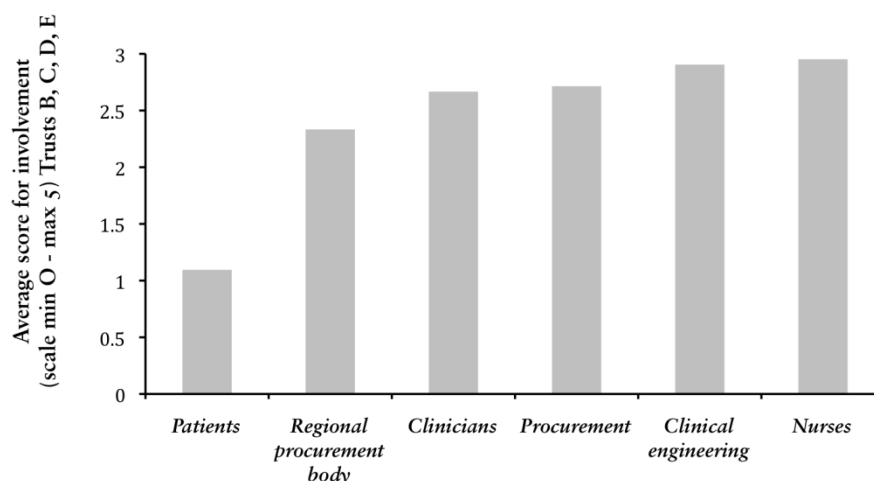


Figure 21: Extent of involvement in infusion device purchasing process for stakeholder groups at Trusts B, C, D and E

The key observations pertaining to stakeholder engagement were as follows:

- In almost all cases, patients were selected as ‘never (directly) involved’ unless the patient will have direct contact with the device (e.g. PCA pump)
- Nurses and clinicians are often involved.
- National Procurement (or an equivalent national agency) is involved if they have an established contract for that device.
- Engineering and Procurement are, of course, always involved in decision-making.
- Pharmaceutical purchasing procedures are tightly regulated, controlled, and has guidance from larger consortiums. They even have a separate purchasing stream in Trusts.

Respondents offered extra comments on stakeholder engagement, mostly pointing out how key stakeholders are not involved in decision-making.

Someone in training should have more of a say in purchasing equipment... I think only senior staff are involved in evaluating products. But that is where we go wrong. I think ward-based staff need to be involved. Senior staff who are experienced are usually consulted. I think what's missing is that the person actually working with the device should be involved before it's put in service.

TRAIN.cl_E1

I'm not involved in the process... certainly don't know the... If for instances I wanted to buy five pumps that were not standardised I would have to go see the Director of Finance with a written evaluation and probably sit there and have to scream and say I want those pumps as opposed to anything else...

TRAIN.tec_B

I've never been asked for information on the error rate of a specific pump. ... [if asked] we could [provide that information]

RISK_D

I place orders for drugs but not for devices, procurement don't get involved because drugs don't come under that.

PHA_D2

Choosing the device is a combined effort.

ENG.tec_D

They also point out that involvement of stakeholders is a dynamic process that is dependent on the device and its operator. Patients are normally not involved unless it is a device that they would have to operate themselves:

Unlike a lot of other pumps, with the PCA pump, there is patient participation because the patient is activating that infusion device... so that will be a factor in the trial - what the patients feel about activating the device.

CLIN.nurs_E5

...[Nurse involvement] depends on the product.. Yes for infusion endoscopy, but it depends on the responsibility held by the ward.

ENG.snr_E

We would like to involve patients but, with all due respect, it's almost like asking your patient which needle they expect to be stuck with.

TRAIN.tec_B

Involvement depends on who is the primary user of the equipment. Some equipment is for personal use by the patient in which case they would be involved.

ENG.snr_C2

We only involve the patients if they are physically using the pumps.

CLIN.nurs_E4

Finally, observations were made on the importance of noting the separate procurement routes or strategies operating with the purchase of one device. For instance, if a device also requires extra equipment, consumables and pharmaceuticals, various purchasing bodies are involved.

Pharmacy purchasing is quite separate from the devices in terms of involvement in decision making.

PHA_C

Summary of learning about stakeholders

The key learning from this section is summarised in these bullet points:

- The different roles played by the stakeholder group groups in each purchasing process step were assigned (Table 18).
- The results strongly suggest that not everyone involved in the process has a clear understanding nor consensus about who makes decisions and who is involved.
- Patient involvement is device-dependent. This gives us clues about who is perceived to be an 'end user' when it comes to purchasing. And also, who is perceived to be a 'purchaser'. To some, this means the administrative tasked assigned to the person making the order. To others, this is a collective term.
- There is an inconsistency of interpretation of roles in medical device purchasing among different stakeholders
- Clinical input is divided from the rest of process, but is present at the start (except for pharmaceutical products, where 'risk department' is involved)
- There is less involvement of patients for infusion device purchase, but acknowledgement of necessary involvement of Nurses and EBME (more than Clinicians and Purchasing) for decision-making.

5.3.2 Decision-making

Resources for making purchasing decisions

Respondents were first asked to indicate with which guidance they are familiar, or may have previously used as reference for making purchasing decisions. The exact list of

resources referred to are those in the second question of the questionnaire in Appendix II. The results are summarised in Table 19.

	Risk (n=3)	Training (n=5)	Engineering (n=6)	Clinical (n=10)	Total
HUMAN RESOURCES					
Medical Equipment (or Device) Committee	3	5	6	9	23
Medical Device Coordinator	1	2	3	7	13
INTERNAL DOCUMENTS AND SYSTEMS					
Internal register for recording errors	3	5	6	8	22
A defined list of approved infusion devices	3	3	5	8	19
(with accompanying documentation?)	3	2	5	7	17
An internal medical device policy or set of guidelines covering the purchasing process	3	3	5	7	18
(with guidelines for standardisation?)	3	3	6	7	19
(with guidance on device replacement?)	2	3	6	6	17
(with guidelines for) centralisation?	1	4	4	4	13
Device specification that considers safety features of new devices to order	3	3	3	5	14
Other documentation for purchasing	2	2	5	5	14
Pre-purchase Questionnaire (PPQ)	1	2	3	0	6
NATIONAL GUIDANCE					
Medicines and Healthcare products Regulatory Agency (MHRA): Device Bulletin 98 (01) the Management of equipment in hospitals and the community	3	4	5	5	17
National Institute for Clinical Excellence (NICE) guidelines	3	3	3	7	16
MHRA Incident Reports for infusion devices	3	4	5	8	20
Controls Assurance Standards	3	2	3	3	11
Bath institute of Medical Engineering (BIME) recommendations	2	2	5	3	12
National device alerts	3	2	2	3	10
Collaborative Procurement Hubs recommendations/contracts	2	2	2	3	9
An equipment library (or equivalent)	2	1	2	4	9
Royal College of Anaesthetists guidelines for practice (for training purposes)	1	1	2	5	9
Skills for Health guidelines for practice for training purpose	1	3	0	2	6
Royal College of Pharmacists guidelines for practice for training purposes	0	3	0	5	8
NHS Purchasing and Supply Agency PASA Tendering documents	0	0	2	5	7

Table 19: Number of respondents who used or are familiar with available resources

Table 19 highlights some key observations:

- ‘Regulatory’ guidance, such as that from MHRA and NICE, all are guidance with which they were familiar, but guidance from PASA or Royal colleges varies.

- Purchasing documents (e.g. Pre-purchase questionnaire, PASA documentation, BIME device evaluation data) are almost unknown to pharmacy respondents.
- The differences in resources used give another indication of the separation of maintenance/engineering staff and those based more on the front-end or pharmaceutical management.

Drivers for making individual purchasing decisions

These responses correspond to the fourth question on the questionnaire in Appendix II. The results are not statistically valid, and there were also differences in interpretation in many of the phrases used in the questionnaire. However, the key findings are shown here as they did show a few trends worthy to note:

- ‘Device history’, ‘quality’, ‘safety’, ‘robustness’, ‘ease of use’, ‘after sales support’ and ‘reliability’ ranked high no matter what the role
- Supplier image or brand generally not important
- Technical/engineering staff recognise importance of working relationship with sales representative

Below are some of the sample comments that illustrate these findings:

I would always concentrate on the user first rather than the design. I compare medical devices to cars, and I've my car in the car park now and the car park is not doing anybody any harm, it's only likely to do any harm when I get in the car and drive it.

ENG.snr_C2

CE marking doesn't give any indication of quality or safety or reliability.

RISK_C

If we have two products then one we have experience with working with the company and we've got on OK with ... we'd like to use them again.

TRAIN.tec_D

I wouldn't go with a company if it didn't give me any training.

TRAIN.tec_D

During these responses, some further comments were made that did not relate directly to the questions asked during the interviews, but served to highlight issues further and provide insights into the situation.

Firstly, the knowledge of the resources available was not common to all, as pointed out earlier.

I'm aghast at how many people have not seen MHRA guidelines... it's the ward level people who don't know.

ENG.snr_C1

A member of the risk department points out the intrusion made by sales representatives on their control processes:

We want purchases to be independent and neutral and want to avoid reps coming and building...I don't like reps going in and having too much influence on the process.

RISK_D

Medical device coordinators are not used by all Trusts but can play a key role in establishing links between the clinical and technical considerations of device purchase and use. They usually purchase “for the Trust” and have a particularly holistic understanding of device needs. However, respondents were not always sure who this medical coordinator was for their own Trust, and different names were given for the same role.

Device committee that's me, and...[Engineer's name]

ENG.snr_C1.

Maybe it is him...

TRAIN.tec_B

We do not have one medical device coordinator, it's coordinated by the MD committee.

PHA_B

I think there is a committee... you'd have to ask [ENG.snr_C1]

RISK_C

Medical device coordinator comes under the realm of clinical engineering team

RISK_D

Culture and mindsets

The questionnaire also invited respondents to comment on changes in the NHS, and changes to purchasing practice. This was to elicit the attitudes and mindsets of current stakeholders with regard to current practice, and gauge willingness or need for improvement further.

Respondents were first asked whether or not change was necessary, and the response was overwhelmingly positive, although some claimed the changes have already occurred and safety is being taken into account in decisions, from their personal perspective:

I disagree that it would require significant cultural change. I think it should be relatively straightforward.

PHA_B

We do have some quite well defined procurement processes and I think increasingly they are taking safety into consideration which is good...

ENG.snr_C

National awareness campaign is hugely important to raise awareness. To engage people and recognising that there are significant benefits in taking a national approach [or] a sub-standardised approach at things.

PHA_B

We almost need to identify champions across the NHS who can actually support the NHS Trust with a lot of these things, so we've got a sort of patient safety coordinators in each of the regions... actually working with individual Trusts to try and support the introduction of new equipment or help us with business cases...

PHA_C

Using collaborative procurement hub is good way to assess risk...

PHA_C

[Conferences] enables the targeting of key people.

RISK_C

An online resource kit and to bring together many of the aspects that you would have, and I suppose want to use these tools to measure and help plan the next processes out.

RISK_C

[We need] more about PASA structure because Trusts do try and comply with those things, people who are looking after patient safety have to compete with the Board's attention, finance...which has much higher national priorities.

TRAIN.tec_D

I think we need more honest thorough the whole NHS (honestly admit when we are having a hard time implementing good practice)

RISK_D

I'll tell you what you need; you need purchasing for safety champions - -individuals in Trusts who can engage people in a tradition, working in a clinical area where they can influence the vision.

PHA_D2

Summary of learning on decision-making influences

The key learning from this section is summarised in these bullet points:

- Dispersed use of any national guidance among the stakeholders but heavier reliance on internal policies, measures, and human resources to control the management of devices.
- Not all ‘purchasers’ are familiar with all guidance available, and this varies according to Trust area
- What “purchasers” rank as important for making purchasing decisions relates mostly to the training and maintenance given by the supplier. Little value is given to the internal capacity of their workforce to comply with training and usability requirements. The expectations lie slightly more with the supplier.

5.3.3 Process Elements

Control measures

The group that was most interesting in its responses was the EBME department. This is the one group that assumes most control of the process. The general idea seems to be that EBME has the know-how with regards to medical equipment specifications; that they are the ones to turn to. They also seem to think that others are likely to buy ‘oddities’ unless they have some control of the process. It is also within their remit to keep abreast of new products on the market.

In some instances it was commented that the presence of policies may not necessarily make a difference in practice, as end-users would still purchase outside of these policies;

I would've thought there's a policy for purchasing but I haven't seen it. I'd like to think there is.

TRAIN.cl_E1

It's not a policy but it should be. It would stop ad-hoc purchases. For 17 yrs I've been doing this and we've been trying to stop ad-hoc purchases. It's getting better but still happens... whether it's revenue or capital, device purchases have to come through the committee, so that's how we ensure control at the moment.

ENG.tec_E1

No reason to make it [device management] a policy, it doesn't add any clout!

ENG.snr_C1

We have a medical device policy ... they cannot initiate a purchasing process without going through medical device committee so it's already monitored...

TRAIN.tec_B

I think we've got a policy that lays down standardisation.. We've certainly got a process....nothing can be purchased from the Trust unless it's been signed off by the guys who run the medical devices committee and that will go through [TRAIN.tec_B] because they make sure the training implications are there...

RISK_B

The control the Trust has got is [useful]. .. People can't go off and just by anything... process doesn't just rely on [TRAIN.tec_B], I mean there's a department who oversee the process... it is a system that's reliant on a number of functions.

RISK_B

What is considered far more useful, which resonates with the literature, is the standardisation of product models and the use of libraries, as means of controlling the use of devices:

Standardisation is a must really...

RISK_B

Before we opened the equipment library we used to get lots of errors cos we couldn't get hold of equipment, but actually people would hide in their places and when you actually did that with library we found that some equipment hadn't been used for a month...

TRAIN.tec_B

Reporting and feedback

Incident reporting features in the patient safety literature as a crucial element for both measuring and improving patient safety. While the culture of reporting has increased, its quality and true efficiency is questioned. Many of these incidents relate to device reporting and, and this aspect of device management was therefore also questioned with the participants. Overall, the response was not in favour of current reporting systems, despite recognising the general importance of feedback for future purchases:

These people [clinicians] don't have time to do it. They already have jobs which are about system safety and so it's a complete inaccurate reflection of what is happening.

CLIN.pha_B

I think medical staff are generally less willing to have a complaint to make but I don't know how effective it is in terms of assistance or feedback and how reliable it is.

CLIN.pha_C

There's by no means a 100% recording. If we stop to record every time, you know, the prescription would be very slow, getting too slow... hopefully errors are picked up but they're not all recorded. .. Only the very severe errors are put onto the computer database.

RISK_C

It could always be better and it depends on the quality of investigation...

RISK_C

Incident reports that relate specifically to medical devices can be more complex to report given that the cause of error can be difficult to assess, as noted by the respondents:

Medical device failure is the one that is reported on the most, and particularly to do with infusion devices.... People will be blaming the machine as well.

TRAIN.tec_D

Inventory Management

Respondents on the front end, such as nurses, tend to put auditing measures in place to keep track of their equipment, suggesting a sense of ownership of the device in the ward;

I do that personally [monitoring pumps]. We tend to name our pumps, they all have different names so that can then be monitored.

CLIN.nurs_E1

We do in pharmacy keep their stock levels and then we audit them to make sure that the levels are correct

PHA_B

We are trying to have a sort of agreement between management of equipment between hospitals from the community..... it's quite a big issue in terms of tracking equipment... I think the whole idea of RFID is quite helpful.

TRAIN.tec_B

Some of the problems in tracking have also to do with the disjointedness of the different asset management systems in hospitals.

We won't have access to finance and they won't have access to certain fields in our database.

ENG.tec_E1

The use of the equipment library was also favoured but with mixed feelings on its value:

I would also like to think there's a library. My background is in acute and I know there is a librarian for the neo-natal department - looks after massive room with all equipment, he's fantastic...

CLIN.doc_E

I don't think we should have an equipment library I am totally against that. (Q: Why?) Well, the concept of having to go somewhere to get something you use all the time ... is daft. If you only use equipment rarely, that's fine. But if they only use

it rarely they shouldn't be using it, they should know how to operate it... and my view is that wards should get equipment resourced... in general terms... wards are quite apart physically. And to have senior nurses running around in hospital trying to find pumps is daft. They should put the pumps where they were used... and OK if you have a very large amount of pumps you should be able to borrow them.. But you don't need to have a library set up. If you look at costs to set up equipment library you have got to have a librarian and another librarian for support ... and if u just put money into having more pumps you wouldn't need the library.... (Q: What about speciality specific libraries for those specialties that run the whole time?) Yes sometimes they do... The sick children's hospital has an equipment library which works well in a small hospital.

ENG.tec_E1

For a scheme like an equipment library to work, however, it was noted that support from management is needed, and a coordinated effort throughout departments. This is mainly due to the differences in device use – from their frequency of use, to handling required, training, and distribution throughout the hospital.

Generally it probably would get rid of a lot of barriers. In pain [department] ones we probably have a library because we store them somewhere and epidural recovery, all go back to the bay, controlled by the pain team. So no one clinical area owns the PCA pumps, they are controlled by pain team. So that works for us. But for rest of hospitals, pumps should perhaps be used in library.

CLIN.nurs_E2

I'm not sure if we want [a library]. If it has equipment that is electronically tagged that would be completely different from having one that is central within hospital. There are times in specialist areas that they would have devices that weren't currently in use. ... I think u could have it for general use in areas, but specialist areas really need their own stock.

CLIN.nurs_E1

Don't know if a central one [has one] but certainly each hospital will. We have one. In general it depends as there are many different devices. With regards to PCA

and epidural which I deal with, they are held in particular areas and labelled accordingly. Nurse or midwife will fill out where it went. I think with some other infusion pumps probably each ward has own store and know where to go to if they want to borrow more. A central one...I guess probably [ENG.snr_C1] would have a central note of what pumps are where, so there is a central library somewhere.

TRAIN.cl_E2

In one instance, the library actually was claimed to contribute to a reduction in device incidents, although this was only shown anecdotally:

We have an equipment library on each site so you have to say it's been an enormous success. We've seen a reduction in the number of incidents related to lack of equipment, complaints about the lack of equipments. So phenomenally from branch 250 incidents in a year down to almost nothing.

TRAIN.tec_D

Goal alignment

Comments alluding to the alignment of goals, both within the organisation or hospital, and nationally, received mixed responses. The introduction of 'targets' and 'objectives' were not always favoured, and the structures within the organisation were sometimes seen as impositions on improvement on good practice.

We have so many targets and objectives set for us as an organisation that I think you would be in great danger of damaging the profile really of the project and in wrapping it up in a target because it would just then become one of many and I think if you had an awareness campaign, you'd be much more likely to engage clinical staff and they are the people you've got to engage in there.

RISK_D

People have a pretty good understanding of what is good practice and a strong desire to improve on practices but they're inhibited by structures within the organisations and often a lack of understanding.

TRAIN.tec_D

In order for anything to change it must be set as an objective, really.

ENG.tec_D

Overall, however, the importance of aligning goals, and establishing a common vision for safe purchase, was welcomed.

Summary of learning on process characteristics

The key learning from this section is summarised in these bullet points:

- Management of devices varies considerably among Trusts
- Not every Trust has the same elements of an asset management system (e.g. library, device trainer/coordinator), and the reasons are mostly ‘historical’
- Improvements or changes in practice are attributed to key individuals; many other practices are ‘historical’.
- Differences in practice driven by Device Type & Individuals involved

5.4 Summary of Conclusions from Results II

Answers to the first set of research questions were collected directly from the data and are summarised next. The intention was to answer those shaded, but glimpses of other boxed ones found too.

Research Sub-Questions

1. What is current practice in medical device purchasing?

Who are the stakeholders and what are their roles in purchasing?
What type of knowledge and competence do these stakeholders have?
What are the resources and drivers for purchasing decisions?
What other factors influence current practice?

2. (How) does current practice present risks to healthcare delivery services?

What challenges and risks are present in current practice?
How are the factors of current practice different from good practice?
How do these factors impact the healthcare service?

3. Where are areas for improvement on current practice?

How do the stakeholders themselves view improved practice?
How can factors in current practice be managed towards improvement?

The answers to these questions are summarised below.

1. *Who are the stakeholders and what are their roles in purchasing?*

- A purchaser usually refers to the person who places the order, but in practice incorporates roles in Engineering (Maintenance), front line staff (User) and clinical governance (Training).
- Patient involvement is device-dependent. There is less of involvement of patients for infusion device purchase, but acknowledgement of necessary involvement of Nurses and EBME (more than Clinicians and Purchasing) for decision-making.
- There is an inconsistency of interpretation of roles in medical device purchasing among different stakeholders. For instance, the 'end user' may also be the 'purchaser'. However, to some stakeholders, a 'purchaser' means the administrative tasked assigned to the person making the order. To others, this is a collective term.

2. *What type of knowledge and competence do these stakeholders have?*

- True knowledge of equipment ergonomics, safety and design (beyond regulatory indicators, focus on quality vs. cost assessment) is scattered among stakeholders, and device use competence is not adequately monitored.
- Clinical input divided from the rest of process, only at start (except for pharmaceutical products, where ‘risk department’ is involved)
- The awareness and use of national bodies and agencies varied among stakeholders. In general, PASA is known to anyone from Finance, Procurement and Engineering, but not really to those towards the front-end of device use. This includes names of the agencies themselves (such as Collaborative procurement Hubs, or Pre-Purchase Questionnaires)
- End-users are not always aware of the options available for replacement equipment (e.g. ward storage options, neighbouring wards loans, use of equipment library); nor of whom to turn to for advice on purchasing decisions, and their available budget for new purchases.

3. *What are the resources and drivers for purchasing decisions?*

- Each device has its own characteristics that determine its criteria for choice, as well as stakeholder engagement.
- What “purchasers” rank as important for making purchasing decisions relates mostly to the training and maintenance given by the supplier. Little value is given to the internal capacity of their workforce to comply with training and usability requirements. The expectations lie slightly more with the supplier.
- Dispersed use of any national guidance among the stakeholders but heavier reliance on internal policies, measures, and human resources to control the management of devices.
- Internally evaluated equipment or use of BIME recommendations help guide device choice, but this is mainly used by EBME/Clinical Engineering staff.

4. *What other factors influence current practice?*

- Communication of requirements to supplier from consumable to drug to device exists in some cases.
- Adopting new devices through trials preferred, as this gives the end-user some time to get used to the device and evaluate it in practice.
- Although error-reporting culture has increased in the past five years, the quality of these is still questioned. They are not seen as entirely reliable for monitoring device use history and repair.
- Not every Trust has the same elements of an asset management system (e.g. library, device trainer/coordinator), and the reasons are mostly 'historical'.

The focus of Results II: Observations of Current Practice was to confirm initial observations and obtain a more formal understanding of current practice. However, during the discussion and through inductive analysis of the data, elements of the influence of purchasing practice on healthcare delivery were raised through the discussions. These discussions served as introductions to areas of potential risk both to the purchasing process itself, but with little allusions to the potential risk to the delivery of care. It is the third set of results in the next chapter that will now focus on case studies that exemplify some of these risks through different means. These case studies give concrete evidence of how such factors have contributed to poor healthcare delivery. Chapter 7 then discusses these factors in terms of process improvement.

Chapter 6

RESULTS III:

Risks and Challenges in Current Practice

This section contains further case studies used to answer the main research question below, but with a discussion at the end of the chapter of how each case study demonstrated evidence to answer the research sub-questions:

Research Sub-Questions

1. What is current practice in medical device purchasing?

Who are the stakeholders and what are their roles in purchasing?

What type of knowledge and competence do these stakeholders have?

What are the resources and drivers for purchasing decisions?

What other factors influence current practice?

2. (How) does current practice present risks to healthcare delivery services?

What challenges and risks are present in current practice?

How are the factors of current practice different from good practice?

How do these factors impact the healthcare service?

3. Where are areas for improvement on current practice?

How do the stakeholders themselves view improved practice?

How can factors in current practice be managed towards improvement?

The three themes are illustrated through a series of examples, each contributing, in part, to each sub-question. This chapter first describes each of the case studies and the discussion at the end summarises the key learning points in context of the three answered sub-questions.

The studies include:

1. Development of process maps of the purchasing practice at Trust A, building up to a workshop where risks in the process were identified. Insights and observations from both the process of developing the maps, as well as the identification of risks before and during the workshop, are shared.
2. Three Case studies covering the standardisation of thermometers (Trust A), an evaluation of infusion pumps (Trust E) and the purchase of dialysis machines (Trust A) show a variety of challenges in purchasing decision-making.
3. Three very different medical device purchasing process routes of Trust A are sketched out, with a discussion on the possible reasons for their variation.

6.1 Overview of Challenges and Risks

The factors addressed through the data beyond its basic aims are summarised in Table 21 below. Similar to other chapters, Table 21 gives a summary of the factors addressed in this chapter, indicated in red.

	1	2	3	
<i>Factors considered</i>	<i>Current Practice</i>	<i>Risks to Healthcare</i>	<i>Improvement Areas</i>	
<i>Stakeholders</i>	<i>Stakeholder definition</i>	✓		
	<i>Device knowledge & competence</i>	✓	✓✓✓	✓
	<i>Process knowledge</i>	✓✓	✓✓	✓✓✓
	<i>Stakeholder engagement</i>	✓✓	✓✓	✓✓✓
	<i>Resources for decisions</i>	✓	✓✓✓	✓✓
	<i>Drivers for decisions</i>	✓✓	✓	✓
	<i>Culture and mindsets</i>	✓✓	✓	✓
<i>Process</i>	<i>Process description</i>	✓✓	✓	✓✓
	<i>Control measures</i>	✓✓	✓✓✓	✓✓✓
	<i>Reporting and feedback</i>	✓✓	✓	✓✓
	<i>Pressures on process</i>	✓	✓	✓✓✓
	<i>Inventory management</i>	✓✓	✓✓✓	✓✓✓
	<i>Goal alignment</i>	✓✓	✓✓✓	✓✓✓
<p><i>Key to Data Sources:</i> ✓: From Literature (Chapter 2) ✓: From Results I (Chapter 4) ✓: From Results II (Chapter 5) ✓: From Results III (Chapter 6)</p>				

Table 20: Data gathered from Results III (Risks and Challenges in Current Practice)

The research questions are addressed next in light of the three case studies, but also build on learning gained in the first set of results and Exploratory Studies.

6.2 Identification of Process Risks

This section describes the development of process maps to model the purchase of medical devices at Trust A. Process maps were not intended to be perfect descriptions of the process, but rather as tools to elicit insights from and engage with relevant stakeholders. As pointed out in the literature, a form of representation of the system is important for eliciting process risks (Jun 2007, Karsh & Alper 2005). The maps were then used to lead to a risk workshop to identify current control measures and proposed control measures. Throughout this section, reference is made to Appendix III, which contains selected process maps to show the evolution of the diagrams.

6.2.1 Process Map Development

As can be seen in Figure AIII_1 in Appendix III, the first process map is a skeleton of the process introduced as a very rough draft. The diagram is repeated below in Figure 22 and is the first one, which was then populated by interviews with the participants themselves. Various iterations of the diagrams resulted in the rest of the pictures in Appendix III, but a description and a few examples are included here.

AIII_1 to AIII_5: These diagrams show the process ‘as it is’. Each diagram shows different levels of detail depending on the stakeholder interviewed, as each one shed light on the particular process section which was in their remit.

AIII_6 to AIII_7: In follow-up interviews, respondents started to comment on how the process is ‘to be’, from their perspectives. These comments were gathered, in part, in the initial interviews as well, but included only in these diagrams.

AIII_8 to AIII_10: Through the analysis of the process ‘as is’ combined with hypothetical ‘to be’, and further refinement through participation at the MEC Procurement Subgroup meetings that these sets of diagrams were then created. The most developed version of the process maps is shown in Figure 23, copied from the Appendix, and the colour key shows the different aspects of the process depicted:

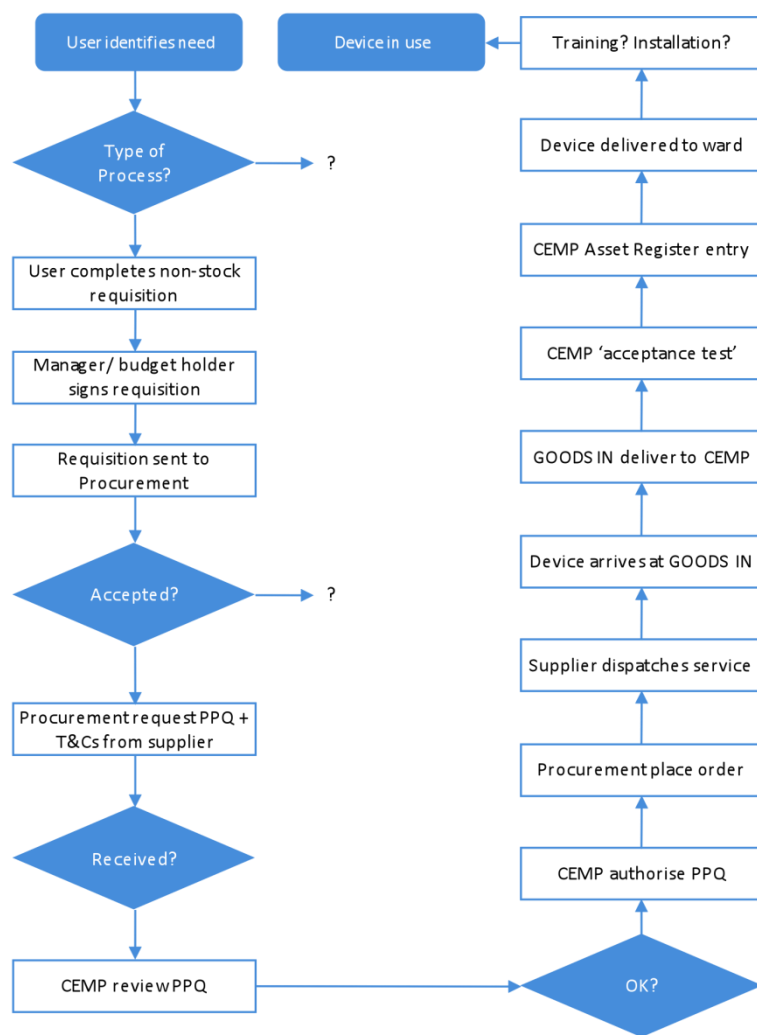


Figure 22: First ‘rough sketch’ process map used (copy of AIII_1 in Appendix III)

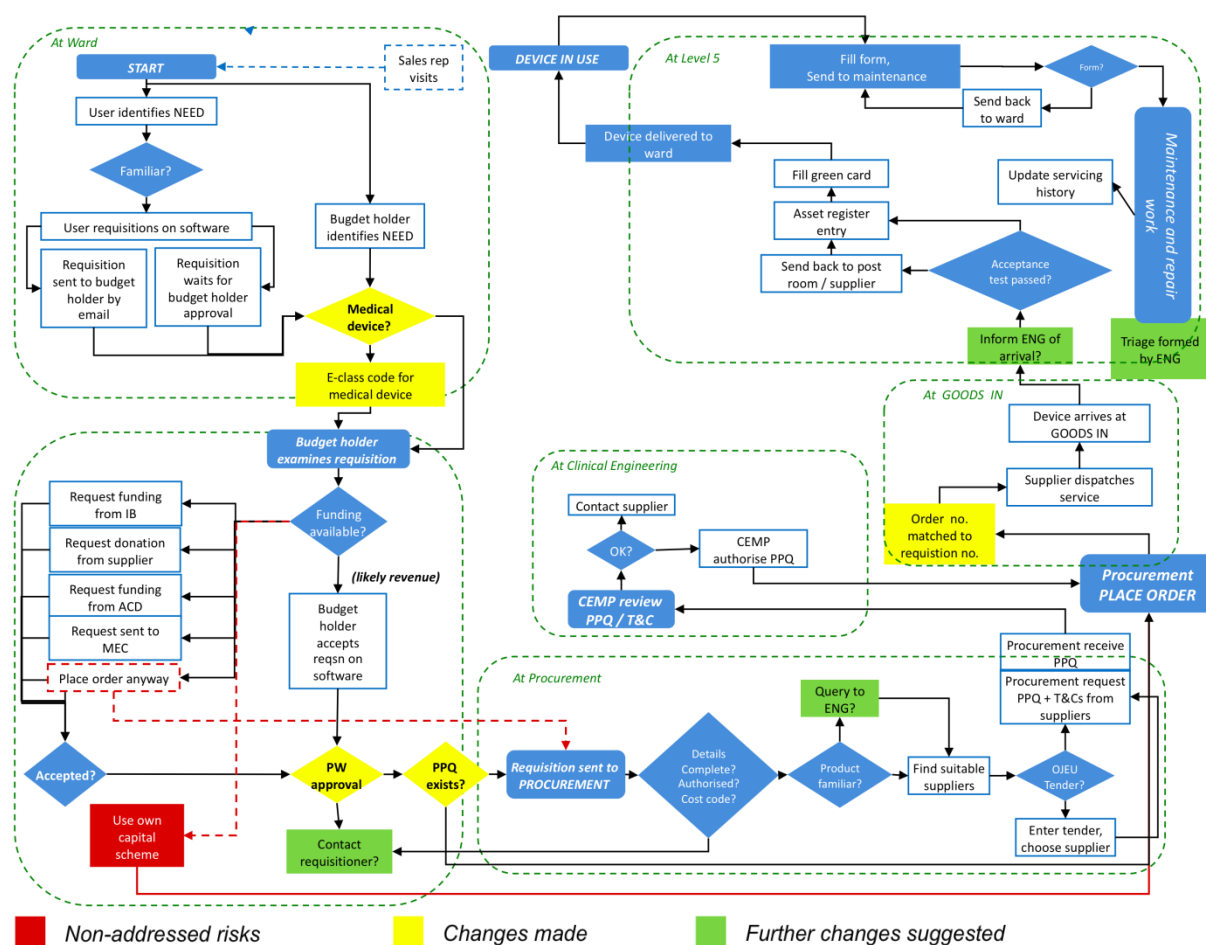


Figure 23: Developed version of process map (copy of AIII_8 in Appendix III)

As pointed out earlier, 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.

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 clump various 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 is AIII_9; this was the one used for the workshop.

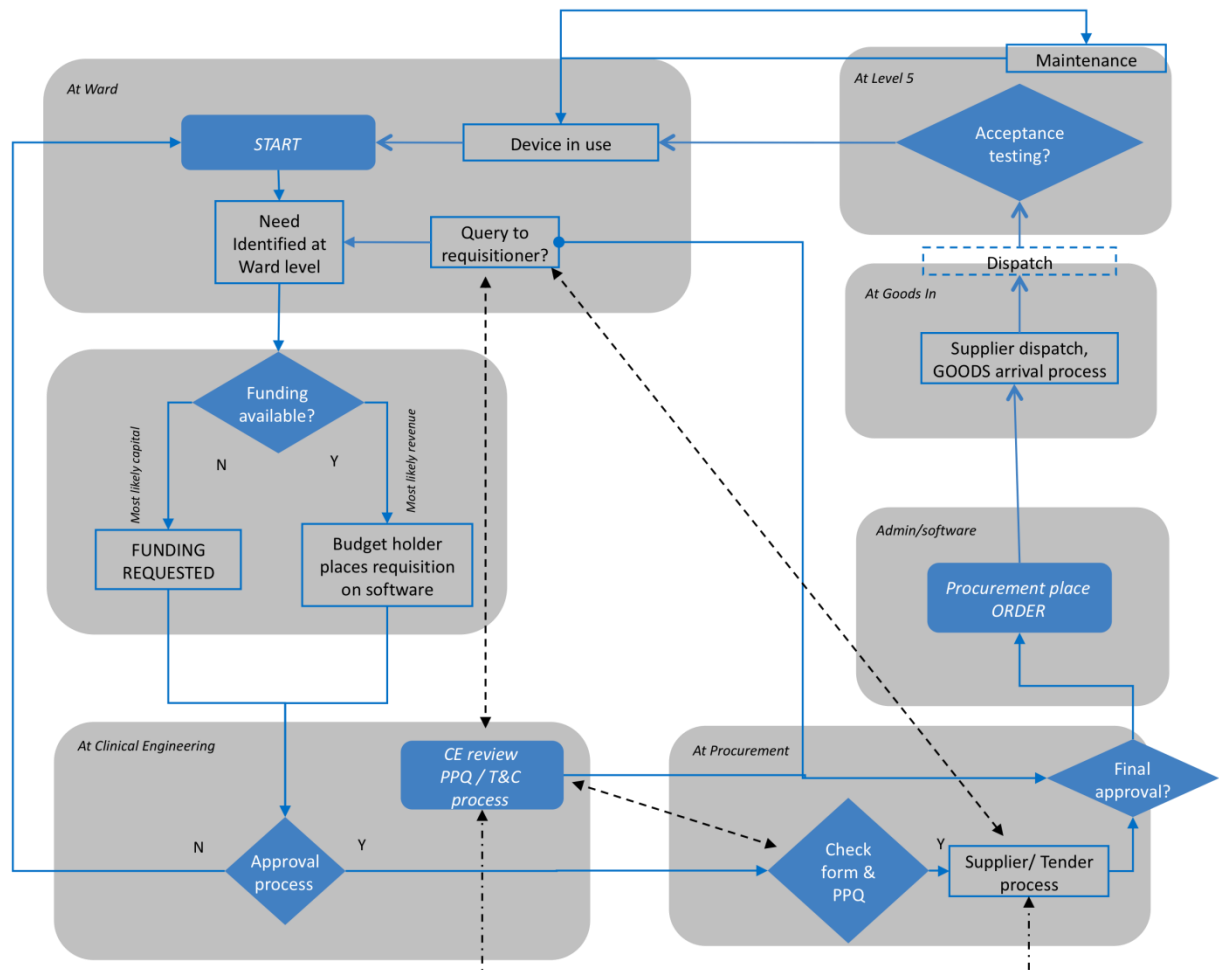


Figure 24: Process map used for risk workshop (copy of AIII_9 in Appendix III)

Having completed a process map tool 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.

Purchasing process as a System

Given the substantial involvement with this particular group in Trust A, measures were taken to reduce potential bias that may have been developed through an ongoing interaction between the researcher and the interviewed stakeholders. To this end, the

overall perspective and direction of the research process and the subject matter were to be re-addressed. In order to realign the research process with the initial direction: the consideration of the purchasing process as a ‘system’, the system was characterised by the following components:

<i>System components</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 21: Components of medical device purchasing system for Trust A

The above system components were established both in discussion with participants and through analysis of the previous observations made during this study. Having established the system components, the boundaries for the study, and the anticipated inputs and outputs of the system, the participants at the workshops would have a more coherent

understanding of the intention of the workshop. Table 21 was presented to the stakeholders invited to the workshop as a guideline for the upcoming discussion. Preparations for the risk workshop were then initiated.

6.2.2 Evidence of Risk Prior to Workshop

During the studies described in Results II, various observations were made that suggested the presence of risks in the process. Selected comments are listed in Table 22.

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 even voiced by the very same stakeholders. A selected of these issues voiced or observed between December 2005 to September 2008 are listed below:

- The remit of the MEC Procurement Subgroup needed to be revisited. The underlying knowledge is that they are responsible for purchasing under the Medical Equipment Committee (MEC) - but they only manages capital devices.
- EBME feels they need more control of purchases.
- Requisitioners/end-users still consider some medical devices as 'consumables' which does not give them true understanding of their use and risks.
- Revenue devices are not centralised and could benefit from being as controlled as capitally funded devices as they are also medical devices with similar risks.
- Development of the equipment catalogue is too much work - currently not supported by internal resources and tendering obstacles.
- The web portal idea was supported from Jan 06, but took almost 2 years time to get going.

- Bypassing control measures could be avoided if the nomenclature of devices in the software was improved.
- No true audit of equipment exists.
- Managing maintenance contracts seems an issue; and not all ward managers are aware of their existing contracts, even if they are potentially paying for a service they are not using.

6.2.3 Preparation for Risk Workshop

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. The various risk assessment methods have been introduced in the literature review. In this study, however, a modification of these formal methods was necessary due to the existing methods used within the organisation and the time limitations available for this part of the study. On consultation with the risk manager at Trust A, it was felt that participants were more likely to respond accurately if they used a method familiar to them within the Trust. Additionally, this would also mean 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.

Challenges for planning risk workshop

Following a meeting with the Risk department at Trust A, 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 2 hours.

Date	Comments made	Source
May-02	<i>End user is not always aware of the cost/funding source when ordering</i>	MEC committee
	<i>Ordering under the wrong budget is possible</i>	MEC committee
	<i>More control is needed by Clinical engineering</i>	MEC committee
	<i>With the new [electronic purchasing system] there will be new expertise in purchasing by the clerks. - new dynamics.</i>	Head of Procurement
Sep-02	<i>Wards have different timescales for putting in their requests for new contracts</i>	MEC committee
	<i>Entries are still incorrect or missing in catalogue purchase options for [electronic purchasing system]</i>	MEC committee
Oct-02	<i>Medical device planning is still an issue for the trust</i>	MEC committee
Feb-03	<i>I had an £8k order under medical device e-class code under revenue budget; it was a form of pump. I rejected it as this should be a capital purchase. User came back saying the item was needed for surgery urgently – it was an expensive internal pump (i.e. a consumable by usual terms) so I had to ask them to re-requisition it.</i>	Head of Clinical Engineering
	<i>Recently there was a MAC 3500 for theatres which had been sitting there for a few days. I sent an email to [Theatres Technician Head] saying that this is not standard anymore, as it spends more time being fault at Medical Electronics than in clinical use. So we now have [another model]. There was a delay in him replying to me which delayed the whole process really.</i>	Head of Clinical Engineering
Jul-03	<i>The [process] is interesting. I need a new PC, just a PC. Basically it is £500 that has to go through the loop of one of my staff requisitioning it, I approved it, it went to someone not in my loop for my budget - interesting. Then .. Someone ..then someone.. then to the Head of Engineering and Medical Physics, then I thought 'this is ridiculous'!</i>	Point of Care
	<i>The Chief Exec has not been on [electronic purchasing system] since April [to approve the purchase]!</i>	Head of Procurement

Table 22: Anecdotes alluding to failure modes in purchasing process

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 simply arrive at some consensus as to where potential risks in the current practice exist. Furthermore, it was also noted that the hospital had already adopted its own 'Risk Assessment' method for monitoring incidents, coordinated through the Risk Department as described earlier. All participants invited to the workshop would therefore already be familiar with this matrix and be comfortable with its use. Therefore, a compromise was reached in the method applied: elements of tradition risk analysis methods were adopted, but the exercise was conducted by a representative from the Risk Department in the hospital's own format.

The participants at Trust A were already familiar with this matrix as it had been used in other service contexts, but never in relation to the purchasing of medical devices as a 'service'. Some preparation prior to the workshop was therefore required to familiarise the participants with the method and obtain individual responses to risk assessments. These steps are described after a description of the risk matrix tool used at Trust A.

Risk Matrix Tool for Trust A

The process of risk assessment at Trust A begins with mapping the service to be assessed. At the meeting/workshop, a selection of 'what if' questions are used as prompts. A particular hazard is identified and its potential causes and consequences are assessed. The team assess the hazard's risk using their risk (available from the governance or risk department), and determine if further mitigation is required. Further mitigation should be considered wherever the risk is assessed as medium or high. Then, the team develop relevant recommendations to control the high/medium risk hazards, and re-assess the risk with these recommendations in place. If the risk is still high, further recommendations should be developed. 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.

For the risk analysis itself, a selection of methods are suggested: failure modes and effects analysis (FMEA); healthcare failure modes and effects analysis (HFMEA); hazard analysis and critical control points; hazard and operability; barrier analysis and the development of

risk controls; probabilistic risk assessment. This tool/matrix is used once a potential incident or hazard has been identified and hence relates to the assessment of that incident. The tool is shown in Table 23.

This tool is used in the following steps:

Step 1: Identify the likelihood of the incident occurring; choosing from Rare (1), Unlikely (2), Possible (3), Likely (4), Almost Certain (5).

Step 2: Assign a consequence to the incident; in context of Table 23.

Step 3: Assign a Risk Rating to each event by calculating “Likelihood x Consequence = Risk Rating”) and the results are mapped onto a matrix; which are shaded green, yellow and red to indicate low, medium and high risk.

(Steps 4 and 5 involve setting new control measures and monitoring these, but these are not covered within this exercise).

<i>Consequence</i>	<i>Injury to individual(s)</i>	<i>Impact to service</i>	<i>Financial loss/ HSE action</i>	<i>Adverse publicity</i>	<i>Potential for complaint/ litigation</i>
<i>Insignificant (1)</i>	No obvious harm	No disruption to level or quality of service	No financial loss	No publicity	No potential of complaint or litigation
<i>Minor (2)</i>	Minimal / Non-permanent harm	Low disruption to level or quality of service – staff health and patient care not compromised	<20K	Media Enquiries	Complaint possible
	e.g. first aid required, extra observation or minor treatment needed	Failure to meet national targets (over 1 QTR)			Litigation Unlikely
<i>Moderate (3)</i>	Semi-permanent harm (up to one year) e.g. hospital treatment required, fractures, over 3 days off work, incidents that require external reporting, increased length of patient stay	Moderate disruption to level or quality of service – staff health and patient care compromised	£20K - £500K	Local media coverage	High potential for complaint
		Failure to meet national targets (over 2 QTR's)	Improvement Notice	<3 days national media coverage	Litigation possible
<i>Major (4)</i>	Permanent or long-term harm e.g. harm over a period of one year, misdiagnosis leading to poor prognosis, neurological disability	Temporary Service Closure	£500K - £1M	>3 days national media coverage	Litigation expected
		Extended failure to meet national targets	Prohibition Notice		
<i>Catastrophic (5)</i>	Death (as a result of the incident)	Extended Service Closure	>£1M Prosecution	International publicity	Litigation Certain

Table 23: Consequence/Impact to service descriptions as used in risk assessments at Trust A (taken from Trust's internal documents)

Pre-workshop 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 24 (AIII_11 in Appendix), which includes both revenue and capital devices as it is a high-level view of the system. It is understood that some devices that may normally fall under a revenue category may still take a capital route of purchase and so only a 'likely' distinction is made in the diagram.

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 further. Another prompt used during the interviews was potential scenarios of failure modes of risks in the process. These had already been encountered in previous selected quotes included Results I and II and listed below:

- Requisitioner inputs incorrect e-class code (purchase not identified as medical device and by-passes system)
- Requisitioner assigns an 'immediate purchase' to the order (device identified by EBME post-purchase only)
- Device delivered directly to ward (by-passes acceptance testing)
- Requisitioner makes purchase when no funding available
- Budget holder/approver cycle causes major delays

The potential incidents in the list above were then re-written as ‘Failure Modes’ with associated consequence and likelihood. Any of the above was said to be at least possible and, in some cases, occur frequently (Likelihood range from 3-5). Depending on the device purchased and its own associated risk, the consequences may include harm to individual, moderate to high impact to services caused by delays, and moderate financial consequences. 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. An attempt to map these causes onto the failure modes above is diagrammed below, following indications given by the participants themselves and also insights gained from observations during studies in Results II. The diagram also lists the consequence and likelihood of these risks as elicited from these first interviews:

6.2.4 Workshop Results

The decision to hold a workshop was supported by the Medical Equipment Committee to highlight the risks and control measures in the purchasing of medical devices. The results were as follows, shown in Table 24 with assigned control measures proposed during the workshop. It must be noted here that many of these risks had been observed in earlier studies with this Trust, including in the Exploratory Studies.

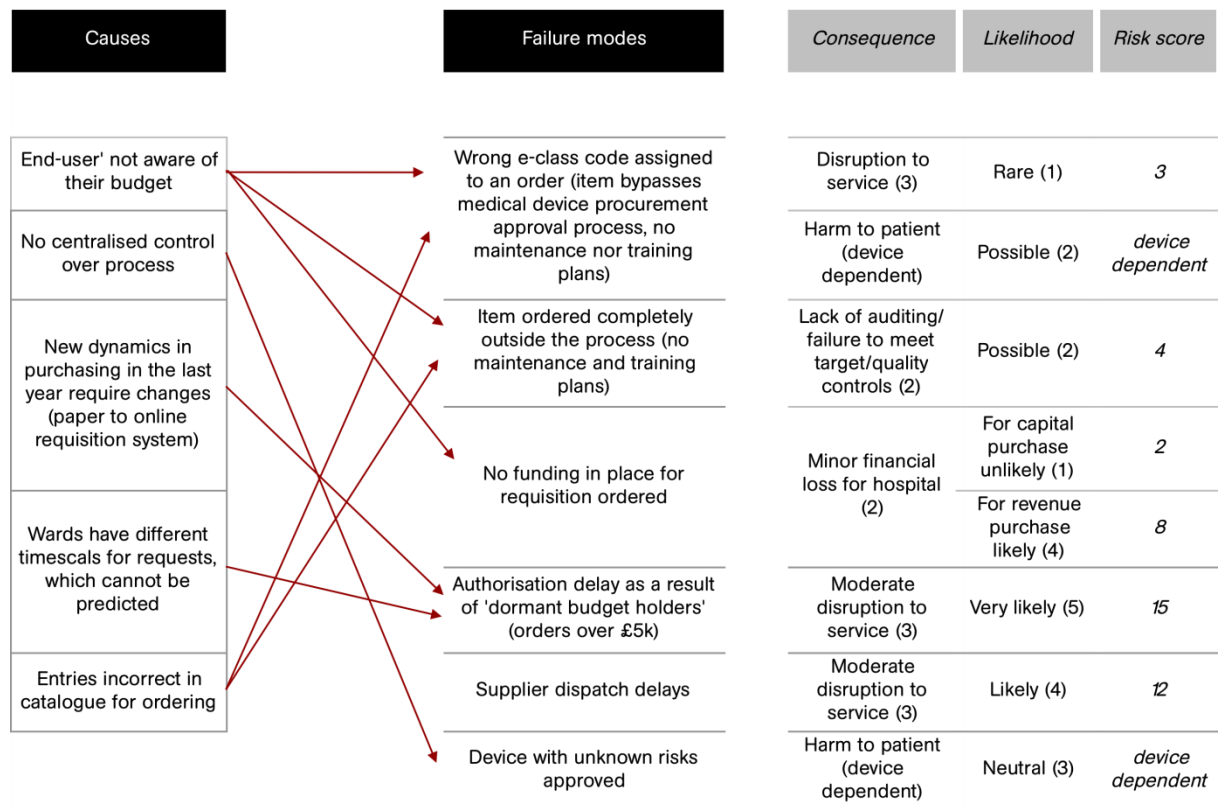


Figure 25: Failure modes found in workshop linked to original causes

Risk evidence results

An analysis of all these observations, together with the results of the workshop, were then summarised below in Table 25 showing the connection between risks as identified in each stage of research process: preliminary interviews, to observations during meetings, to the workshop itself. These have been partitioned according to each process step (i.e. using AIII_11 in Appendix III).

Some of these issues were addressed later in designing the framework. The recurring issues, and those that received consensus from the risk workshop were all included as necessary points to be aware of in purchasing decisions.

PROCESS STEP	FAILURE MODES	DISCUSSION ON CURRENT CONTROLS	FUTURE or IN-PROGRESS CONTROLS
<i>1. Identifying need for new purchase</i>	Unclear distinction between medical device/other equipment	The new medical device policy contains a definition for the trust.	Further dissemination of medical device definition to be pursued if necessary. Simplification of e-class coding to ensure all orders for medical device to pass by Engineering
<i>2. Identifying funding source</i>	User unclear on appropriate funding source	A purchase for a capital item cannot be made against a revenue budget, as has always been the case. Each budget holder is aware if they have a capital budget or not. The distinction between capital and revenue items is not solely a financial one. It usual	Appropriate dissemination of this knowledge throughout trust to be implemented.
<i>3: Placing the requisition</i>	User (deliberately) chooses wrong e-class code (deliberately or unintentionally)	Currently no method to monitor this. Controls include: pre-selected trusted budget holders, independent 3rd party authorisation.	Such occurrences can be uncovered retrospectively if required.
	User uses 'tick box' facilities for immediate purchase (system bypassed)	It was acknowledged that some departments need this facility, but its use could be restricted. A report on its use cannot be run unless a field is available that can be flagged on system. Current control measures apply to all purchases. 'Tick box' purchases also pass through clinical engineering as do other purchases.	Facility can be switched off if necessary (controlled by Procurement)
<i>4. Budget holder approval</i>	Budget holder is away (approval process delayed) Hierarchy does not represent operational hierarchy (system bypassed)		Major revisions in redefining budget holders and requisitioners. Automatic emailing to be adopted throughout the Trust.

Table 24: Failure modes and controls; results from risk workshop at Trust A

Corresponding PROCESS STEP	Category	From Observations	Pre-workshop interviews	RISK WORKSHOP
1. Identify Need	To end-user, medical device could be consumable Information available to end-user incomplete Sales reps instigate purchase	Unclear if appropriate nomenclature exists Equipment catalogue too much work - internal resources and tendering obstacles	Item not always identified as a 'medical device' during purchase	Unclear distinction between medical device/other equipment
2. Place requisition	User can bypass system as non-medical device	-	Requisitioner may enter false e-class code. E-class codes may not include all devices which should be classed as medical devices	User (deliberately) chooses wrong e-class code (deliberately or unintentionally)
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	MEC is responsible for approving only capital devices - no regard for existing equipment in wards (esp revenue purchases). Strategy for revenue purchases still needs to be refined, more work required	-	User unclear on appropriate funding source
4. Approval process	Non-involvement of Electronics (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 Non-involvement of Electronics (maintenance) Training involvement at start known in theory, not in practice Individual personalities can drive process Full audit of asset base not available, 3 registers exist	-	-	Budget holder is away (approval process delayed)
5. Execute purchasing process	Delays to the service exist through approval process Purchasing also handles non-medical device purchases	-	Back and forth exchange of PPQ examination between Procurement and Clinical Engineering. Buyer may not always pick up on speculative requisitions	-
6. Arrival at Goods In	Receipt of MD not always identifiable	-	-	-
7. Acceptance test	-	-	-	-
8. Installation and induction	End-user unaware of different device models available	-	-	-
9. Use and maintenance	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	No true audit of equipment exists	Purchase/finance asset register does not link with ENG asset register	-
10. Feedback systems	Devices not fully traceable in hospital Servicing reports incomplete Non-involvement of End-users	Managing maintenance contracts seems an issue	-	-
Control of overall process	Policy to reach practice takes time ENG has an overall trust in its ability to control system	Web portal supported, but took time to get going ENG feels they need more control of purchases	Requisitioner may still by-pass system through 'immediate purchase'	User uses 'tick box' facilities for immediate purchase (system bypassed) Hierarchy does not represent operational hierarchy (system bypassed)

Table 25: Summary of risks identified in purchasing process at Trust A

Impact on Trust A practice

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 Trust for ten years and some of these same issues kept coming up. Only now did we have the focus to address them.

FIN.proc_A (Head of Procurement)

I think the process map gave us the focus to concentrate on the issues in a more holistic sense.

ENG.med_A (Head of Medical Physics and Clinical Engineering)

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 process 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.

6.3 Challenges in Purchasing Decision-making

The challenges in making purchasing decisions are demonstrated through case examples, each pointing to particular issues discussed at the end of the chapter.

6.3.1 EXAMPLE 1: Evaluation and Standardisation of Thermometers

One of the recommended steps by stakeholders in previous chapters as an ideal route towards safe purchasing practice is to ‘standardise’ on product models following a formal ‘evaluation’ of their use. This case serves as one example of achieving such a step, and the rationale behind such an exercise. The example chosen is the standardisation of

thermometers. During the time of this project, Trust A was in the process of conducting a trial for new thermometers to replace their existing set throughout the hospital. This section delineates the observations made during the trial along with the rationale for its inception.

All the information gathered here is presented as that gathered by the Trust itself in putting this case forward. It therefore is a reflection of what this particular Trust, and the individuals involved in driving this standardisation process, have chosen to take into consideration.

Rationale for the process

The evaluation process was initiated by a member of the research division at EBME in Trust A. Having attended a meeting for thermometry he was exposed to new thermometer models available on the market. The conclusion from this meeting was that tympanic thermometers were not the best available on the market for their use, but one tympanic supplier had the market share at the time. Around 40 different models were available on the market, but the ones chosen for consideration were those recommended from this meeting. There were other reasons for conducting an evaluation internal to the Trust:

Supplier-driven Reasons: The model used at the time was that by a tympanic supplier, referred to as T_1. There was no formal agreement with them for the management of thermometers within the Trust, but a ‘verbal agreement’ (Trust A, personal communication) with the EBME department. This agreement required that this supplier would provide the Trust with the devices free of charge, or for a nominal figure of £5, along with a 3-year warranty with the device. It was the supplier that wanted to secure a 3-year formal agreement on the basis of consumable purchase, due to the risks associated with minimal commitment.

Internal user habits: A high number of Model T_1 thermometers were being stolen.

Accuracy/Device usage: A model by another supplier had previously been used (referred to as T_3A), but these were considered “flimsy” and “kept breaking”. However, another model by this supplier (T_3B) was an improved version; the tip was made of metal and was smaller.

Financial considerations: Usually, thermometer consumables are negotiated by NHS Logistics. The supplier for T_1 had indicated that they would provide the thermometer device free of charge, but the price for consumables was fixed.

Background to thermometers and their clinical use

Body temperature is recognised as a vital clinical sign and a keystone of nursing and medical practice and for keeping patient records (Trust A Clinical Engineering 2008). Core temperature for a normal range is between 36.8 °C to 37.9 °C, but invasive procedures are required to access these body sites. Thermometers serve to access other sites for intermittent body temperature, such as the mouth, axilla, rectum, ear canal, and forehead. These sites do not always coincide with core temperature (offsets range from 0.55 °C to 1.25°C). Estimates of core temperature are therefore attained through the device's internal algorithm.

Thermometers form an important part of the healthcare service. The following points highlight the importance of their correct choice, configuration and use:

- Most wards have in their protocol to measure core temperature only, but only one of these models gives the core temperature. From experience, the team noted that nurses have not always shown awareness of the difference between these two measurements, and simply expected a 'number' (e.g. 37.5 °C), which may or may not be a display following the device's internal algorithm.
- Due to the existence of different models with internal algorithms, a robust standardisation policy of both thermometer and configuration of the algorithm is required.
- The cost of overnight stay in ICU estimated in excess of £1000. A wrong temperature measurement could lead to an unnecessary overnight stay. Core temperature is a vital clinical measure in the discharge criteria.
- Erroneous measurements due to 'faulty' devices or configuration put extra strain on resources by triggering other wrong diagnosis and create potential anxiety to patients.

The most common types of thermometers are:

Electronic contact thermometers (metal covered thermistor probes placed on)

Infrared tympanic thermometers (IRET)

Other types include mercury in glass and chemical (phase change) thermometers

At the time of the evaluation, Trust A predominantly used an IRET model (Model T_1 in this report), with approximately 400 devices used in the Trust (Trust A Clinical Engineering 2008). The objective of the study was to assess the quality of the new thermometers on the market compared to the existing one. This was done by testing the intra- and inter-operator variability and to validate accuracy, when using these four different models of thermometers: T_1, T_2, T_3A and T_3B.

Methods used and factors considered

The study was conducted in two parts:

Part 1 protocol: inter and intra-operator operability: Twenty-one consecutive measurements on one hundred consenting adult subjects were carried out by two trained operators.

Part 2: clinical variability: The clinical accuracy of the selected devices were compared to a reference standard - an invasive general purpose temperature probe

Four different models from three suppliers were considered for evaluation at the Trust, and the technical evaluation team considered the following criteria:

Anticipated total required throughout the Trust (between 100-700 units)

Type of technology for measurement

Consumables required

Details of contract offered

The responses from the participants were to focus on usability. Participants had to indicate their level of satisfaction according to the thermometer's following characteristics:

Ease of use

Accuracy

Cleaning protocol

Patient reaction

Results of the evaluation

The study concluded that:

Intra-operator repeatability analysis and Inter-operator reproducibility analysis indicates acceptable mean differences for all devices (Trust A Clinical Engineering 2008).

Based on this data, they concluded that T_2 is inappropriate for clinical use. Both IRTT models from the third supplier were also acceptable, however, when considering accuracy the T_3 should only be used in ear mode (T_3B) and not core mode (T_3A). Model T_1 remains a clinically acceptable choice of thermometer for routine estimation of core body temperature (Trust A, personal communication).

Two major concerns centred the criteria for evaluation: cost of the device (lifetime) and accuracy. The cost calculations included: covers, batteries, cleaning, repair cost, calibration, warranty, and response time which then helped them calculate: initial purchase cost, batteries/year, cleaning per year, covers/year, repairs/year, calibration. In the end, the chosen device was actually the most expensive one. The authors of the report also wrote the following:

“This [study] indicated the importance of using a holistic approach when selecting a thermometer for the Trust, i.e. both financial and clinical issues should have a strong influence on the decision” (Trust A Clinical Engineering 2008).

Key learning

The learning main points from this study, relevant to this thesis, are listed below:

Drivers for purchase:

The motivations and drivers for standardising on this device were:

Usability

User habits (devices were stolen)
Costs/consumables package
Types of technology available
Supplier/design changes

Many of these issues resulted in standardised consistent measurement because of differences in readings between different makes of thermometer (algorithm and operator-device dependent differences)

The criteria used to evaluate products:

Cost was a main consideration but was not above inter and intra operability and accuracy of the devices. The recommended device was actually the most expensive one. The preference of the staff was also considered strongly.

The main stakeholders driving the process:

Staff from EBME were the drivers of the evaluation process. It must be noted that Trust A has a branch dedicated to research in EBME. Publishing these results were also a motivating factor for conducting the evaluation.

The case itself does show challenges in the process of conducting standardisation per se (such challenges are depicted in the infusion pump case study later), but it serves to highlight the importance of standardising on particular types of devices. According to the authors of this study, thermometers are characterised by their critical path in the patient pathway – a wrong reading can lead to unnecessary increased costs in overnight stays. The device is also characterised by its internal design complexity. Each model has its own correction software to provide the required reading, and while the different settings on the thermometers can be modified to suit a ward's needs, errors can still occur if the user is expecting a different number on display.

6.3.2 EXAMPLE 2: Purchasing of Dialysis Machines

A very different piece of equipment to thermometers is the dialysis machine, primarily used to provide a replacement for lost kidney function. The equipment is therefore far larger,

with greater design complexity, and used mainly in one area of the hospital: a dedicated dialysis centre. The equipment works by removing waste from the body through diffusion and ultra filtration via a semi-permeable membrane. The two primary types of dialysis are peritoneal dialysis, where a sterile solution containing minerals and glucose is run through a tube into the body, haemodialysis, which is the subject of this case study.

Rationale for the process

In 2002 a protocol was written by the Head of Renal Technical services, outlining the need for a new haemodialysis machine supplier. The reason given was that their primary vendor (Supplier X) supplied reliable and adaptable machines, but their second vendor (Supplier Y) retains “serious design and component faults, which the manufacturer has been unable to rectify” (Trust A Reports 2001-9)

At the time, the Trust was running 46 machines in five clinical areas: in one chronic care area, in three acute areas, and the community. Machines run for over 5000 hours per annum. The working life of a haemodialysis machine is 7 years. This document proposed therefore to replace the following (in decreasing order of priority):

From supplier X

- 4 machines purchased in 1990 in acute inventory
- 8 machines purchased between 1988 and 1990 in community
- 12 machines purchased between 1993 and 1995 in the dialysis centre

From supplier Y

- 9 machines purchased in 1997-8

The proposal in this document was to have preliminary discussions by the dialysis department, including clinical, nursing and technical representation. The list of potential vendors and products were derived through consensus by a selection of nursing and technical specialists, who helped design machine specification and supervise machine evaluation. However, a series of documents were written up leading up to this final proposal. An analysis of these documents, which highlight how the requests were made, is described in this section, following some background to the criticality of dialysis care.

Background to dialysis care

Haemodialysis works by pumping the patient's blood through the blood compartment of a dialyser, exposing it to a semi-permeable membrane. The cleansed blood is then returned via the circuit back to the body. This allows the removal of several litres of excess fluid during a typical 3 to 5 hour treatment. Studies have demonstrated the clinical benefits of dialyzing 5 to 7 times a week, for 6 to 8 hours. In general, studies have shown that both increased treatment length and frequency are clinically beneficial.

Events leading to purchase requests

In order to progress with this proposal by the dialysis department, three key documents had previously been written:

1997: report on dialysis centre written by Biomedical Equipment Manager

2000: written by Head of Renal Technical services on "status and future requirements"

2001: report on "factors affecting the purchase of haemodialysis machines"

The following phrases, quoted from these reports, illustrate the challenges faced by the authors of the reports:

"I have after some deliberation compiled a report, which seeks to detail the importance of operational time in the role of the haemodialysis machine. I have also considered the clinical risks and financial pressure involved in operating haemodialysis machines beyond their safe working lives... This report is derived from an assessment of the existing machine stock and from my 23 years renal experience". (Trust A Reports 2001-9)

The report clearly states reasons for the request and the specific characteristics of haemodialysis machines and serves to "clarify the reasons why haemodialysis machines cannot easily be compared to other types of Biomedical equipment":

"Substantial differences [exist] between haemodialysis machines and other biomedical equipment", for instance computer-managed control, blood handling

module and fluid management components – all indicative of the complexity inside the machine...

...The role of the haemodialysis is unique; it is a chemical factory with the job of producing from raw components a clean (sometimes sterile), physiologically balanced solution comparable to blood...

...It must function within tight tolerances, dictated by national and international standards. It must also be self-cleaning, programmable, reliable and safe. The main factors affecting its safety and reliability stem from the wear and stresses to components that derive from this ‘chemical factory’ process.”(Trust A Reports 2001-9)

A detailed description of the operational, financial and clinical problems associated with haemodialysis machines is then given. In particular, as a way of differentiating this particular piece of equipment from others, emphasis is made on the reliability, safety and the ability to adapt to changing clinical goals.

Finally, an outline of why the current stock of haemodialysis machines do not satisfy these goals and requirements for the treatment of dialysis patients, to end with a strong conclusion and recommendation that all twelve haemodialysis machines over 10 years old should be replaced as soon as is practically possible. They also call for the Trust’s capital funding allocation to the dialysis centre should be reviewed in light of the technical and usage information provided in this document.

The next stage in this process was to fill out a request to the Medical Equipment Committee, requesting £337,500 (2001). This particular form is comprehensive in that it asks all the questions that match the life-cycle of the device and take into account the financial considerations of newly purchased equipment as a whole. This standard form queries the intention of the requisition, i.e. if it is replacing, and/or increasing existing capacity, and the options for sharing the equipment with others. According to this document, the new purchases would bring no increase to staffing and user training as they were replacements, and consumables would fit within existing contract; and consequently no increase in revenue costs. However, the workload was anticipated to increase by 10% per annum.

Such requests were made for five consecutive years (2003/4 to 2008/9) and were rejected every time for unknown reasons.

Key learning

Although most of the interpretation of the document can be very subjective; what is pointed out here is the existence of frustrations towards Board Level management. This may or may not be typical of other Trusts, but it echoes the dissatisfaction stated in the previous evidence gathered in this study. The case served to highlight the importance of multidisciplinary engagement and empowerment and acknowledgement of those responsible for purchasing and maintaining equipment, but this cannot overcome the hurdle of allocating the required funds to clinical and technical need.

6.3.3 EXAMPLE 3: Evaluation of Infusion Pumps

This case examines an example of an evaluation exercise conducted at Trust E for replacing and purchasing new Pain-Control-Analgesia (PCA) pumps. Though the documentation leading up the evaluation was obtained from the Trust's internal files, the data for the evaluation day itself and the interviews held subsequently form part of this research.

Rationale for the process

New pumps were to be distributed across all pain-control teams throughout the Trust. This was not the first evaluation of its kind as there had been a previously conducted evaluation (2007) to replace PCA pumps and starting to replace older volumetric pumps. The sum requested for total replacement £605k, but only £200k was made available, which was insufficient to replace all pumps. Therefore, to ensure standardisation, the Trust opted to replace the volumetric pumps where it was possible to realise significant reductions in consumable costs (Trust E Report 2008).

This evaluation described here, held in 2008, did have full stakeholder engagement from the start. It was conducted in three stages:

Stage 0: Selection of suppliers for participation of evaluation meeting

Stage 1: 'Show and tell' evaluation meeting

Stage 2: Trial period

Background to infusion devices

Infusion devices are used throughout the hospital and are used to administer therapeutics, such as analgesics, antimicrobials, blood products, chemotherapy, nutrients and so forth. The whole infusion device or system consists of the infusion pump (device), the giving or syringe set (usually considered the 'consumable'), and the fluids administered (pharmaceuticals). Infusions can be continuous infusion consisting of small pulses of infusion, intermittent infusion with a "high" infusion rate, and patient-controlled infusion on-demand, usually with a pre-programmed ceiling to avoid intoxication. The rate is controlled by a pressure pad or button that can be activated by the patient, which is the case for the device considered here, patient-controlled analgesia (PCA).

Details of evaluation project

Standardisation of products for Scotland at the time of this project was also closely related to the new governmental policies on framework agreements. The procedure starts with National Procurement (equivalent to PASA for Scotland), who convene a working group to issue an EU tender and evaluate responses for a particular product type. A framework contract is then issued, covering products from two or more suppliers and including contract costs covering all of Scotland.

For volumetric infusion devices, the framework agreement included products from 4 suppliers. Hospitals who wish to order are required to carry out a mini tender exercise to select a preferred device from the 4 suppliers, which was the procedure adopted in this Trust. The Head of Clinical Engineering for Trust E had short listed 4 models/different suppliers and asked them to liaise with respective medical physics team at each site to arrange for bringing in a pump for evaluation by pain control team (before evaluation day). Each selected hospital in the Trust had different medical physics teams and pain control teams, and different existing models being used (3 adult and one children's teaching hospital). The experience of the stakeholders involved in this study were gathered for the purposes of this thesis and described next.

Results of Stage 1: Show-and-tell day

These comments were gathered as part of this research to elicit stakeholder perception on how the evaluation process was conducted and on standardisation in general.

Many participants offered their opinion on the process of standardising itself, and the balance needed between absolute standardisation and the exigencies of each ward.

While I know some of my colleagues around Scotland disagree with me, I do not believe that standardisation necessarily means one model only. In particular, for volumetric pumps, over 4 major acute hospitals and a few smaller ones, we have argued that we should standardise on 2 or perhaps 3 models.

ENG.snr_E

Similarly, comments were made about the evaluation day itself. Participants were grateful that it occurred, but offered suggestions on improving it. There was also a suggestion that some suppliers might be more disadvantaged than others, noting that subjectivity cannot be removed from such an evaluation process.

I'm just not 100% sure how useful that exercise is... The last representative... came to see us yesterday and my view of the pump changed completely from what I thought [previously] at the meeting, and now is one of the ones we'd like to try... The pump came across in the meeting quite badly [and it was the first time we saw it as it was not available before]. But the trainer was very good, the one who came to see us last Friday... quite confident and showed us how robust it was.

CLIN.nurs_E1

I just wish we had all the pumps before and the paperwork before it. It went ok.

CLIN.nurs_E2

I felt sorry for the last company as I felt they are at a disadvantage, and they were a bit unsure...

CLIN.nurs_E1

The most comments offered were those around the involvement of stakeholders in the decision-making process and in the evaluation process. This was especially of nurses who

may usually have felt out of the decision process in the past and welcomed this process as an opportunity to voice their opinion on device choice.

I'm glad we are involved in this; we have no influence in medical devices... but if we feel that our opinion counts, it is a more positive experience. So this evaluation has been good. I'm not coming here thinking why am I involved... these products need to last for 5 years; it's not going to be replaced. So we need to move to a pump to give us with the reliability that we have had so far...

CLIN.nurs_E1

I think the right people were represented at evaluation... [it] was all done very well.

CLIN.nurs_E3

The right people were involved

CLIN.nurs_E4

However, it also surfaced that the communication of the reason for this exercise and the need for new pumps may not have been optimal;

With this new pump there hasn't been a lot of guidance as to why we have changed over. The division was changing over so we were just told [to show up on the day].

TRAIN.clin_E

After the show-tell evaluation day, the stakeholders taking part in the evaluation were sent a questionnaire to decide on which pumps would go through to stage 2. A set of questions for technical evaluation and one for clinical evaluation were included. The types of comments made on the pumps are described below:

Pump1: It was a concern that the pump can start up in non-PCA mode, this new design concept (while potentially beneficial to the supplier and design), "may not be secure or robust enough"... "Awkward locking mechanism; separate parts will get lost".

Pump2: The pump, or perhaps supplier is “known to be very reliable”. They also noted that they offered an “excellent”, and the design is considered “simple, robust and secure”.

Pump3: It was “not robust enough”, although apparently the company had voiced to be willing to develop the design. Other concerns were that it was “very portable, so may get lost or stolen”. They also mentioned that it is “awkward and fiddly to use”.

Pump4: It was considered to be “well constructed” with a “clear display” and “good safety features”, although the “user interface could be sturdier” but there were concerns about the supply of consumables.

Pump2 and Pump4 were selected for evaluation at all adult sites. The children’s hospital opted to evaluate Pump3 due to “different operating requirements” but it was not ready for clinical evaluation.

Results from Stage 2: Device Use Trial

For Stage 2 of the evaluation process, a two-week trial of the pumps in the clinical areas took place, while technical assessments were conducted by Medical Physics staff at each site. During this stage, assessment criteria for the clinical staff were:

- General impression
- Controls and displays
- Training and manuals
- Functional/operational
- Patient safety aspects
- Patient’s perception
- Free text, subjective comments

For the technical assessment, ratings were given based on:

- General impression
- Build quality

- Ease of maintenance
- Ease of cleaning
- Configuration ease of control
- Technical manuals
- Patient safety
- Anti-tamper and locking
- Technical training and support
- Availability of spare parts
- Subjective free text comments

Both sets were given ‘equal weighting’ in the overall evaluation.

Final device selection

The main concerns in the returned evaluations were related to size, age and after sales support. Clinical staff preferred Pump4, and technical staff preferred Pump2, though both pumps met clinical need. The results were presented in a comprehensive report shown with quantitative figures of the results of the evaluation forms.

All stakeholders were invited again to a meeting to select the final pump. The document reflects a long discussion that was very comprehensive, and during which all results presented and all once again invited to submit a view. Neither model met needs of sick children but these would be evaluated in future. It was agreed that if the issues with Pump4 could be resolved, this would be purchased (issues about longer-term support provided by them). It was also agreed that pumps should be with medical physics before staff training began.

Key learning

This was a comprehensive evaluation process, which showed an open and transparent process, inclusive of the relevant stakeholders in the life-cycle of the device (training, maintenance and end-users). Good personal links were established with the suppliers and the sales representatives. More involvement and openness on the rationale for conducting the evaluation in the first place could have been communicated somewhere along the process.

Part of the reason why the process worked as a cohesive whole is that there was mutual respect for the department driving the process (the individuals at the EBME unit). In turn, participation and engagement in the trial was welcomed.

6.4 Discussion on Challenges and Risks

This discussion is in direct response to the research sub-questions:

2. (How) does current practice present risks to healthcare delivery services?

What challenges and risks are present in current practice?
How are the factors of current practice different from good practice?
How do these factors impact the healthcare service?

The key learning points arising directly from these case examples are listed first, followed by further analysis on this learning, and its contributions to the research questions.

6.4.1 Learning from Case Examples

Example Case 1: Process Mapping and Risk Identification - Device purchasing practice has holistic consequences in the management of healthcare

The example at Trust A highlighted the holistic consequences of device purchasing processes. Feedback from the participants was overall positive and highlighted how the research process as well as the systems techniques acted together as catalysts to make improvements to stakeholders which might otherwise have operated in silos. New control measures were assigned for the group to follow. In the short term, the process itself and its new control measures are now regularly assessed by the MEC Procurement Subgroup. Long-term improvements to care and efficient delivery of equipment to patient care are yet to be assessed.

Example Case 2: Thermometers - Standardisation of device models is particularly useful for devices used throughout the hospital and of critical importance in avoiding usage errors.

The case itself does not show challenges in the process of conducting standardisation per se (such challenges are depicted in the infusion pump case study later), but it serves to highlight the importance of standardising on particular types of devices. According to the authors of this study, thermometers are characterised by their critical path in the patient pathway – a wrong reading can lead to unnecessary increased costs in overnight stays. The device is also characterised by its internal design complexity. Each model has its own correction software to provide the required reading, and while the different settings on the thermometers can be modified to suit a ward's needs, errors can still occur if the user is expecting a different number on display.

Example Case 3: Dialysis - Current practice in division of allocated funds for capital and revenue devices can create obstacles to fulfilling clinical and technical requirements.

Although most of the interpretation of the document can be very subjective; what is pointed out here is the existence of frustrations towards Board Level management. This may or may not be typical of other Trusts, but it echoes with dissatisfaction stated in the previous studies. The case served to highlight the importance of multidisciplinary engagement and empowerment and acknowledgement of those responsible for purchasing and maintaining equipment, but this cannot overcome the hurdle of allocating the required funds to clinical and technical need.

Example Case 4: PCA pumps evaluation - Multidisciplinary stakeholder engagement helps address all clinical, technical, and financial considerations for purchase, especially when conducting an evaluation of a new model on which to standardise.

This was a comprehensive evaluation process, which showed an open and transparent process, inclusive of the relevant stakeholders in the life-cycle of the device (training, maintenance and end-users). Good personal links were established with the suppliers and the sales representatives. Part of the reason why the process worked as a cohesive whole is

that there was mutual respect for the department driving the process (the individuals at the EBME unit). In turn, participation and engagement in the trial was welcomed.

6.4.2 Risks and Challenges that impact Healthcare Service

The key risks and challenges exemplified in these case examples are highlighted here, and linked back under general topics identified in both the literature and the results in the previous chapters. As with previous chapters, the factors table (presented earlier in Table 20 for this chapter) points out the main factors considered within this chapter. As identified in the risk workshop at Trust A, all failure modes and risks identified are initiated in the early steps in the purchasing process. In a more generic diagram of the process, these would correspond to the first four steps in the process:

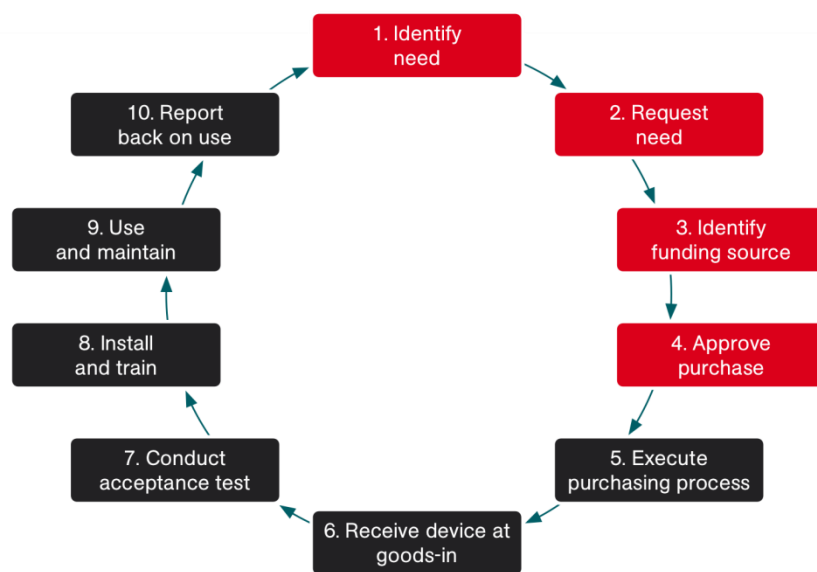


Figure 26: Failures in the system highlighted in the first four steps in the process

The risks in current practice, their variance from good practice, and the potential impact to healthcare services, are discussed in light of the factors in Table 7.

Challenges relating to stakeholders

The main factors relating to stakeholders observed in this study relate to the following parameters:

Stakeholder definition

Device knowledge & competence

Process knowledge

Stakeholder engagement

Resources for decisions

Drivers for decisions

Culture and mindsets

Both purchasing and operations management theory identified the important role that a purchasing manager plays in any supply chain, as they provide a vital link between the operation itself and its suppliers. This is especially applicable to medical device purchasing given the displacement between the end-user and the supplier. Although this study identified various stakeholders that also adopt the role of the purchaser (for instance, doctors and nurses who initiate a requisition), ultimately someone is responsible for managing that particular process. Sources specific to medical device purchasing identified the EBME representatives, or Clinical Engineers, as a key player in providing the link between clinical stakeholders and financial stakeholders. This study also confirmed this observation.

However, among the healthcare community these stakeholders may not always be obvious. There is an inconsistency of interpretation of roles in medical device purchasing among different stakeholders. For instance, the 'end user' may also be the 'purchaser'. However, to some stakeholders, a 'purchaser' means the administrative tasked assigned to the person making the order. To others, this is a collective term. It was also noted that stakeholder involvement is device-dependent. For instance, there is less of involvement of patients for infusion device purchase, but acknowledgement of necessary involvement of Nurses and EBME (more than Clinicians and Purchasing) for decision-making. Each device has its own characteristics that determine its criteria for choice, as well as stakeholder engagement.

As pointed out in the risk workshop, in particular the types of failures that can occur in this process are delays in the service and, in some cases, harm to patient through these

delays. The timing of the process itself need not take long in theory, but, in practice, there are plenty of anecdotes presented in both this chapter and the preceding ones to illustrate delays or mismanaged processes. While the consensus at the risk workshop was that controls are required early in the process to avoid failures later, these are not necessarily sufficient. A more holistic approach and proactive approach on behalf of all stakeholders involved, even those at the later stages in the process, are required. This requires adequate *stakeholder engagement*, and hence *knowledge of the process* for these stakeholders. This is mainly because this is not always a linear cyclical process, despite it being diagrammed as such for explanatory purposes in this study. For instance, the very same requisitioner is the one that will end up using the device; and the trainer who later needs to impart usability skills on to the end-users could also have a say in the preferred model.

Another layer of complexity is due to the varying *stakeholder* groups coming from different areas within the healthcare service, which are part of the process in theory, but not in practice. Given that purchasing stakeholder group are not clearly *defined*, even when a consensus is reached for who the end-user and purchaser is, their roles and responsibilities and capabilities understanding differs. In Figure 26, each process step can correspond to a different number of stakeholders belonging to a varying level of organisational hierarchy within the Trust. The *engagement* of these stakeholders is not always present. This was also depicted early in the Exploratory Studies but was shown in practice. The example of the evaluation project at Trust E is a clear example of how stakeholder satisfaction can be achieved with a more open and engaging, holistic purchasing approach.

Another problem right at the front end of the process is the lack of a common understanding of ‘what is a medical device’ and ‘the importance of a medical device purchase’ among purchasing stakeholders, or appropriate *device knowledge and competence*. This is specially the case among the end-users, but can extend in some instances among the members observed in the ‘medical equipment sub-committee’ and its subgroups. The evidence also suggests the lack of full *process knowledge* or awareness of capabilities of purchasing system and its control failures. A potential reason behind this is another main source of conflict particular in Trust A: lack of process ownership and ‘device’ ownership. Certainly a more proactive device ownership by the end user could contribute to a more proactive approach to gain the knowledge, skills and language needed to voice their requirements to the rest of the stakeholders in the purchasing process. At the

same time, any particular stakeholder group, at least not at Trust policy level, does not officially own the process itself. While in practice this has naturally come to the EBME department as the main holistic process knowledge owners, it has been shown that certain purchases have bypassed their controls. Furthermore, even if the culture already supports the role of EBME, problems can arise if this authority is not recognised at Board Level. This was the case for the dialysis purchase example, which presumably for financial obstacles, was not able to argue for this purchasing case despite showing clear clinical and technical, and even financial benefits for its requests.

As identified in this study, the knowledge base for each of those considerations sits either in different departments within a hospital, or in different stakeholder groups. For instance, clinical input is mostly elicited at the start of the process (except for certain types of purchases that have a clinical lead practitioner). In line with good practice identified in the literature, as well as a direct consequence of the finding that a medical device requires input from different stakeholder knowledge bases, a clear requirement is also the collaboration and engagement required between them within both the process design or within the culture of the organization. The engagement of these stakeholders is currently not always present, and are indicative of the ‘silo’ mentality alluded to in literature. This was also depicted early in the Exploratory Studies but was shown in practice. The example of the evaluation project at Trust E is a clear example of how stakeholder satisfaction can be achieved with a more open and engaging, holistic purchasing approach.

Technical knowledge, in combination with clinical knowledge can also encompass device usability, but device use competence is not adequately monitored. Financial and purchasing process knowledge is also scattered. The awareness and use of national bodies and agencies varies among stakeholders. In general, PASA is known to anyone from Finance, Procurement and Engineering, but not really to those towards the front-end of device use. This includes names of the agencies themselves (such as Collaborative procurement Hubs, or Pre-Purchase Questionnaires). Finally, end-users are not always aware of the options available for replacement equipment (e.g. ward storage options, neighbouring wards loans, use of equipment library); nor of whom to turn to for advice on purchasing decisions, and their available budget for new purchases.

According to these findings, what “purchasers” rank as important for making purchasing decisions relates mostly to the training and maintenance given by the supplier. Less value is

given to the internal capacity of their workforce to comply with training and usability requirements. The expectations lie slightly more with the supplier and the original ‘design’ of the device and its robustness.

The study also identified the dispersed use of any national guidance among the stakeholders, whilst placing heavier reliance on internal policies, measures, and human resources to control the management of devices. Furthermore, any guidance set out from national agency specific to device evaluations (driven by PASA-related organisations) are mainly used by EBME/Clinical Engineering staff and remain mostly unfamiliar to front end-users.

Furthermore, as pointed earlier in the literature, there are groupings along the supply chain created either by regulators, suppliers, the market, or by organizations such as PASA that differ in their classification criteria. By the time the device reaches the hospital and is added to the general catalogue of electronic purchases, there is little distinction between a medical device purchase and other purchases such as stationary. The controls appear later at the back-end of the process, where the authorisation of the requisition reaches EBME department. But, as seen in the studies, this does not always occur and purchases do bypass this control. If the end-user would be aware of such risks at the start, the risk could be reduced.

Challenges relating to the Process

Setting priorities for use of inventories, apply a degree of control to each item; and then investing in an information processing system that can cope with their particular set of inventory control circumstances, all form part of good practice in asset management. As was noted in the Exploratory Studies, a full audit of the current processes, or the equipment situation is virtually ‘impossible’ given the changing environment and extension of equipment to community care. Most Trusts do not have a full, up-to-date, complete audit of their asset base, and the few Trusts examined in this study have two if not more different asset management databases. The implications of this are that when reviewing expenditure for both capital and revenue-funded equipment, these are not done in the context of current equipment distribution, since this information exists in different patches throughout the Trust. The purchasing process is therefore somewhat disassociated from the medical device asset management process. An example of this is the equipment library,

which loans out devices to lessen the purchasing expenditure for each ward, but is itself under-funded to provide its service.

At the highest level, everyone's goal is to support patient care with adequate equipment resources. This study provides evidence to show that other sub-goals, when not aligned to this ultimate goal, may lead to poor delivery of the goal.

Another indication from good practice was the assessment of risk of the process of purchasing. As noted from the study at Trust A, risk assessments on services or processes were not new to the stakeholders involved, but were new to the context of a purchasing process. This may largely be due to the lack of 'ownership' of any particular individual or stakeholder group of the purchasing process, which itself was indicated strongly during the workshop.

One of the unnecessary divides in the process, which does affect purchasing and hence the delivery of care, is the allocation of funding on devices, which constitutes an added *pressure* for decision-making. When a device is identified as a capital or revenue expenditure a separate purchasing route is taken and, particularly in the case of more expensive capital equipment, the purchase risks further delays to the service due to its numerous approval procedures. It is not claimed that rigorous controls and protocols should not be in place for device purchases, but what could change is the prioritisation to such rigour. Certainly in Trust A, revenue purchases do not go through the same procedures simply due to their lower price. However, the risks identified here apply to any given medical device – be it an expensive or cheaper one. Attention to true clinical and/or service factors which could serve as better measure of the amount of rigour required per purchasing decision, and not the unit price. This would require an *alignment of goals* from the Finance unit to the Clinical and Technical units.

Feedback structures may be in place but have received some criticism even by stakeholders in this study. Although error-reporting culture has increased in the past five years, the quality of these is still questioned. They are not seen as entirely reliable for monitoring device use history and repair. Also, many of the elements of asset management systems differ from Trust to Trust and these have to then be established according to the resources and priorities available to each organisation.

When the purchasing process is placed in context of a more general device management process, further complexities that affect effective purchasing are evident. As was noted in the Exploratory Studies, a full *inventory* of the current processes, or the equipment situation is virtually ‘impossible’ given the changing environment and extension of equipment to community care. Most Trusts do not have a full, up-to-date, complete audit of their asset base, and the few Trusts examined in this study have two if not more different asset management databases. The implications of this are that when reviewing expenditure for both capital and revenue-funded equipment, these are not done in the context of current equipment distribution, since this information exists in different patches throughout the Trust. The purchasing process is therefore somewhat disassociated from the medical device asset management process. An example of this is the equipment library, which loans out devices to lessen the purchasing expenditure for each ward, but is itself under-funded to provide its service.

The practical complexities of the purchasing system are one of the reasons for the inefficiencies displayed in the purchasing process. Part of this complexity is the existence of multiple input reasons for entering the purchasing process pathway. This dynamic environment creates added *pressures* on the process. The early stage purchaser, or requisitioner, is also the end user, and while their drivers for purchasing may be clear, they may not necessarily have a holistic knowledge base of the process and may therefore bypass *process controls*. Such conflicts in policy and practice are also due to ‘lack of manpower’, ‘time constraints’, ‘misunderstanding of process’, ‘disconnects in communication’ – all terms collected from phrases used in observations at Trust A and contributing to further pressures. Many top-level management barriers affect ideal *goals* such as evaluation and standardisation, and from these few case studies, it can be seen that the motivations can sometimes be solely financial.

Another device management factor that has surfaced from these case studies is the variety of devices managed by a hospital, and the different forms that this management takes due to the particular characteristics of devices. Even the three examples in these studies: thermometers, infusion devices, and dialysis machines, have particular characteristics, which determine what type of purchasing pathway they take. Taking Trust A as the context, these devices, although all potentially part of the same ‘medical device purchasing process’ actually show different pathways in practice. Figure 27 shows the three different

routes that are present in Trust A. The dialysis machine is treated as a capitally funded purchase and takes the ‘regular’ purchasing route and control procedures discussed earlier.

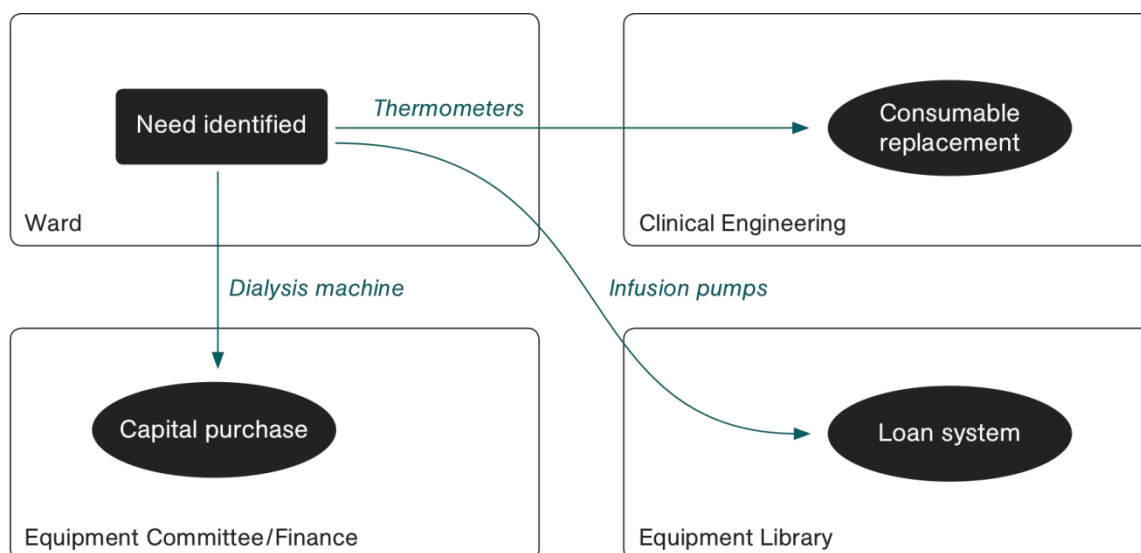


Figure 27: Different purchasing routes taken by devices

Infusion pumps are mostly, though not entirely, purchased by the equipment library and then loaned out to wards (some wards will still buy their own). Thermometers are treated almost as consumables as they are purchased by EBME and then distributed to wards and replaced when needed. These distinctions have come about partly for historical reasons, but partly due to the particular exigencies of these devices. Any holistic purchasing system for medical devices should take such requirements into account. This is another argument for distinguishing devices from other purchases within a hospital – not only are they associated with particular risks, but their sheer diversity in both use and clinical criticality necessitates further distinction.

6.5 Summary of Challenges and Risks

These challenges and risks observed, relating to the factors considered, are summarised in Table 26.

	<i>Factors considered</i>	<i>Challenges observed in Current Practice</i>
<i>Stakeholders</i>	<i>Stakeholder definition</i>	<i>Purchaser' refers to a variety of stakeholders</i>
	<i>Device knowledge & competence</i>	<i>Scattered device knowledge; Skills variations in device use competence</i>
	<i>Process knowledge</i>	<i>Scattered process knowledge</i>
	<i>Stakeholder engagement</i>	<i>Operational stakeholder divisions; Disconnects in communication</i>
	<i>Resources for decisions</i>	<i>Scattered resources available for purchasing decisions</i>
	<i>Drivers for decisions</i>	-
	<i>Culture and mindsets</i>	<i>Lack of process ownership; Lack of device ownership</i>
<i>Process</i>	<i>Process description</i>	-
	<i>Control measures</i>	<i>By-passing of controls</i>
	<i>Reporting and feedback</i>	<i>Incomplete device error records</i>
	<i>Pressures on process</i>	<i>Range of device choice; Lack of manpower</i>
	<i>Inventory management</i>	<i>Incomplete and multiple device inventories; Multiple servicing arrangements</i>
	<i>Goal alignment</i>	<i>Purchase routes distinguished by price thresholds; Misplaced management support</i>

Table 26: Challenges observed in current practice relating back to the factors considered

The next chapter brings the learning from the three results chapter into a general discussion of findings, as well, as a discussion on the potential improvements that can be made. This leads into the motivation for designing a framework that captures the issues gathered in this study.

Chapter 7

SYNTHESIS:

Improvements and Framework

Having gathered evidence and presented elements of current practice in medical device purchasing (Research Sub-Question 1), as well as presented risks in current practice (Research Sub-Question 2), this next chapter focuses on areas of improvement (Research Sub-Question 3).

The aim of this study was to answer the following research questions, of which those discussed further in this chapter are shaded in grey:

Research Sub-Questions

1. What is current practice in medical device purchasing?

Who are the stakeholders and what are their roles in purchasing?

What type of knowledge and competence do these stakeholders have?

What are the resources and drivers for purchasing decisions?

What other factors influence current practice?

2. (How) does current practice present risks to healthcare delivery services?

What challenges and risks are present in current practice?

How are the factors of current practice different from good practice?

How do these factors impact the healthcare service?

3. Where are areas for improvement on current practice?

How do the stakeholders themselves view improved practice?

How can factors in current practice be managed towards improvement?

The three sets of Results (I, II, and III) focussed on the earlier research questions in this 'Research Questions box', as indicated in each respective chapter. The aim of this chapter is to focus on the potential for improvement. A discussion of current practice, with a comparison to good practice, not only provides evidence of suboptimal practices, but also highlights the need for improvement. The direction and strategy for such improvements form the basis of the motivation for developing a framework also introduced in this chapter). This framework is presented that captures the main findings in diagrammatic form and serves potential improvement purposes.

7.1 Overview of Improvement Measures

Guidance on possible improvements measures arose both from the literature and the stakeholders views themselves, both of which are described here.

7.1.1 Improvement Measures from Literature

The literature pointed to established principles on improvement measures from management sciences to design process improvements. Unless a new design of purchasing in hospitals is adopted, what can be achieved within the current context is an improvement on current practice – tending towards what the literature identified as continuous improvement. As noted earlier, the healthcare literature refers repeatedly to the PDSA cycle as one such method. This suggests a rather retrospective approach to assessing the quality and risk in a process, which was evident even in the way the risk workshop was initiated and conducted at Trust A – the risks were highlighted after events occurred. It is therefore suggested that even the first phase – planning – is not executed with the associated risks involved. The literature warns of such bad practice in organisations that tend to ‘fire-fight’ rather than plan for potential risks.

According to Clarkson and Eckert, in order to create improvements, the organisation needs to take into account (Clarkson & Eckert 2005): *Current-state goals; Stakeholder intentions; Contextual forces*. Such approaches are particularly useful in this context, where the purchasing decision is made by stakeholders belonging to different teams with varying knowledge of the process and of the product being purchased. These three considerations were incorporated into the design of the questionnaire used as the basis of the semi-structured interviews in the study, as well as taken into considerations in the design of the research questions, as explained in Chapter 3. To reiterate briefly, the current-state goals as well as stakeholder intentions were elicited through discussions on drivers and intentions and attitudes towards purchasing for safety, and the contextual forces formed the basis of many of the parameters on which the findings were clustered throughout the study (in the form of a ‘parameters’ table populated in each chapter. This table is re-visited in this chapter, particularly in the discussion on which factors can be managed to improve on current practice.

The following sections address these considerations for improvement centred around the research questions: on the stakeholders’ own views on improved practice, and how factors currently present in current practice can be managed towards improvement.

7.1.2 Stakeholders' Views on Improvement

This data was collected as part of the semi-structured interviews held at all the Trusts, centred around the questions in the Questionnaire. Although a small part of the data collection, it served to highlight stakeholders' own views on where improvements could be made, and whether or not the 'culture' of the NHS is ready for such improvements.

Participants in the interviews were asked two sets of questions, as laid out in the Questionnaire in Appendix II on what would be most useful if new purchasing for safety measures were to be adopted. The full list of options are available in Question 6 in Appendix II. These were also combined with any other data emerging from the interviews in other parts of the data collection.

Consistent support was given for the following recommendations:

- Introduce medical device coordinators
- Keep stakeholder groups separate
- Educate end-user or medical device purchasing
- Flexibility according to device type
- Board level support
- National awareness / campaign

Differing views were received for the following ideas:

- Tick box approach to assess purchasing practice
- Training on purchasing practice
- Set Trust objectives

Other examples of control measures, which were suggested by the stakeholders through the interviews, and relate closely to recommendations in the literature, include:

- Standardise on device models to avoid errors from end-users
- Conduct evaluations and trials of models before final purchase
- Communication of requirements to supplier from consumable to drug to device

- Audit device use and repair
- Incorporate purchasing process into a more general asset management system (e.g. library, device trainer/coordinator)

In general, the recommendations arising from the views of the stakeholders themselves focus more on the engagement and process within the organisation, or measures that empower the purchasers and end-users themselves. This leaves room for improvement on a local process level, which constitutes the main contribution of this thesis. Recommendations for local improvements are discussed next by a comparison to good practice, referring again to the theory in the literature, to then investigate its applicability to this context.

7.2 Managing Current Factors towards Improvement

The literature points towards good practice in purchasing, to efficient operations management and general context for improvements in patient safety. Instead of listing the main pointers given in each separate field of practice, elements of good practice from operations management and purchasing practice are linked to the device purchasing guidelines, and discussed in context of the findings gathered in this study. This is to ensure the discussion is centred around the context of medical device purchasing and healthcare practice, and not just a direct comparison of two fields of practice.

7.2.1 Distinguishing features of Medical Device Purchasing Process

From the literature it is already clear that medical device purchasing is a domain of its own, although it has parallels to purchasing in other safety-critical contexts. Elements of good practice can of course be adopted from other industries, but an understanding of the context of use for such purchases needs to be taken into consideration. The three key elements are clinical, technical, and financial considerations:

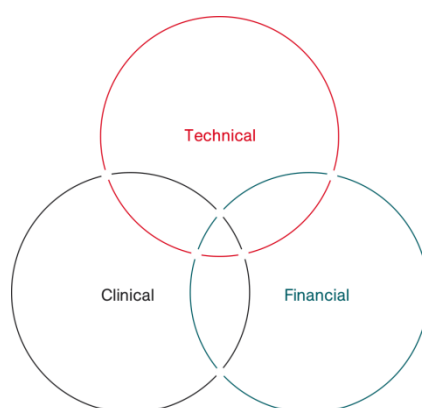


Figure 28: Three considerations particular to medical device purchasing

The contextual forces identified in this study can relate to the influence factors found to influence the purchasing process. In this study, a set of influence factors on the purchasing process were identified: contextual forces or factors that affect current practice. These factors are considered in discussing potential recommendations in the next sections.

7.2.2 General areas of Improvement

Having presented a discussion on how some of these factors are contributing to risks and where improvements could be made at the end of the last chapter, a list of these recommendations are now included in Table 27:

	<i>Factors considered</i>	<i>Challenges observed in Current Practice</i>	<i>Potential recommendations</i>
<i>Stakeholders</i>	<i>Stakeholder definition</i>	<i>Purchaser' refers to a variety of stakeholders</i>	<i>Define stakeholders appropriate to device</i>
	<i>Device knowledge & competence</i>	<i>Scattered device knowledge; Skills variations in device use competence</i>	<i>Recognise variety in device characteristics</i>
	<i>Process knowledge</i>	<i>Scattered process knowledge</i>	<i>Disseminate process overview</i>
	<i>Stakeholder engagement</i>	<i>Operational stakeholder divisions; Disconnects in communication</i>	<i>Engage clinical, technical, financial stakeholders</i>
	<i>Resources for decisions</i>	<i>Scattered resources available for purchasing decisions</i>	<i>Build repository of resources for decisions</i>
	<i>Drivers for decisions</i>	<i>-</i>	<i>Include quality, usability, safety considerations</i>
	<i>Culture and mindsets</i>	<i>Lack of process ownership; Lack of device ownership</i>	<i>Create culture of device ownership on purchase</i>
<i>Process</i>	<i>Process description</i>	<i>-</i>	<i>Create process overview</i>
	<i>Control measures</i>	<i>By-passing of controls</i>	<i>Promote process ownership; control at start</i>
	<i>Reporting and feedback</i>	<i>Incomplete device error records</i>	<i>Create feedback loops for purchase & use history</i>
	<i>Pressures on process</i>	<i>Range of device choice; Lack of manpower</i>	<i>Re-prioritise funding and resource allocation</i>
	<i>Inventory management</i>	<i>Incomplete and multiple device inventories; Multiple servicing arrangements</i>	<i>Create library or other loaning options with audit</i>
	<i>Goal alignment</i>	<i>Purchase routes distinguished by price thresholds; Misplaced management support</i>	<i>Engage Management to promote evaluation and standardisation</i>

Table 27: Potential areas of improvement addressing challenges observed

Although so far each factor has been clustered as those relating to ‘stakeholders’ and the ‘process’ of purchasing, it can be seen from the table that some of these challenges and recommendations overlap between these two groupings. In the next table, these recommendations have been re-written in more generic form and verse, with the assumption that each particular line and factor has implications on both the stakeholders and the process. The recommendations are now termed under new groupings:

→ *Considerations to do with buying the ‘right’ device at the time of individual purchase*

→ *Considerations to do with ‘rightly’ managing the process of buying devices*



<i>Factors considered</i>	<i>General recommendations</i>	
<i>Stakeholder definition</i>	<i>Adequate multidisciplinary stakeholder engagement should be sought with due consideration of the clinical, technical and financial requirements of the device to be purchased.</i>	 <p><i>Considerations for 'buying the right device'</i></p>
<i>Device knowledge & competence</i>		
<i>Process knowledge</i>	<i>The reason, purpose, and intended use of a new purchase needs to be communicated as a set of requirements, rather than specific device choice.</i>	
<i>Stakeholder engagement</i>		
<i>Resources for decisions</i>	<i>Evaluation and Standardisation of device models are required where appropriate</i>	
<i>Drivers for decisions</i>	<i>Stakeholders in the purchasing process need to be aware of their role as collective purchasers.</i>	
<i>Culture and mindsets</i>		
<i>Process description</i>		
<i>Control measures</i>	<i>The process of purchasing itself needs to be recognised as part of a wider device management and healthcare delivery service.</i>	 <p><i>Considerations for 'managing the process'</i></p>
<i>Reporting and feedback</i>		
<i>Pressures on process</i>	<i>Process control measures are needed; and process owner refined for each purchase type</i>	
<i>Inventory management</i>		
<i>Goal alignment</i>		

Table 28: Considerations for each purchase, and considerations for the purchasing process

This terminology used relates back to Figure 8 (repeated here) which seeks “Purchasing Process User Needs”, requiring their own “Validation” to check if the overall process delivers the user needs, and also seeks “Purchasing Process Design input”, requiring its own “verification” to see if the process has the correct elements in its design. Extending these concepts, in brief:

Validation asks the question: *Are we buying the right device?*

Verification asks the question: *Are we buying the device rightly?*

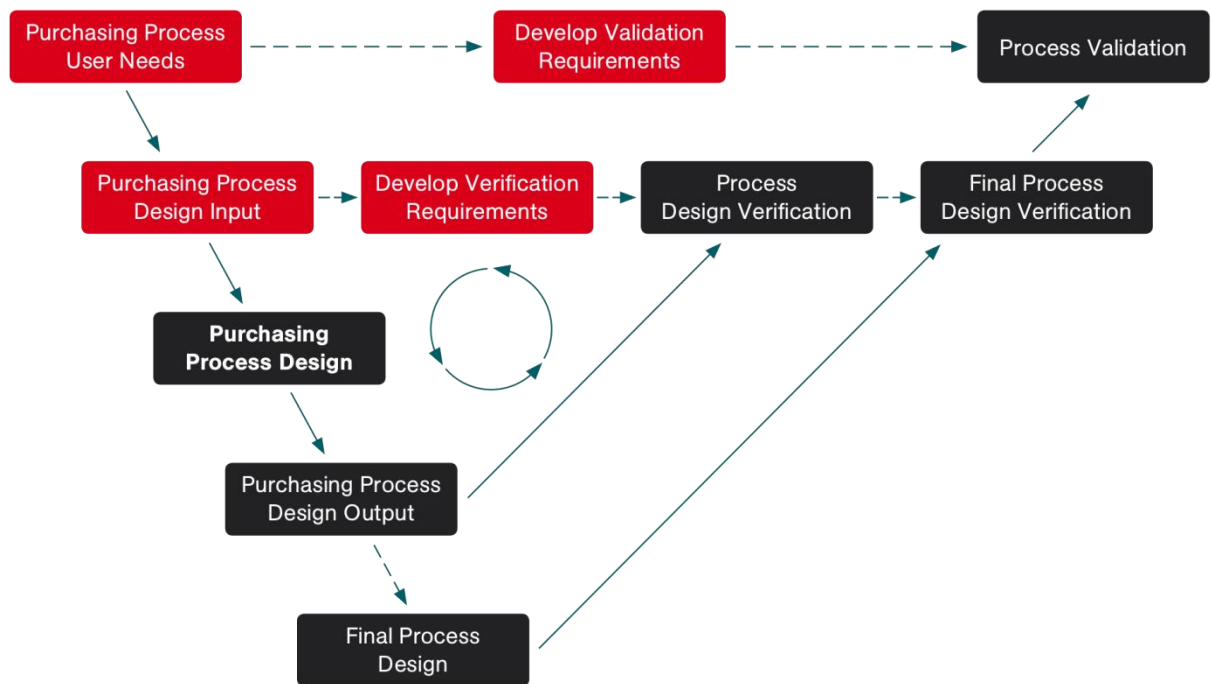


Figure 8 (repeated): Activities associated with purchasing process validation, adapted from (Alexander et al. 2001)

To elaborate on this terminology further, the following table describes the types of questions that would be appropriate for these two validation and verification aspects of the purchasing process, in the context of medical device purchasing.

<i>Sample Questions</i>	
FOR PURCHASE VALIDATION	<i>What do I need?</i>
	<i>Do I need to buy?</i>
	<i>What to consider when buying?</i>
	<i>Who to consult?</i>
	<i>Which to buy?</i>
	<i>What devices are already in inventory?</i>
FOR PROCESS VERIFICATION	<i>Why do capital/revenue devices differ in purchasing controls?</i>
	<i>How can we track users' competence in device use?</i>
	<i>How can we monitor our maintenance contracts?</i>
	<i>How can our device error records better serve device choice?</i>
	<i>Who owns this process?</i>
	<i>How can we continuously monitor process controls?</i>

Table 29: Samples questions for individual purchases (validation of purchase) and for elements of purchasing activity (verification of purchasing process)

At the highest and most ambitious level of process improvement, these are offered as recommendations for improving on current practice. For the purposes of this study, further analysis was conducted to assess realistic improvements that could be made in the shorter term on current practice, given the insight obtained during the research process. These recommendations, leading to the motivation and design of an overall framework are described next.

7.2.3 Specific areas of Improvement

While ideally all factors for improvements would be considered for improving on current practice, it is important to take into consideration the realistic scenarios encountered in current NHS context. The factors have been termed either variables or constraints for the purposes of short-term improvement.

Constraints: Device Knowledge; Culture & Mindsets, Pressures on process; Drivers for decisions

It is not claimed that these are not changeable over time, but are assumed to be current constraints going by the evidence that these factors are embedded into the system, and have been for a long while as observed in the studies. They are therefore factors that affect practice, positive or negatively, but are not addressed as recommendations in this project. For instance, it is not assumed that one can change people's different knowledge of device ergonomics, unless training for physicians and nurses and technicians changes over time. Cultures and habits are also difficult to change in one organisation but can happen over time. The complexity factors that add pressures on the process include the variety of equipment, the difficulty to track and audit equipment, and the variety of routes taken to make decisions about device purchases given the sheer diversity of devices purchased in any given hospital.

Variables: Stakeholder definition and engagement; Process Knowledge; Requirements communication; Control measures; Resources for decisions

What can be changed in the short-term is how stakeholders are engaged, especially given their varying backgrounds. Greater awareness of the process can be disseminated to all involved stakeholders; or measures can be found that can communicate requirements; and provide new control measures.

Recommendations for improvements in this study focus solely on what is believed to be possible to change, in other words – improvements on current practice. The framework developed therefore assumes that the factors termed 'constrains' act exactly as that – constraints on the process, but that the variables are changeable in the foreseeable future. This constitutes the motivation for the design of the framework.

7.3 Framework Design

This section includes a motivation for designing the framework and the method for its design.

7.3.1 Motivation for Framework

The theme throughout this thesis has been that a medical device involves clinical, financial and technical considerations. This is what distinguishes it from other purchases in a hospital. Through the observations made in current practice, reinforced by some of the case studies, areas of improvement were identified, as discussed in Section 7.2.3. These areas of improvement relate to support for making individual purchasing decisions as targeted to whoever is acting as a purchasing stakeholder (purchase decision validation), and to those designing and monitoring the purchasing processes as a whole (purchase process verification). Each of these, in turn, can be explained through sample questions relevant to these two perspectives. Finally, the factors considered within these two perspectives were classified into variables or constraints for the purposes of this study.

The framework introduced in this section focuses on making improvements on what have been termed 'variables'. Table 30 shows which variables in particular are addressed with the design of the framework:

	<i>Sample Questions</i>	<i>Factors considered</i>	<i>Variable/Constraint?</i>	<i>Addressed in framework?</i>
FOR PURCHASE VALIDATION		<i>Stakeholder definition</i>	<i>v</i>	✘
	<i>What do I need?</i>	<i>Device knowledge & competence</i>	<i>v</i>	✓
	<i>Do I need to buy?</i>	<i>Process knowledge</i>	<i>v</i>	✓
	<i>What to consider when buying?</i>	<i>Stakeholder engagement</i>	<i>v</i>	✓
	<i>Who to consult?</i>	<i>Resources for decisions</i>	<i>v</i>	✘
	<i>Which to buy?</i>	<i>Drivers for decisions</i>	<i>c</i>	✓
	<i>What devices are already in inventory?</i>	<i>Culture and mindsets</i>	<i>c</i>	✘
FOR PROCESS VERIFICATION	<i>Why do capital/revenue devices differ in purchasing controls?</i>	<i>Process description</i>	<i>v</i>	✓
	<i>How can we track users' competence in device use?</i>	<i>Control measures</i>	<i>v</i>	✘
	<i>How can we monitor our maintenance contracts?</i>	<i>Reporting and feedback</i>	<i>v</i>	✓
	<i>How can our device error records better serve device choice?</i>	<i>Pressures on process</i>	<i>c</i>	✘
	<i>Who owns this process?</i>	<i>Inventory management</i>	<i>v</i>	✓
	<i>How can we continuously monitor process controls?</i>	<i>Goal alignment</i>	<i>v</i>	✓

Table 30: Factors considered in design of the framework

The framework therefore is designed with two intents:

1. As a representation of the issues addressed at each stage of the life-cycle of the medical device in a hospital (intended mainly for end-users/original requisitioners)
2. As a self-assessment tool for those with more holistic process knowledge for medical device purchasing (e.g. EBME or Procurement) to measure its own capacity for addressing all relevant issues in medical device purchasing decision-making.

7.3.2 Designing the Framework

The data used for the design of the framework came mainly from two sources: the process representation of device life-cycle (repeated in Figure 29 below) and the list of themes derived from coding the data from interviews. The process of coding and analysing these themes has been described in the coding section in Chapter 3 (Section 3.3.2), and its content is elaborated further here.

As noted in Section 3.3.2, the issues were re-arranged to correspond to particular stages in the life-cycle of a medical device within a hospital. Put simply, for each theme it was asked, “Where in the life-cycle does this theme become relevant?”. As was seen in Figure 16, there were originally ten distinct sub-processes under which to cluster these themes. However, during this analysis, it became clear that some of the issues gathered certain issues were common to more than one process step. This led to a new format for clustering, which resulted in the six new groupings shown in Figure 29 below.

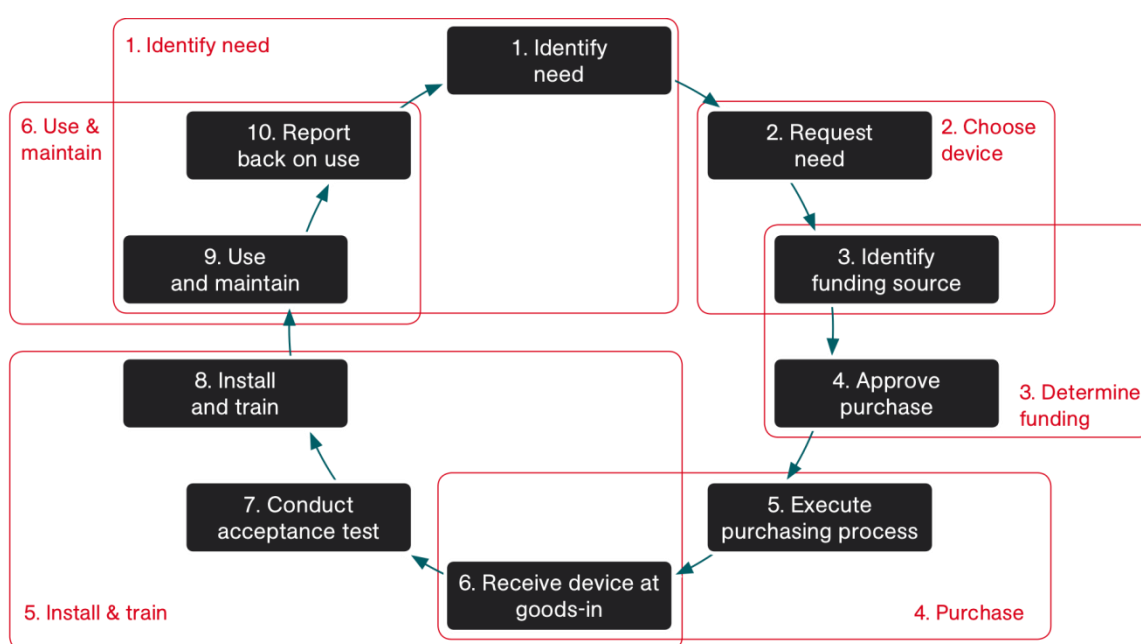


Figure 29: Clustering of process steps

The final list of themes from the data clustered within these process steps and issues are shown in Figure 30.

WHEN?	1. Identify need	2. Choose device	3. Determine funding	4. Purchase	5. Install & Train	6. Use & Maintain
WHO?						
end-user	yes	yes			yes	yes
budget holder	sometimes	yes	yes	sometimes		
engineering	sometimes	yes	sometimes	sometimes	yes	yes
supplier	sometimes	yes		yes	sometimes	sometimes
training		yes			sometimes	sometimes
procurement			sometimes	yes		
finance			yes	yes		
WHAT?	Alternative stock	Usability & Training	Benefit vs. cost analysis	Delivery instructions to supplier	Time for adoption of device	Loaned equipment tracking
	Catalogue options	Relationship with supplier	Board level engagement	Consult Procurement Hubs	Linked asset registers	Track devices leaving hospital
	Clinical need	Servicing needs	Use of Medical Equipment committee	Control of delivery on site	Incident reporting & analysis	Track devices in hospital
	Reason for purchase	Device/ consumable/ drug specification	Capital investment plan update	Communicate requirements to supplier	Variations in skills in device use	Record of equipment servicing and failure
	Available funding	National data on device	Revenue and capital budget options	Resources for administering purchases	Education on device use	Competency for available servicing in-house
	Potential suppliers	Evaluation & standardisation	Current equipment distribution & prioritisation	Update catalogue of equipment	Culture of device ownership	Comprehensive, open and honest, error reporting

Figure 30: Considerations for device purchasing in various stages of device life-cycle

Using the representation in Figure 29 as a baseline, and the data in Figure 30 as the content, different designs for the framework were explored, to test its appropriateness for its potential intended use. Various forms to represent these processes and main stages were explored, but the main versions are included in this thesis.

7.4 Framework Design Versions

The three main forms were designed to meet the following criteria:

1. A basic flow chart of main stages in the cycle
2. A comprehensive cyclical life-cycle with its main 'issues' incorporated inside each stage
3. A more simplistic model that represents main stage-gates, but still includes key issues relevant to each stage

These three versions were designed and demonstrated back to previously interviewed stakeholders for feedback. Their development stages are described in detail next.

7.4.1 Version 1: Flow-chart

The first version is a basic flow-chart, keeping in line with the process map style of diagramming used for most of the data capture at Trust A. The diagram addresses each stage in the life-cycle's key considerations in very simple form. This flow-chart is mainly aimed for general hospital-wide use, to show the differences in key considerations at each stage of the process. The list on the right is an added text for those with more holistic process knowledge, to keep track of what aspects of the process (from requirements to building knowledge) are being addressed in each stage of the process.

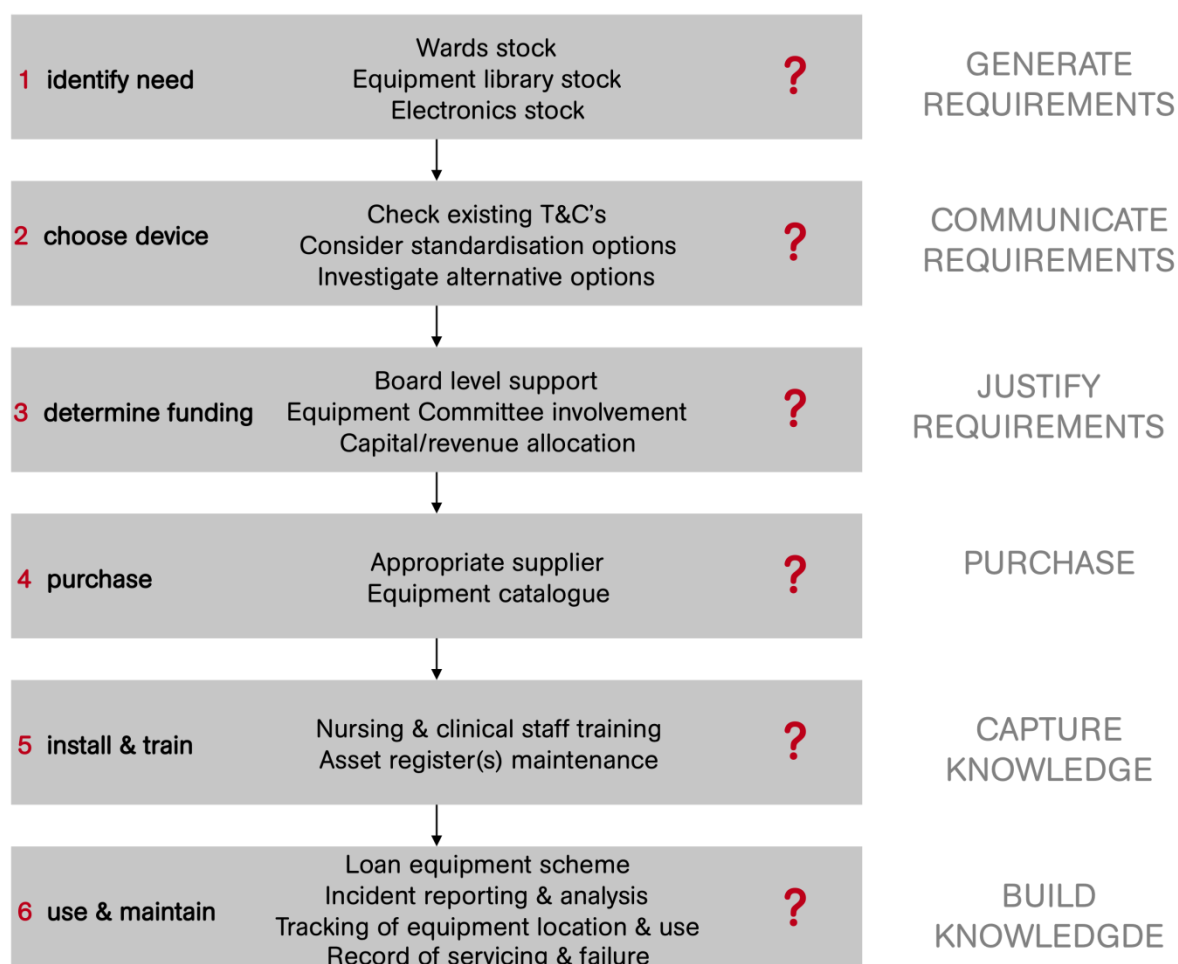


Figure 31: Framework Version 1: Flow chart

The feedback from this version, though only shared with a few stakeholders from Trust A, was not overwhelmingly in favour nor against it. This figure was shown after the later

cyclical versions, which resonated with the participants far more. However, it was agreed that the consistent and simple descriptions of each process stage were “useful” and “clear”. The figure serves as a good starting point for dissemination of process information in a hospital.

7.4.2 Version 2: Life-cycle wheel

The second version is a comprehensive cyclical life-cycle with its main ‘issues’ incorporated inside each stage. The conceptual design is based largely on Gough’s (Gough 2004) wheel for the life-cycle of packaged products for consumers. This same design had been used for the design of medical devices for home-use (Gupta 2007). The advantage of this model is that it allows for a grading scale with regard to each issue. Users of the wheel would assess the extent to which their organisation or group considers each of these factors. This approach lends itself to the maturity and organisational matrix models discussed earlier, and already familiar in some healthcare settings. These factors or issues were therefore designed to fit around a ‘purchasing life-cycle wheel’ as follows:

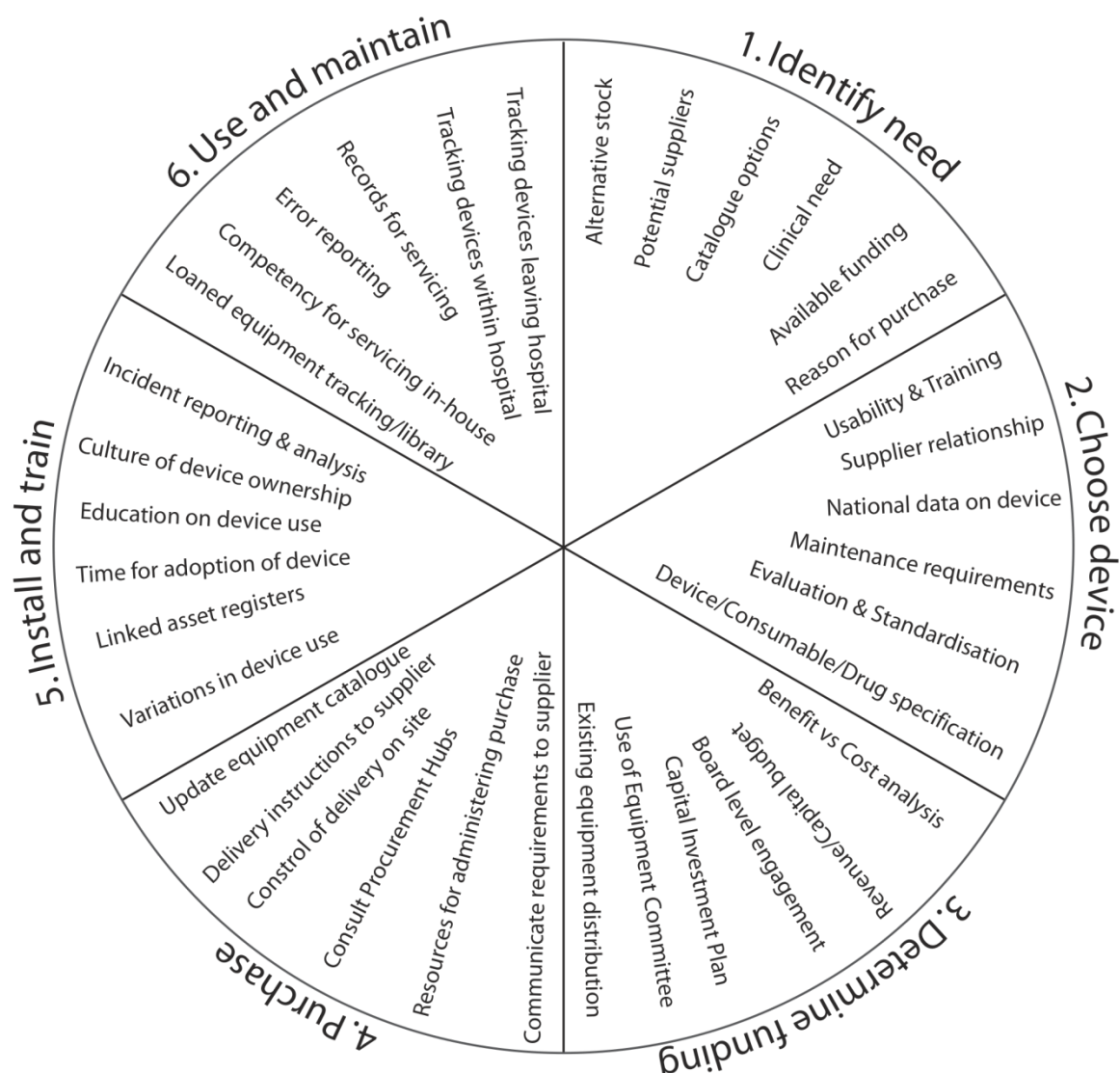


Figure 32: Framework Version 2: Life-cycle wheel

However, the use and format for this particular instance varies from the original concept. In Gough’s case, each issue had a grading scale for the organisation to assess to what extent the designer took into account that particular issue in the design process for any given product. In the first version, although this potential use was described to the participants, it was also highlighted that the diagram could be used as it is, with no grading scale, depending on its intended audience.

Although each issue is allocated a stage in the life-cycle, the types of stakeholders involved at each stage (and hence the ones that need to take into account those particular issues) will vary according to the Trust's organisational hierarchy. Secondly, while this represents one life-cycle process for 'a purchase' (for either one device or a group of devices), it is understood that such cycles may be happening in parallel at any given time during the running of a hospital and its operation. Decisions about device purchases occur at ad-hoc times. Therefore, the issues within the wheel do not have any hierarchy.

The feedback received for this version was mixed. Comments were requested on the accuracy of the wording and issues noted, usability, and adoption by end-users.

On accuracy and completeness

Very comprehensive!

Point of Care practitioner

You've captured a lot of issues here!

Head of EBME

Potential suppliers should come later in need communicated area.

EBME administrator

I have no problem with the wording.

Nurse

On overall structure and usability

Would be inaccurate to add stakeholders as engineering are involved throughout the process, as may the end-user.

EBME administrator

These comments were incorporated into the design of the next version.

7.4.3 Version 3: Stage-gate diagram

Following the feedback and further analysis, a third version was created based on the assumption that certain 'stage-gates' were present in the cycle; starting from the definition

of need right to the point where the need is fulfilled. The main concept for the stage-gate, as a development of the original process steps shown in Figure 32, led to the following diagram:

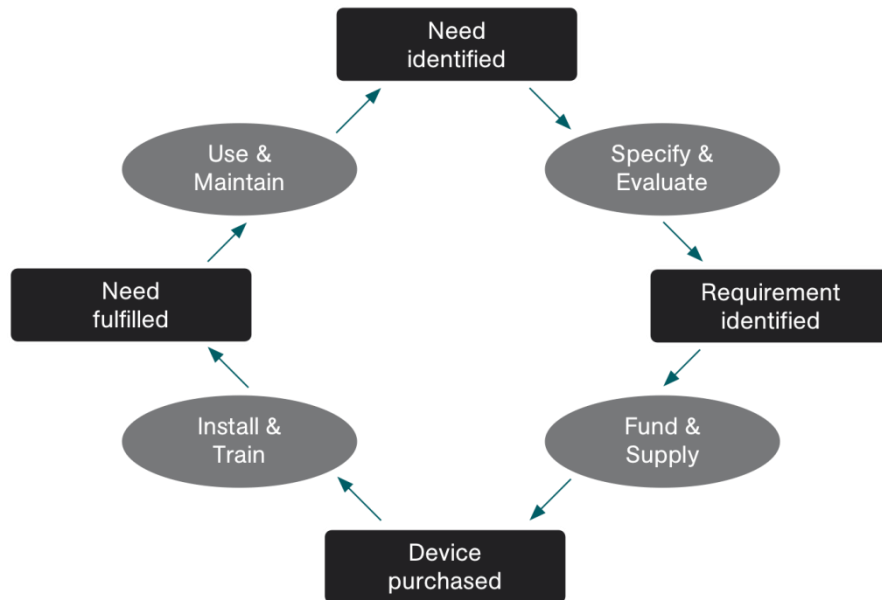


Figure 33: Concept for stage-gate version of framework

This concept shown in Figure 33 was used to design what became the preferred design, shown in Figure 34.

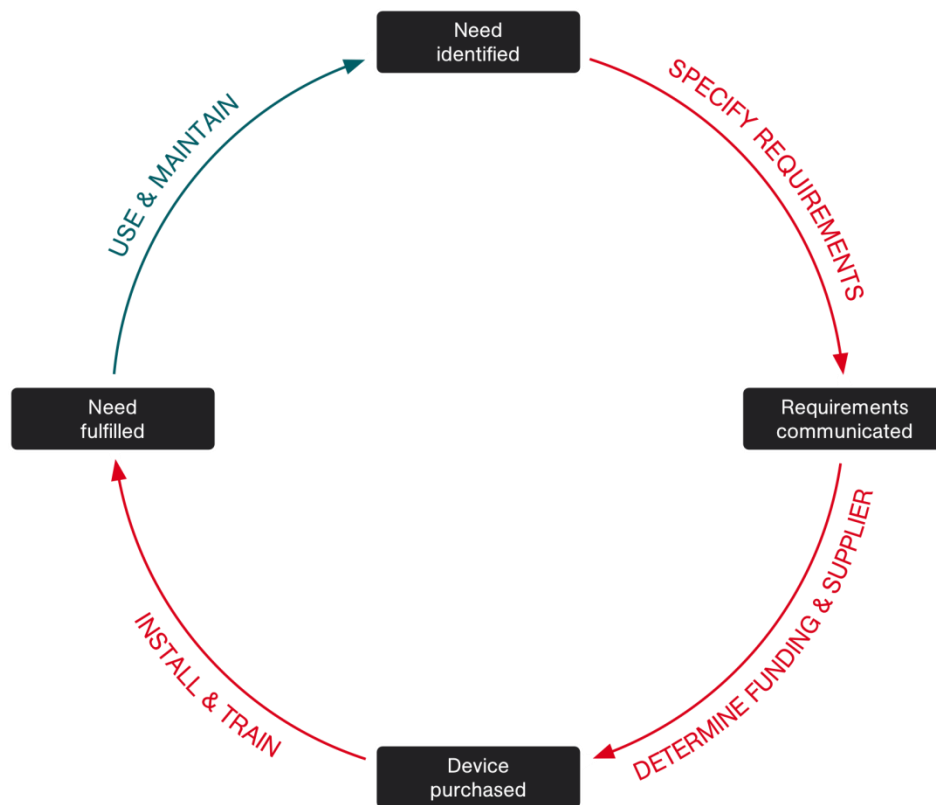


Figure 34: Framework Version 3: Stage-gate Cycle

This version also received some comments from respondents. It was mainly used to test the accuracy of the wording used in the main stages in the cycle of a medical device, in preparation for the next framework design.

It took me a while to get what you are trying to communicate with the other diagram [Version 2], but this [Version 3] is much clearer...more simple... I agree with the 4 stages, yes, the arrows are in the right direction. This covers most of procurement activity for a device.

EBME Research and Development

You'd be hitting similar group of people with 1 and 3... 2 is just more detailed and not for everyone. We could understand it.

Head of EBME

This diagram is fine, nice and easy!

Renal dialysis technical manager

I think you don't just mean specify requirements, you mean specify and evaluate before you make a decision.

Head of EBME

The blue arrow in the diagram was highlighted as being a different process to the rest. On design, this was intended to stand out as this is the stage where the knowledge about the device increases, and hence the internal capacity of the organisation or 'purchasing team' to start the new purchasing cycle increases with each new purchase. It was pointed out by some participants that the internal capacity of the organisation extends to the first stage: specify requirements, as well. Given the crucial role in requirements specification in affecting the next stages, and the differences in requirements that each specific device has, this is also a large learning area per purchase, and increasing in capacity to specify requirements increases the organisation's device purchasing performance. These ideas are incorporated in the final design introduced next.

7.4.4 Applicability of Framework

The final stage in testing this initial framework concept consisted of modifying the main concept model to test its applicability to various devices and to different scenarios. As a starting point, Version 3 was modified to include the factors/considerations in Version 2, as shown in Figure 35.

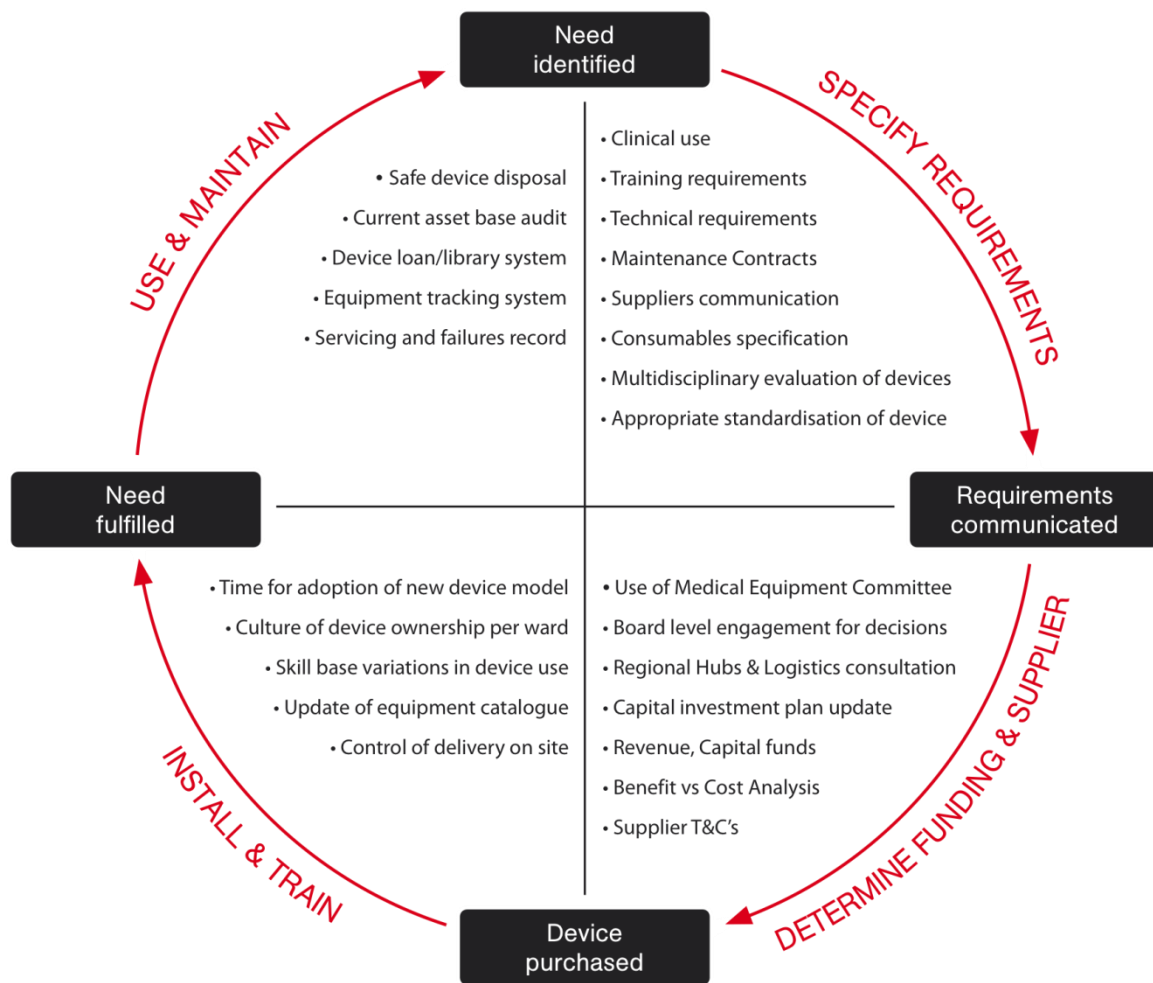


Figure 35: Framework combination of Version 2 and 3

This design combines Versions 2 and 3 closely, as it has stage-gates for the process but also includes some of those key issues that require consideration within those stage gates. These were presented to stakeholders for feedback, firstly by testing variations for different device purchase routes, and then discussing its potential for general use in different hospital scenarios and potential changes in structures.

Framework variations for device

Representatives from the initial group of stakeholders were chosen, and were asked to comment in particular on their own experiences in purchasing a particular type of medical device. The results of this feedback are described next:

Thermometers: Commenting on the thermometer study conducted at Trust A (Case Example 1 in Chapter 6), the respondent commented how the technology behind thermometers is different to other devices given that most of the complexity is encased in the device. He also commented that they are “so cheap anyway and all the technology is inside, the manufacturer knows all that. The main cost goes into the consumables.” The device is not serviced in-house and sent back to supplier when faulty, and so the purchasing arrangements with the supplier do vary. It is also not a capital funded device and the funding is already allocated, so the procurement process in-house is different. Specifying requirements was very important in their process as they had to conduct a scientific study to see which one to use for their particular clinical needs. A consideration perhaps not captured in this diagram is a risk assessment on infection control, which is important for this type of device that is disseminated throughout the hospital and requires new consumables on each use. Finally, the culture of device ownership is important for a device like this one, which can “easily go missing because it is so small”.

Renal dialysis equipment: The considerations for renal dialysis equipment do not vary much for the main framework design – most of the issues are considered in the purchase, or at least were considered by the respondent. The main difference was the use of other funds such as charitable sources, which is more characteristic of a device that is more expensive and specialised. Experiences are also shared across Trusts in other dialysis centres to find out which suppliers are recommended.

Infusion pumps: All of the considerations were perceived to be applicable to infusion device purchases. In addition, the respondent pointed out the importance of national evaluations (such as BIME) and also emphasised the importance of risk assessments with the introduction of a new device.

These comments were incorporated into the model to observe consistencies and the potential for applicability of different device purchase scenarios. The working samples are presented in Figures 36a,b,c, which incorporate these various comments by either omitting phrases from the original list of issues or shows new additions in italics.

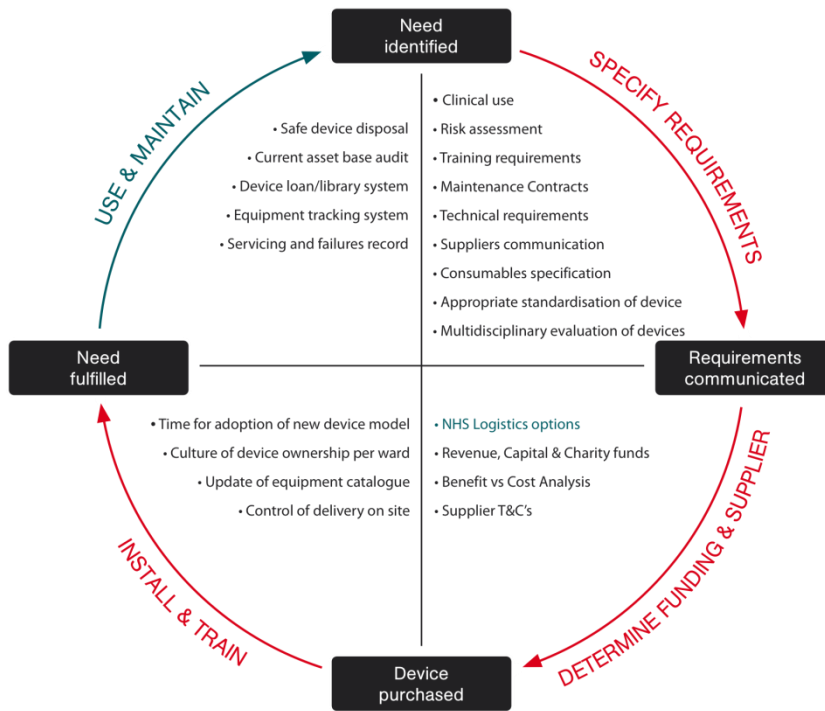


Figure 36a: Framework modified and trialed for thermometers

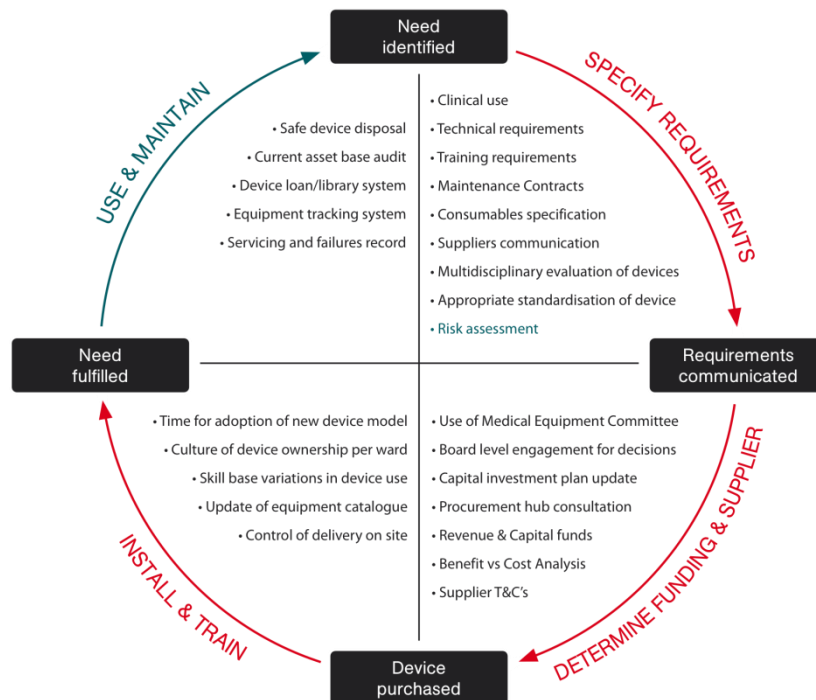


Figure 36b: Framework modified and trialed for infusion pumps

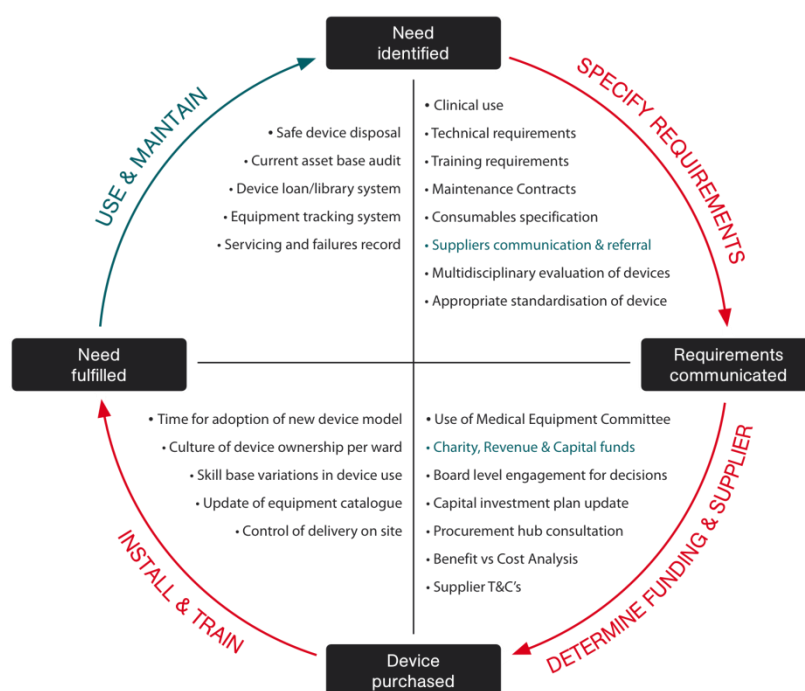


Figure 36c: Framework modified and trialled for renal dialysis machines

Framework applicability/usability feedback

Finally, the framework was discussed with stakeholders with more holistic process knowledge of the purchasing system. Two respondents were chosen from Trust A for this purpose: Head of EBME and the Deputy Finance Director, both of whom had been involved in the study and were familiar with the process and contributions of the research project.

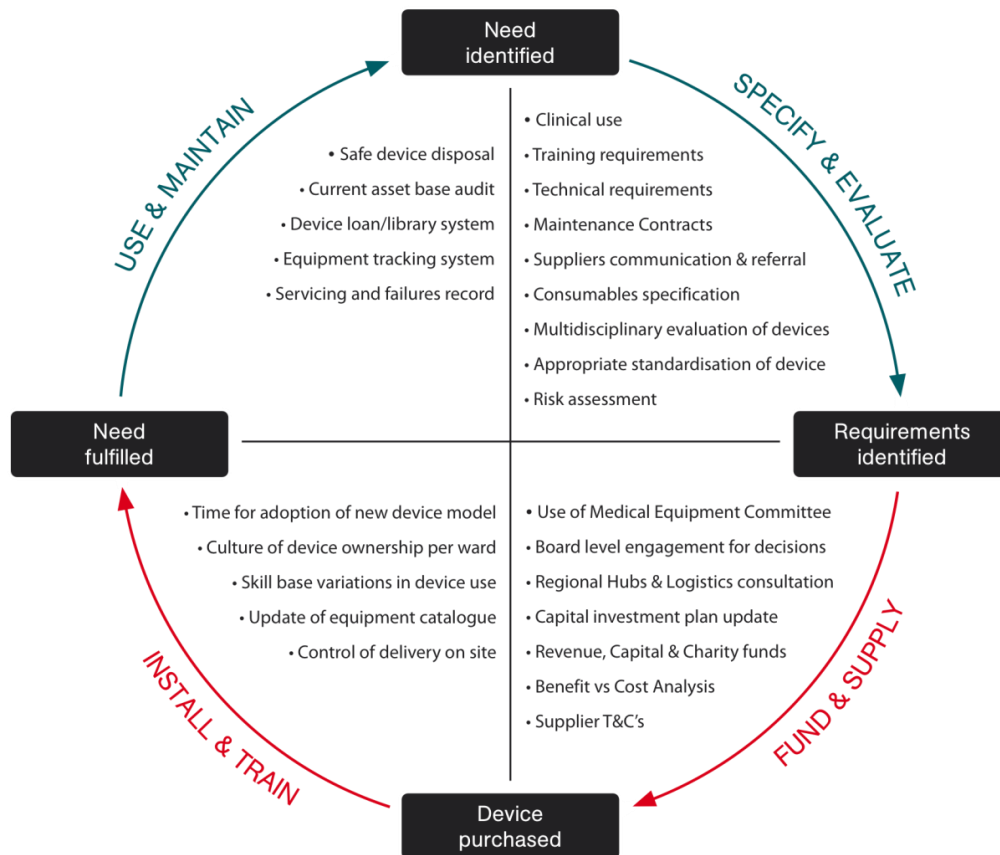


Figure 37: Framework: Final design

The respondents offered comments on the general design of the framework in its final version, as shown in Figure 37, which takes in all the considerations put forth by the respondents:

I prefer this format to the earlier version - I don't need to rotate myself vertically to read this one! The content is very similar though, so I remain happy with it. I don't think it's meant to explain everything in one slide, but rather to provide an aide memoire of topics relating to each part of the process - which you can then expand on if required. This is something you would give to new people who tend to be in silos, but if they have a diagram that shows them other bits of the process of how we exercise control and how they fit into it... so if it's simple like this one, it's useful for that!

Deputy Director of Finance

The diagram tells me to ask myself why I want this piece of kit, it then takes me through why, what should be the requirements and specifications, what do I need to run it... then takes me how to do those things and how to fund it. So it's good. ...I can see it also points out things that we perhaps don't do particularly well, like 'time for adoption of new device'... and 'equipment tracking system'. Skill base variations is not really applicable if you standardise on equipment. ... interesting... The culture of device ownership is interesting too. There's lot of evidence to say that if you give individual wards their budget, they take more care of their equipment.

Head of Clinical Engineering

Finally, an interesting observation came from the distinction between the red and blue arrows. This was initially intended to represent processes that remain the same (blue) and processes that change according to the device purchased (red). However, it was pointed out that many changes are being undergone both in health policy as well as by the suppliers' equipment services. The new 'Managed Equipment Services' provided by many mean that less servicing may have to be done in house, and the communication and relationship between suppliers and purchasers will become far more significant:

The BLUE/RED divide is perhaps not so much related to individual devices, but with the changes in the NHS and supply chain management that occur. In a way, with Management Equipment Services offered by suppliers, they will do all the bottom bits, and we still have to get the top half right in terms of requirements specification. Specify and evaluate varies completely depending on device. Funding varies depending if its revenue/capital, mainly done on price... Install and train is the same processes regardless of device. Use and maintain also will be the same procedures but differs slightly for device and skill variations.

Head of Clinical Engineering

The key message in both these respondents is the importance of identifying, specifying and communicating requirements, regardless of the device purchased, the hospital's context, and the policies changing around the public and private sector.

As a means of relating the framework back to the systems discussions in earlier chapters, Figure 38 demonstrates the integration of such a purchasing cycle as part of the wider device management and healthcare delivery system (a modification of Figure 9).

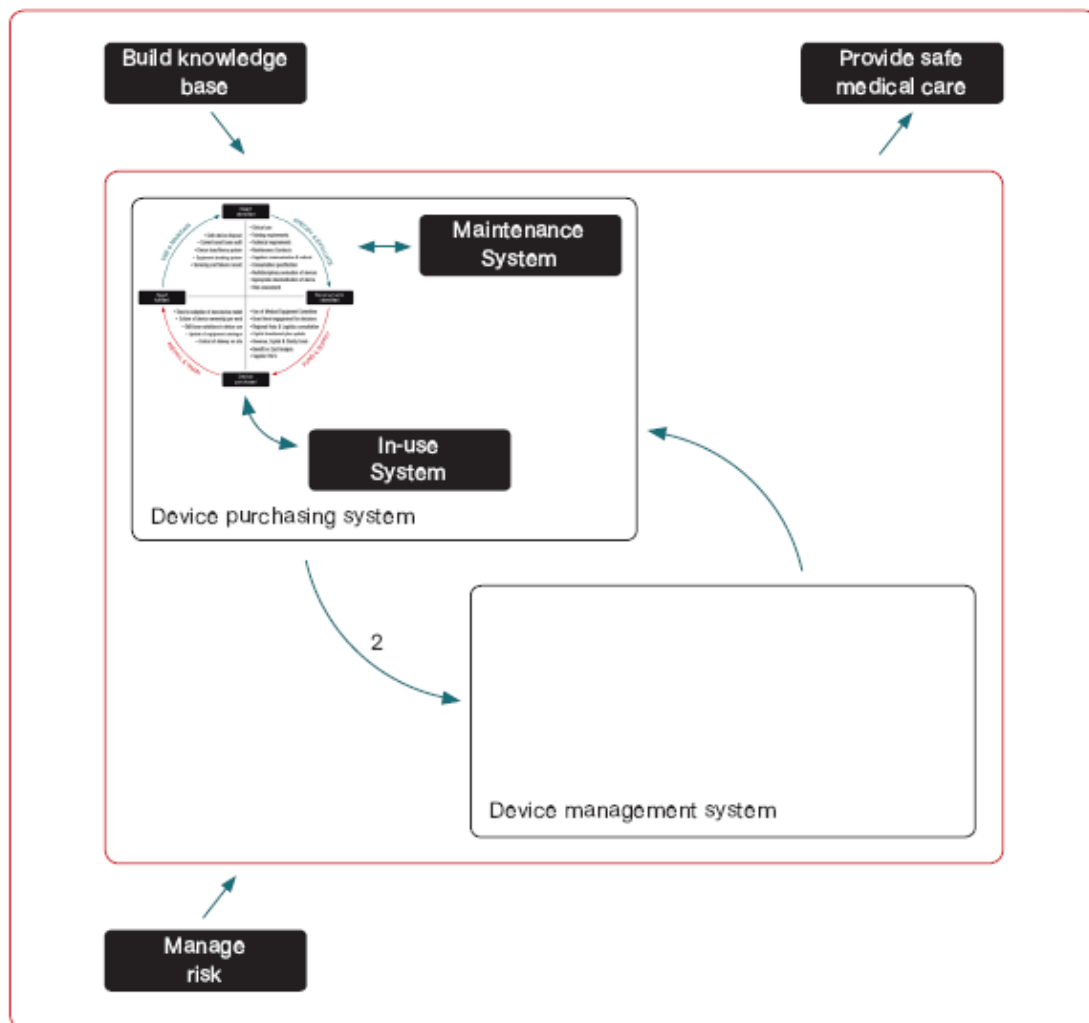


Figure 38: Integration of framework into wider healthcare delivery system

Given this wider context of the system, it can be inferred that the suggested framework is presented for use when the new purchase involves such a systems change. For instance, standard daily purchases that have already gone through processes of evaluation, standardisation and all the other factors considered within the framework, need not repeat

the process suggested in the framework. The trigger for consideration of these issues is effectively the recognition of anticipated ‘systems change’ with the new purchase.

The most obvious and comprehensive way of deciding whether or not systems change is required is, of course, to actually go through the process itself and recognise no need for going through the checklist. However, in some situations this is an unnecessary task, especially in routine purchases or in cases where a purchase is required urgently. The most simple way of answering it, in context of Figure 38, would be to ask if healthcare delivery system changes would be required, in other words:

“Would the healthcare management system require re-design with this new purchase?”

A list of trigger questions that serve to give details to the above question would have to be drawn up by the organisation itself, but a sample is suggested here, some of which are reactive to previous events, and some of which are proactive:

1. **Previous incidents:** Did the previous purchase cause an incident? (where an event has resulted in actual or potential harm to patients or practitioners)
2. **Hazard identification:** Do service providers using this device have local concerns and themselves identified potential hazards with this device?
3. **Service re-design:** Are changes planned to an existing service or system that surrounds this device use, or is there a new service planned which includes the use of this purchase?
4. **External directives:** Are there new policies or mandates that concern devices that also necessitate system changes?

This trigger is indicated in a modified version of the framework shown in Figure 39, to suggest that at any time during the ‘Use & Evaluate’ section of the life-cycle of the device, such wider system questions are to be considered before the cycle is triggered once again for a new purchase. The ‘Use & Evaluate’ also is intrinsically linked to Figure 5 presented earlier in Chapter 2. In addition to the suggested system changes may come from either the manufacture and supply process or the internal hospital processes, once again emphasising the intrinsic sharing of risk and responsibility throughout the device life cycle.

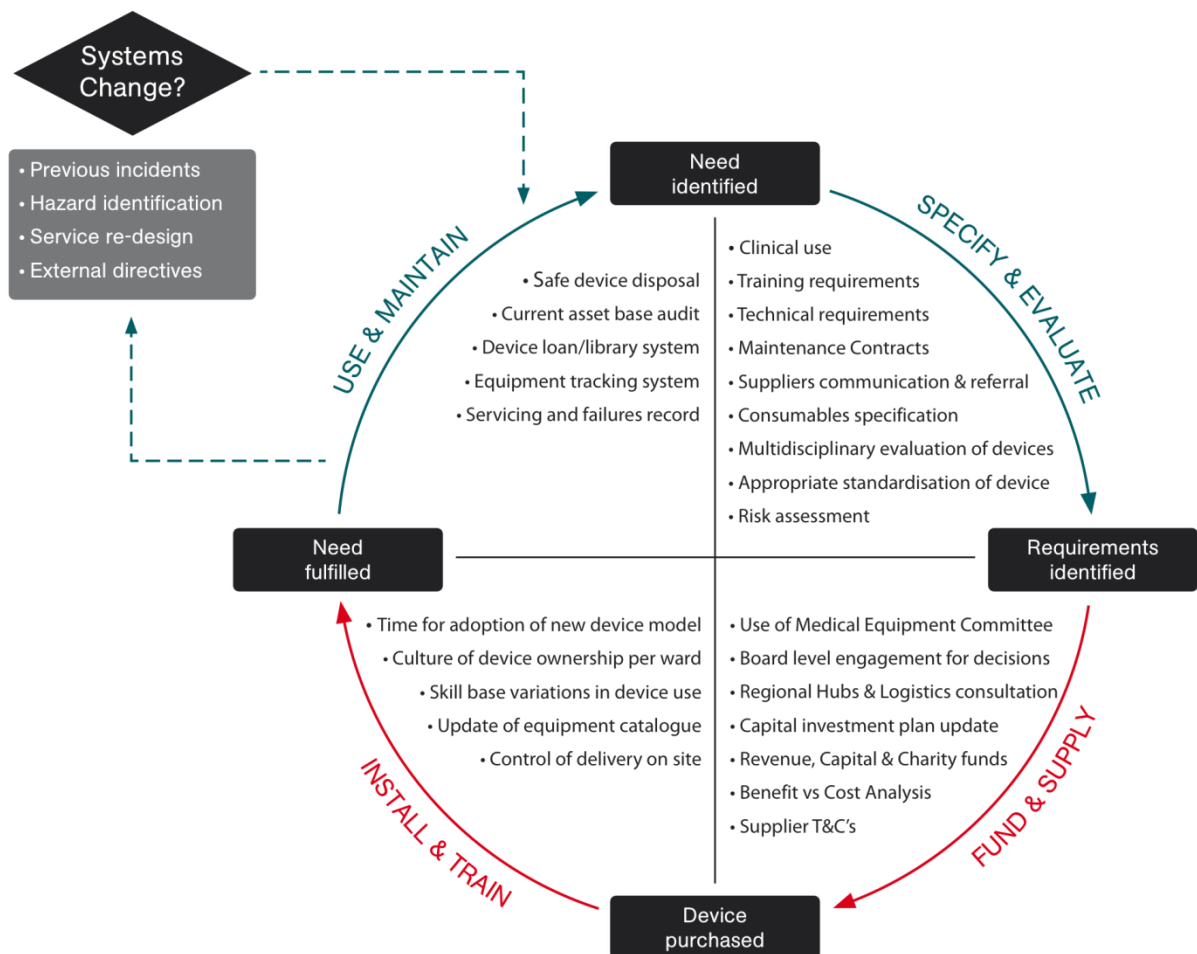


Figure 39: Framework: Final design with system trigger

7.5 Summary of Improvements and Framework

The main messages in implementing improvements are presented in this chapter, with some consideration of factors that may be more challenging to resolve within a short period of time. Improvement on current practice is therefore suggested, rather than a total change in practice. The framework designed highlights these areas of improvement and issues for consideration during device purchasing processes. Three versions are shown aimed at stakeholders with different levels of knowledge and capacity in terms of purchasing devices. The feedback obtained reinforces the need for disseminating a holistic process model, and the importance of consideration of these highlighted issues.

Chapter 8

CONCLUSIONS

This chapter revisits all the main points derived from each chapter, followed by a summary of key learning and contributions of the thesis and recommendations for future research.

8.1 Chapter Overviews

Chapter 1: This first chapter provided an overview of the research and motivation for its undertaking.

The key message at the start of this thesis was that the research topic presents a gap in the literature in terms of empirical evidence for assessing current practice in device purchasing. Small studies have been conducted but the systems approach suggested here is scarce. The motivation for this more holistic approach is due to the existence of various decision-makers involved in making a purchase, and the potential for addressing an area that can mitigate the risks associated with medical device errors. The need for investigating purchasing in practice and gathering empirical evidence was also highlighted, rather than just collecting policy-level guidance or following national agencies.

Chapter 2: This chapter reviews the current available literature in this field, drawing from different disciplines, and concludes that there is a gap to be filled in current knowledge.

The literature related to this thesis falls under a variety of disciplines but serves different purposes, from pointing towards good practice in purchasing, to efficient operations management and general context for improvements in patient safety. Healthcare design and process improvement methods were also introduced. The importance of defining and engaging stakeholders, having adequate control measures, understanding the drivers and resources available to purchasing decisions, and a general knowledge of the process, were all identified as being crucial to good general purchasing practice. Highlighted as an extra dimension specific to the healthcare context, it was recognised that there are attitudes and cultures specific to the healthcare environment, risks particular to the healthcare service, and further factors that increase the complexity of medical device purchasing systems. Design and systems approaches provide one way of analysing such complexities.

Chapter 3: The direction and evidence gathered in the previous chapter are used to arrive at research questions, followed by an approach and draw on a suitable methodology for the research.

Encompassed within a general realist approach, this study adopts systems theory as a way of approaching the subject, choosing the purchasing process as the ‘system’ and the delivery of care its ‘super-system’. The methodology follows an inductive strategy to provide a description of current practice and, due to limitations of access to healthcare settings, does not claim to provide grounds for proving new theory in terms of purchasing and supply of devices in the NHS. The study does, however, provide an understanding of current practice, and an analysis of the possible factors influencing risks and challenges in current practice. The methods chosen take into account potential bias and the importance of a systematic approach within opportunistic sampling. Furthermore, in line with good design practice as the basis for its approach, the study provides another example of how design practice works in researching one particular healthcare setting or system.

Chapters 4, 5, and 6: These three chapters constitute the main body of evidence supporting the arguments made in this study.

The Exploratory Studies provide a broad understanding of current practice and allow the stakeholders to dream scenarios for improvements. The subsequent chapters then cover Observations in Current Practice through more rigorous research methods, followed by

identifications of Risks and Challenges in Current practice through deeper studies at Trusts in the form of Case Examples. All findings are analysed by the end of Chapter 6 aimed to examine inefficiencies in current practice, and whether and how such practice can lead to risks in the healthcare service.

Chapter 7: This chapter discusses improvements on current practice and introduces a framework to represent considerations pertinent to safe device purchasing.

The factors influencing current practice are analysed to identify where immediate improvements could be made, and which factors constitute issues that would require long-term or major structural changes to the organisations involved. The suggested framework serves to then bring out the main issues in current practice in diagrammatic form, with the aim of serving potential improvements as elicited within the findings.

8.2 Key Findings and Contributions

It is observed through this study that current practice in medical device purchasing in the NHS presents risks to the delivery of healthcare. This has been concluded by different sets of empirical evidence: namely, by comparing current practice to good practice in literature on purchasing; by presenting anecdotal evidence of inefficiencies in the process with an impact on the service; and by eliciting stakeholders' own views on current practice. The findings have then been synthesised into a framework to show the characteristics of a medical device purchasing process that effectively focuses attention on patient safety, in direct answer to the main research question that triggered the study. The other key findings are reiterated in accordance with the research sub-questions, all shown below:

Main Research Question

What are the characteristics of a medical device purchasing process that effectively focus attention on patient safety?

Research Sub-Questions

1. What is current practice in medical device purchasing?

Who are the stakeholders and what are their roles in purchasing?
What type of knowledge and competence do these stakeholders have?
What are the resources and drivers for purchasing decisions?
What other factors influence current practice?

2. (How) does current practice present risks to healthcare delivery services?

What challenges and risks are present in current practice?
How are the factors of current practice different from good practice?
How do these factors impact the healthcare service?

3. Where are areas for improvement on current practice?

How do the stakeholders themselves view improved practice?
How can factors in current practice be managed towards improvement?

8.2.1 Current Practice in Medical Device Purchasing

Key learning in current practice relating to stakeholders and processes are listed here.

Stakeholders, Roles and Knowledge Base

- A purchaser usually refers to the person who places the order, but in practice incorporates roles in Engineering (Maintenance), front line staff (User) and clinical governance (Training).
- Involvement of stakeholders in decisions varies according to the type of device purchased.
- There is an inconsistency of interpretation of roles in medical device purchasing among different stakeholders. For instance, the 'end user' may also be the

‘purchaser’. However, to some stakeholders, a ‘purchaser’ means the administrative tasked assigned to the person making the order. To others, this is a collective term.

- True knowledge of equipment ergonomics, safety and design (beyond regulatory indicators, focus on quality vs. cost assessment) is scattered among stakeholders, and device use competence is not adequately monitored.
- Clinical input divided from the rest of process, only at start (except for pharmaceutical products, where ‘risk department’ is involved)
- The awareness and use of national bodies and agencies varied among stakeholders. In general, PASA is known to anyone from Finance, Procurement and Engineering, but not really to those towards the front-end of device use. This includes names of the agencies themselves (such as Collaborative procurement Hubs, or Pre-Purchase Questionnaires)
- End-users are not always aware of the options available for replacement equipment (e.g. ward storage options, neighbouring wards loans, use of equipment library); nor of who to turn to for advice on purchasing decisions, and their available budget for new purchases.

Resources and Drivers for decisions

- Each device has its own characteristics that determine its criteria for choice, as well as level of stakeholder engagement.
- What “purchasers” rank as important for making purchasing decisions relates mostly to the training and maintenance given by the supplier. Less value is given to the internal capacity of their workforce to comply with training and usability requirements.
- There is dispersed use of any national guidance among the stakeholders but heavier reliance on internal policies, measures, and human resources to control the management of devices.
- Internally evaluated equipment or use of BIME recommendations help guide device choice, but this is mainly used by Engineering staff.

Process factors

- Adopting new devices through trials is preferred, as this gives the end-user some time to get used to the device and evaluate it in practice.

- Although error-reporting culture has increased in the past five years, the quality of these is still questioned. They are not seen as entirely reliable for monitoring device use history and repair.
- Not every Trust has the same elements of an asset management system (e.g. library, device trainer/coordinator), and the reasons are mostly ‘historical’.
- Clinical Engineering or EBME department plays an important role in monitoring device use and management, and hence can act as one body with holistic process knowledge, if adequate resources are provided.

These observations on current practice were then analysed to identify challenges and risks in current practice.

8.2.2 Challenges and Risks in Current Practice

These challenges were summarised in Table 26 shown again here:

	<i>Factors considered</i>	<i>Challenges observed in Current Practice</i>
<i>Stakeholders</i>	<i>Stakeholder definition</i>	<i>Purchaser' refers to a variety of stakeholders</i>
	<i>Device knowledge & competence</i>	<i>Scattered device knowledge; Skills variations in device use competence</i>
	<i>Process knowledge</i>	<i>Scattered process knowledge</i>
	<i>Stakeholder engagement</i>	<i>Operational stakeholder divisions; Disconnects in communication</i>
	<i>Resources for decisions</i>	<i>Scattered resources available for purchasing decisions</i>
	<i>Drivers for decisions</i>	-
	<i>Culture and mindsets</i>	<i>Lack of process ownership; Lack of device ownership</i>
<i>Process</i>	<i>Process description</i>	-
	<i>Control measures</i>	<i>By-passing of controls</i>
	<i>Reporting and feedback</i>	<i>Incomplete device error records</i>
	<i>Pressures on process</i>	<i>Range of device choice; Lack of manpower</i>
	<i>Inventory management</i>	<i>Incomplete and multiple device inventories; Multiple servicing arrangements</i>
	<i>Goal alignment</i>	<i>Purchase routes distinguished by price thresholds; Misplaced management support</i>

Table 26 (repeated): Challenges observed in current practice relating back to the factors considered

8.2.3 Synthesis and Recommendations

Finally, the key findings and main issues pertaining to medical device purchasing and its relation to patient safety were synthesised. Key recommendations were established as relevant to different communities, as well as integrating these issues into a usable framework. The key recommendations address different stakeholder groups, and are summarised according to these groups:

Hospital-wide stakeholders

Given the divided stakeholder base for device purchasing, and yet its implications for all of healthcare delivery, the acknowledgement of purchasing as an important part of healthcare delivery needs to be addressed. Adopting continuous improvement measures, embedding a culture of safety, and monitoring purchasing practice, are all measures that can be implemented towards this goal. A starting point, however, as contributed in this thesis, is building a common knowledge base of purchasing procedures across the hospital for purchasers and end-users alike.

Processes across directorates (collaborations within a Trust)

The importance of interconnectedness and avoiding silo units has been highlighted in this study. Recommendations in this area include the linking of asset management systems, consideration for a shared equipment library, collaboration between departments for the purchase of devices which require a consumable/drug/device combination, and a continuous monitoring of training for device use competence.

Considerations for individual purchasing decisions

Individual purchasing decisions require three main considerations: the clinical, technical and financial aspects of the purchase. Given that the bodies of knowledge for such expertise sits in different departments, collaboration and communication is key for successful purchasing decisions, to then be able to take into account the exact device requirements, training requirements, adequate funding, and allocated resources for its servicing.

Core central control

Finally, given the variances in identifying a true process ‘owner’ for device purchasing in current practice, taking such a step would also help towards improvement. The role of EBME has been identified in this study and in previous literature as an obvious link for clinical and technical issues, but this could be made clearer and engage management support for added resources. Continuous improvement, process risk analysis, and potential re-design of future purchasing systems would necessitate for this, or another similar, central body.

These recommendations were listed in Table 28 and are repeated here:

	<i>Factors considered</i>	<i>Challenges observed in Current Practice</i>	Potential recommendations
<i>Stakeholders</i>	<i>Stakeholder definition</i>	<i>Purchaser' refers to a variety of stakeholders</i>	Define stakeholders appropriate to device
	<i>Device knowledge & competence</i>	<i>Scattered device knowledge; Skills variations in device use competence</i>	Recognise variety in device characteristics
	<i>Process knowledge</i>	<i>Scattered process knowledge</i>	Disseminate process overview
	<i>Stakeholder engagement</i>	<i>Operational stakeholder divisions; Disconnects in communication</i>	Engage clinical, technical, financial stakeholders
	<i>Resources for decisions</i>	<i>Scattered resources available for purchasing decisions</i>	Build repository of resources for decisions
	<i>Drivers for decisions</i>	-	Include quality, usability, safety considerations
	<i>Culture and mindsets</i>	<i>Lack of process ownership; Lack of device ownership</i>	Create culture of device ownership on purchase
<i>Process</i>	<i>Process description</i>	-	Create process overview
	<i>Control measures</i>	<i>By-passing of controls</i>	Promote process ownership; control at start
	<i>Reporting and feedback</i>	<i>Incomplete device error records</i>	Create feedback loops for purchase & use history
	<i>Pressures on process</i>	<i>Range of device choice; Lack of manpower</i>	Re-prioritise funding and resource allocation
	<i>Inventory management</i>	<i>Incomplete and multiple device inventories; Multiple servicing arrangements</i>	Create library or other loaning options with audit
	<i>Goal alignment</i>	<i>Purchase routes distinguished by price thresholds; Misplaced management support</i>	Engage Management to promote evaluation and standardisation

Table 28 (repeated): Considerations for purchasing each device, and for managing the process of purchasing

The framework, presented initially mainly for usability and applicability to different device purchases, presents the main considerations pertinent to medical device purchasing to focus on the wider implications of patient safety. The final design is shown in Figure 39, repeated here.

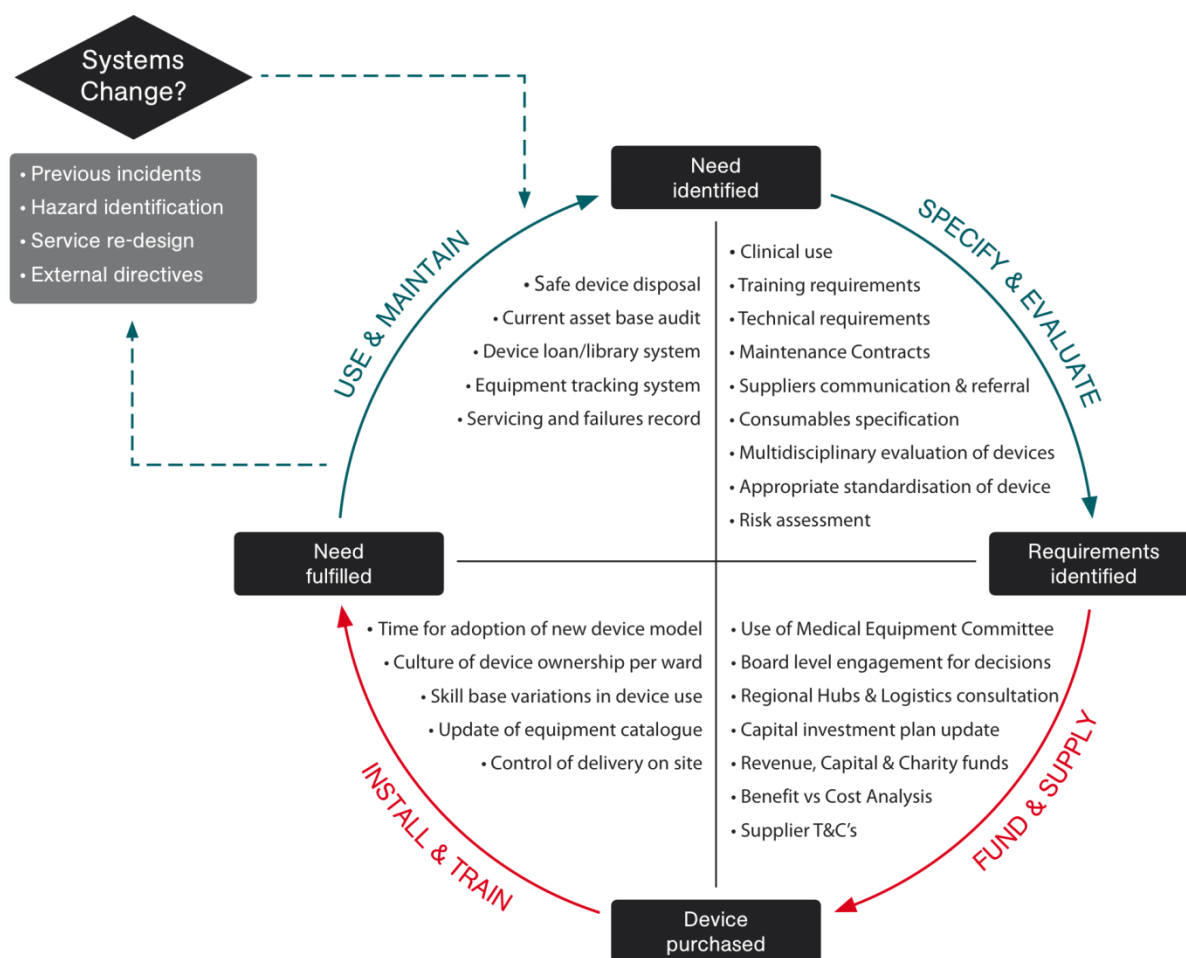


Figure 39 (repeated): Framework: Final design with system trigger

8.2.4 Additional Learning

Taking into account the factors that denote good practice from theory, this study has also contributed potential reasons for such challenges in current practice. The main issues identified are:

- Those mostly involved with devices on purchase not always involved in decision-making (e.g. maintenance, skills training, end-users).
- Purchasing process is disassociated from the medical device asset management process.
- Purchasing stakeholder groups are not clearly defined.

- There is a lack of a common understanding of what is a medical device among purchasing stakeholders.

Additional learning has been gained on the decision-making processes in medical device purchasing and the factors that contribute to the general device management in hospitals. Studying such a process that cuts across the healthcare system has also provided a valuable source of insight into the internal workings of the NHS at local level. The following points, though not expected to be derived from the study, were also noted:

- The value of individual ‘champions’ needed for bringing about change in the NHS, as mentioned both by the participants and by observing such individuals during the study
- Historical and organic patterns of behaviour, as viewed especially in the divides in training structures among end-users and device funding streams
- The organic growth of the use of medical equipment libraries as a means to manage assets
- The role of a ‘Medical device coordinator’, which does not exist in every Trust but is very much valued by those who engage with such an individual
- The clear divide between revenue and capital purchases from a finance point of view, which then inevitably creates a bias in controls on expensive purchases, which may or may not have weightier implications on safety or criticality
- The divided approach to training in skills for clinicians and nurses (including for medical devices)
- The clear divide in regulations and local purchasing structures for Pharmacy and pharmaceutical products, despite its close link to devices (e.g. infusion devices)

Such issues provide extra challenges in the background, in addition to those found in this study. Any recommendations made do not claim to address these, as they are largely historical and relate to the context of our current healthcare service, which may continue to change in the next few years.

8.3 Reflections on Research Process

The research process itself has provided valuable insight into working with NHS organisations; some of these reflections are mentioned here.

Access to the NHS

The study would not have been possible without the relevant contacts made at the various NHS organisations. Working together with PASA in the Purchasing for Safety project was an invaluable source of access to different Trusts and forming links to a wider net of NHS stakeholders. Similarly, the collaboration established with Trusts A and E for the more 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 Trust A was important as the stakeholders viewed this interaction as more than a simple audit, which most consultancies have conducted. 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.

Engagement of participants

During the PASA Purchasing for Safety project, the questionnaires were first sent out as a set of online or email surveys to all participants in their study. Out of the potential total of 32 stakeholders, only 8 responded in this first round. A re-design of the questionnaire, and the combination of a telephone interview together with the emailed questionnaire increased these respondents to a total of 17 and allowed for more open-ended responses. In the end, most of the richness of the data was attained by the extra comments made by participants.

Diagrammatic methods

Jun et al. have pointed out that a single diagram cannot effectively capture various aspects of complex healthcare delivery, which consists of various stakeholders, information and tasks (Jun et al. 2009). The need has been raised for better application of diagrammatic representations to the design of healthcare systems (Edwards 2005). 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 the process, but valuable lessons were learned of how to use such methods, and to what level of detail is required per interview, depending on their background.

Limitations of the study

The general approaches to increase the credibility of the findings, in terms of limitations of sampling, validity, dependability, confirmability, and generalisability, were discussed in Section 3.3.1. 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 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 Trust A 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 Trusts examined (A-E) 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 Trusts examined at the time.

Comments from participants

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 you doing 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, Trust A

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 3 years. We're actually checking in terms of what is ordered in terms of medical devices. We still end up with things within the Trust where we don't know about them and it's not through any formal procurement process, they just seem to appear... That is something we need to look at in more detail. Have people been trained on it, has there been risk assessment, maintenance, why have these people brought it in the hospital? Does our process take too long? Do people want to go around our rules? It's questioning why people do what they do, and how can we change the process to bring them on board.

Head of Clinical Engineering, Trust A

You have done very valuable work in addressing – and clarifying - fundamental and important issues that impact directly on healthcare.

Head of Clinical Engineering, Trust E

8.4 Future Work

While the changes in policy and the NHS were not looked at in detail, there are some, which may have an impact on current practice, and these would be worth examining in the future. PASA will announce its closure in the coming year (2010) and the regional hubs will have more autonomy on purchases. The impact this will have on local Trust practice will be interesting to examine, but various approaches could be taken for such an investigation. As described in the research approach outlined in Figure 2, this study is primarily a descriptive study, for which the synthesis and framework in Chapter 7 provides the starting points for a prescriptive study. This section of future work, therefore, is

categorised under two headings: a set of reflections on repeating a similar study under ‘Descriptive Work’ and suggestions on building on this knowledge gained to implement ‘Prescriptive Work’.

While reading these two types of work, it is worth bearing in mind the previously stated challenges on presenting design research methods and approaches in a healthcare community, as introduced in Section 3.1 under ‘Research Challenges’. As found in the literature, the support for approaches advocated in design research and systems theory is present, but what this means in practice still requires communication with the healthcare community. This certainly reflects the experience in this study and would have to be taken into account in any future work of this kind.

Descriptive Work

Although much of the study already shows the lack of adoption of current guidelines, the more in-depth analysis was limited to Trust A. It is this long-term involvement that truly brought out the insights gained and confirmed observations made elsewhere. The value of such a trusting relationship built with the participants at this Trust cannot be underestimated. If the study could be repeated, therefore, it would be recommended to conduct a similar project with other Trusts in the NHS. The approach would work best by taking a sample of Trusts investigated in parallel, perhaps by different researchers, over a similar period of time (1-2 years) and comparing findings at designated intervals.

This study was focussed on a total of five Trusts. Quantitative studies in the form of a survey or statistics on equipment purchases, savings through standardisation, and so forth would also add value to the arguments made for investing in improving purchasing practice.

While the intention of this study was to survey current practice and spend time analysing its implications, the basic overview provided here could serve as a starting ground to test out pilots of ‘better practice’. This would also reinforce not just the value of the factors identified, but the value of making any improvements at all, before prescriptive work is conducted.

Prescriptive Work

The prescriptive approach involves taking the current learning, synthesis, and framework, and implementing its recommendations in a sample of Trusts. The study would be designed to test the usability of framework in effectively bringing focus on elements of purchasing practice, as well as improve its design and content.

Design approaches have been advocated in this study, using the terminology common to design researchers. However, there may be elements of design activity that already occur both at policy and at local planning level. These were not investigated here, but if recommendations (or the framework) were to be adopted, the current service planning and implementation procedures would have to be taken into account.

8.5 Summary of Contributions

The main contributions of this study are:

1. A picture of current practice in medical device purchasing in the NHS in terms of:
 - a. People (their knowledge base, drivers for purchasing, culture)
 - b. Process (perceptions of an ideal process, issues raised in current process, comparison to policy recommendations to actual practice)
2. Evidence of the influence of purchasing practice on safe healthcare service delivery (through reflections of Results II reinforced by examples in Results III vignettes and results of the risk workshop), shown in:
 - a. A series of ‘factors that influence purchasing processes’.
 - b. Analysis of how these factors can be managed to improve on current practice
3. A framework that highlights the main issues pertinent to device decisions to ensure quality and safety in the process of purchasing, addressing:
 - a. Information needed for end-users who may otherwise be isolated
 - b. Considerations needed for developing whole process knowledge
 - c. System triggers required for such considerations

Donald Berwick of the Institute for Healthcare Improvement in the USA, argues that healthcare services need a change of system, noting that “every system is perfectly designed to achieve the results it achieves” (Berwick 1996). Do we currently have a procurement system that is designed to achieve patient safety? The findings in this study suggest that this is not the case in current practice. A survey conducted in 2004 suggested that there are even barriers to bringing modern thinking and design practice in the NHS as a whole. The report noted that “a direct consequence of this has been a significant incidence of avoidable risk and error” (Department of Health 2003). Part of the recommendations included a systems-based, user-led approach to improving services across the NHS. To achieve this, both the design of the products or services and the medical system (or healthcare system) in which these products are to operate, need to include patient safety in their design, planning and implementation. This concept is not new to the NHS nor to healthcare literature; understanding patient safety as a ‘systems’ problem is therefore increasing, but what does this imply? Perhaps acknowledging that our procurement processes are an integral part of our healthcare delivery system, whether we are the designer, purchaser, or user, would be a start.

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Appendices

Appendix I

Manchester Patient Safety Assessment Framework (MAPSAF), example used for Primary Care, used for workshops for Results I reported in Chapter 4

Appendix II

Questionnaire used for Results II, reported in Chapter 5

Appendix III

Process Map Development for Trust A, described in detail in Chapter 6

Manchester Patient Safety Framework (MaPSaF) – Primary care

01. Overall commitment to quality

A	There is little commitment to the general quality of care provided or recognition of its importance. This attitude is evidenced at Board level and throughout the organisation in the healthcare teams. Very little time or resources are invested in quality assessment or improvement. If any auditing occurs, it lacks rigour and there is no response to what is discovered. Existing protocols or policies are there to meet the organisation's statutory requirements and are not used, reviewed or updated. Maverick behaviour and poor quality of care is tolerated or ignored.
B	A quality framework is developed in response to specific directives or an imminent inspection visit. There is no real motivation or enthusiasm for the quality agenda and what occurs is ad hoc, superficial and concerned with 'looking good'. Auditing only occurs in response to specific incidents and national directives and does not reflect local needs. Little attempt is made to respond to any audit findings. The bare minimum of protocols and policies exist and these tend to be out-of-date and unused unless an incident occurs that triggers their review. Development of new protocols and policies occurs in response to incidents and complaints.
C	There is a defensive attitude towards the quality agenda. The Board and senior managers are motivated by an externally driven agenda and the potential rewards for being seen as quality focused. Frontline staff are not engaged in the process and they see it as a management activity. Lots of auditing occurs but it lacks an overall strategy linking it with organisational or local needs. Audit findings are only used if there is an incident. Staff are overloaded with protocols and policies (which are regularly reviewed and updated) that are rarely implemented. Patients may be involved in quality issues but this is lip service rather than real engagement.
D	There is a genuine desire and enthusiasm throughout the organisation to provide high quality care and it is at the forefront of service delivery. There is recognition at Board/senior management level that quality is everyone's responsibility and that the whole organisation, including patients and the public, need to be involved in developing a quality strategy. These organisations aim to be centres of excellence and compare their performance against that of others. Clinicians are involved in the auditing process and have ownership of it. Audit results are used and lead to quality improvements. Protocols and policies are developed and reviewed by staff and are used as the basis for care provision. Patients and the public are formally involved in internal decision making to encourage a patient-centred service.
E	A quality culture is embedded within the organisation and is integral to all decision making at all levels. The organisation is a centre of excellence, continually assessing and comparing its performance against others both within and outside the health service. Teams and services design and conduct their own audit program, which is outcome focused, in collaboration with patients and the public. In this visionary organisation staff are wary and alert to potential patient safety risks. This may mean that over time there is less need for policies and protocols because patient safety is constantly on everyone's minds. Patients are involved in quality in a routine, meaningful way with ongoing contribution and feedback.

Manchester Patient Safety Framework (MaPSaF) – Primary care

02. Priority given to patient safety

A

A low priority is given to patient safety. The few risk management systems that are in place, such as strategies and committees, are tokenistic and nothing is actually delivered. This is a 'chancer' organisation, believing that risks are worth taking and that if a patient safety incident occurs, insurance schemes can be used to bail them out.

B

Patient safety becomes a priority once an incident occurs but the rest of the time only lip service is paid to the issue apart from meeting legal requirements. There is little evidence of any implementation of a risk management strategy. Safety is only discussed by the Board and/or senior managers in relation to specific incidents. Any measures that are taken are aimed at self-protection and not patient protection. Risks are taken to contain costs.

C

Patient safety has a fairly high priority and there are numerous systems (including those integrating the patient perspective) in place to protect it. However, these systems are not widely disseminated to staff or reviewed. They also tend to lack the flexibility to respond to unforeseen events and fail to capture the complexity of the issues involved. Responsibility for risk management is invested in a single individual who does not integrate it within the wider organisation. It is an imposed culture.

D

Patient safety is promoted throughout the organisation and staff are actively involved in all safety issues and processes. Patients, the public and other organisations are also involved in risk management systems and their review. Measures taken are aimed at patient protection and not self-protection. Risks to patients are identified and action is taken to manage them. There are clear lines of accountability and while one individual takes the lead for patient safety in the organisation, it is a key part of all managers' roles. There is also reporting of patient safety incidents nationally.

E

Patient safety is integral to the work of the organisation and its staff and is embedded in all activities. Responsibility for safety is seen as being part of everyone's role and this is reflected in individuals' contracts. Staff are constantly assessing risks and looking for potential improvements. Patient safety is a high profile issue throughout all levels of the organisation from the Board through to healthcare teams who have day-to-day contact with patients (including support staff such as administrators, cleaners and technicians). Patient involvement in, and review of, patient safety issues is well-established.

Manchester Patient Safety Framework (MaPSaF) – Primary care

03. Perceptions of the causes of patient safety incidents and their identification

A

Incidents are seen as 'bad luck' and outside the organisation's control, occurring as a result of staff errors or patient behaviour. Ad hoc reporting systems are in place but the organisation is largely in 'blissful ignorance' unless serious incidents occur or solicitors' letters are received. Incidents and complaints are 'swept under the carpet' if possible. There is a strong blame culture with individuals subjected to victimisation and disciplinary action.

B

The organisation sees itself as a victim of circumstances. Individuals are seen as the cause and the solution is retraining and punitive action. There is an embryonic reporting system, although staff are not encouraged to report incidents. Minimum data on the incidents is collected but not analysed. There is a blame culture, so staff are reluctant to report incidents. When incidents occur there is no attempt to support any of those involved, including the patients and their relatives.

C

There is a recognition that systems contribute to incidents and not just individuals. The organisation says that it has an open and fair culture but it is not perceived in that way by staff. A centralised anonymous reporting system is in place with a lot of emphasis on form completion. Attempts are made to encourage staff and patients/carers to report incidents (including those that did not lead to harm), though staff do not feel safe reporting the latter. The organisation considers other sources of safety information alongside incident reports (e.g. complaints and audits).

D

It is accepted that incidents are a combination of individual and system faults. Reporting of patient safety incidents, both locally and nationally (for example by the National Reporting and Learning System), is encouraged and they are seen as learning opportunities. Accessible, 'staff friendly' electronic reporting methods are used, allowing trends to be readily examined. Staff feel safe reporting patient safety incidents. Staff, patients and relatives are involved and supported from the moment of reporting through a being open process. The organisation has an open, fair and collaborative culture.

E

Organisational failures are noted, although staff are also aware of their own professional accountability in relation to errors. It is second nature for staff to report patient safety incidents as they have confidence in the investigation process and understand the value of reporting both locally and nationally (for example by the National Reporting and Learning System). Integrated systems enable patient safety incidents (including those that were prevented and/or led to no harm), complaints and litigation cases to be analysed together. Staff, patients and relatives are actively involved and supported from the time of the incident through a being open process. The organisation has a high level of openness and trust.

Manchester Patient Safety Framework (MaPSaF) – Primary care

04. Investigating patient safety incidents

A

Incidents are superficially investigated by a junior manager with the aim of 'closing the book' and 'hiding any skeletons in the cupboard'. Information gathered from the investigation is stored but little action is taken apart from disciplinary action ('public executions') and attempts to manage the media.

B

Investigations are instigated with the aim of damage limitation for the organisation and apportioning individual blame. Investigations are cursory and focus on a specific event and the actions of an individual. Quick fix solutions are proposed that deal with the specific incident but may not be instigated once the 'heat is off'.

C

Senior managers are involved in the investigation, which is narrow and focuses on the individuals and systems surrounding the incident. There is a detailed procedure for the investigation process, which involves the completion of multiple forms – the investigation is conducted for its own sake rather than examining root causes. There is a concern to review procedures or change the dissemination of procedures. Emphasis is placed on placating the patient/carer in a perfunctory way rather than informing, being open and supporting them.

D

Investigations occur in order to gain an independent perspective. The staff involved in incidents are involved in their investigation, which uses robust methods like root cause analysis and significant event audit to identify the contributory factors and system problems that led to the incident. The aim of investigations is to learn from incidents and disseminate the findings widely. Data from investigations are used to analyse trends, identify 'hot spots' and examine training implications. It is a forward-looking, open organisation. Patients are involved in the investigation process and their perceptions, experience and recommendations are sought.

E

The organisation conducts internal independent investigations using recognised techniques (e.g. root cause analysis and significant event audit), which include the staff and patients involved in incident. Investigations are seen as learning opportunities and focus upon improvement rather than judgment and include patient recommendations. The investigation process itself is systematically reviewed by all staff. Fewer serious incidents are occurring through learning from the past. It is a learning organisation as evidenced by a commitment to learn from incident investigations throughout all levels – from the Board through to healthcare terms and support staff.

Manchester Patient Safety Framework (MaPSaF) – Primary care

05. Organisational learning following a patient safety incident

A

It is not a learning organisation as no attempts are made to learn from incidents unless imposed by external bodies such as public enquiries. The aim of the organisation after an incident is to 'paper over the cracks' and protect itself - the organisation considers that it has been successful when the media do not become aware of incidents. No changes are instigated after an incident apart from those directed at the individuals concerned.

B

Little, if any, organisational learning occurs and what does take place relates to the amount of disruption that senior staff have experienced. All learning is specific to the particular incident. Any changes instigated in the aftermath of an incident are not sustainable as they are knee-jerk reactions to perceived individual errors and are devised and imposed by senior managers. Consequently, similar incidents tend to recur.

C

Some systems are in place to enable organisational learning to take place; this may include consideration of the patient perspective. The lessons learnt are not disseminated throughout the organisation. This learning results in some enforced local changes that relate directly to the specific incident. Committees and managers decide on the changes that need to be introduced and this lack of staff involvement leads to the changes not being integrated into working patterns.

D

The organisation has a learning culture and processes exist to share learning, such as reflection, sharing patient perceptions and significant event audit. Changes instigated address underlying causes (i.e. system factors). Staff are actively involved in deciding what changes are needed and there is a real commitment to change throughout the organisation. Hence changes are sustainable. The organisation 'scans the horizon' for learning opportunities and is keen to learn from others' experiences. Organisational learning following incidents is used in forward planning. It is an open, self-confident organisation. There is Board level support for in-depth incident investigations using root cause analysis and significant event audit.

E

The organisation learns from internal and external incidents and is committed to sharing this learning both within and outside the organisation. Patient safety incidents are discussed in open forums where all staff feel able to contribute. Incidents are seen as a learning opportunity – they are inevitable but learning can occur to reduce their likelihood of occurrence. Organisational learning itself is evaluated. Improvements in practice occur without the trigger of an incident, as the culture is one of continuous improvement. Patients play a key part in learning and contribute to subsequent change processes.

Manchester Patient Safety Framework (MaPSaF) – Primary care

06. Communication about safety issues

A

Communication in general is poor. What there is comes from the top down with no mechanism for staff to speak to their managers about risk. Events are kept in house and not talked about. The organisation is essentially closed.

What communication there is, is negative, with a focus on blame. Patients are only given information which the organisation is legally bound to provide.

B

Communication upwards is possible but only after something has gone wrong. Communication is ad hoc and restricted to those involved in a specific incident.

Communication is very directive, with the Board and senior managers issuing instructions. This is a 'telling-off' organisation. The patient is given the information the organisation feels is appropriate and it is a one-way communication.

C

There is a general communications strategy though it is not explicitly linked to the patient safety agenda within the organisation. Policies and procedures related to risk are in place, and lots of records about incidents are kept. There is formal communication between agencies and a large amount of written information is available. Patient comments are obtained and documented but not effectively utilised. This leads to an information overload meaning that little is actually done with the information recorded by staff and received by managers. A risk communication system is in place, but no-one checks whether it is working. Information provided to patients is driven by the fear of litigation.

D

The communications system and record keeping in general are both fully audited. There is communication across organisations facilitating meaningful benchmarking with respect to areas of potential risk. All levels of staff are involved from the Board down, and there are robust mechanisms for them to feedback to the organisation.

Information about safety issues is shared; there are regular risk management briefing sessions where staff are encouraged to set the agenda. Effective communication regarding safety issues is made with patient and public involvement groups.

E

There is equality of communication about safety issues. The Board and more senior staff have an open door policy and realise that they can learn much from the staff that they manage. They expect everyone to know about and learn from each other's experiences, and it happens.

It is a transparent organisation and includes patient participation in risk management policy development. Innovative ideas are encouraged.

Electronic communication mechanisms are well-established and are the preferred mode within the organisation. This is a 'praising' organisation.

Manchester Patient Safety Framework (MaPSaF) – Primary care

07. Personnel management and safety issues

A	<p>Staff are seen just as bodies to fill posts. There is no acknowledgement that personnel management is directly linked to any risk management agenda. There is a rudimentary HR policy, no structured staff development programme and no links with Occupational Health. Recruitment and selection processes are rudimentary. Staff feel unsupported and see Personnel as 'them' and not 'us'. Personnel take on a punitive role following an incident; the language used is negative and poor health and attendance records are seen as disciplinary matters.</p>
B	<p>Job descriptions and staffing levels change only in response to problems, so there are good selection and retention policies in areas where the organisation has been vulnerable in the past.</p> <p>There is a very basic HR policy, but it is inflexible and developed in response to risk management problems that have already been experienced.</p>
C	<p>Recruitment and retention procedures are in place though are distinct from risk management policies. There is a lot of paperwork and the policies are made available for everyone to look at. Credentials are always checked.</p> <p>The procedures for appraisal, incident investigation, staff development and occupational health are there, but are inflexibly applied, and so do not always achieve what they were designed for. These procedures are seen as a tool for the Board and/or senior managers to control staff.</p>
D	<p>There is some commitment to matching individuals to posts. There are also visible, flexible support systems tailored to the needs of the individual. There is review of personnel management processes in light of changes in risk management policy and changes are made when necessary. There are attempts to understand why poor safety performance occurs and to nip problems in the bud.</p> <p>There is genuine concern about staff health, and good systems of appraisal monitoring and review. Patient/carer input on safety and staffing issues is actively sought.</p> <p>There is demonstrable evidence of proactive measures taken in some areas (for example by using the NPSA's Incident Decision Tree following an incident).</p>
E	<p>The organisation is committed to its staff, and everyone has confidence in the personnel management procedures. Personnel management is not a separate entity but an integral part of the organisation. Reflection and review about safety issues occur continuously and automatically, rather than sporadically. There is a policy for employing patients and their representatives. Following a patient safety incident, a systems analysis is used (for example by using the NPSA's Incident Decision Tree) to make decisions about the relative contribution of systems factors and the individual healthcare professional. This process informs decisions about staff suspensions and as such there is a consistent and fair approach to dealing with staff issues following incidents.</p>

Manchester Patient Safety Framework (MaPSaF) – Primary care

08. Staff education and training and safety issues

A	<p>Training has a low priority. The only training offered is that required by government. It is seen by the Board and senior managers as irritating, time consuming and costly. There are consequently no checks made on the quality or relevance of any risk management training given. Staff are seen as already trained to do their job, so why would they need more training?</p>
B	<p>Training occurs where there have been specific problems and relates almost entirely to high-risk areas where obvious gaps are filled. Information about the risk management training available is given to new staff in an induction pack. It is the responsibility of the individual to read and act upon this. Education and training focus on maximising income and covering the organisation's back. There is no dedicated training budget.</p>
C	<p>The training program reflects organisational needs, so patient safety training is supported only if it benefits the organisation. No thought is given to actively involving patients in training. Basic Personal Development Plans are in place so everyone has their own file. However, these are not very effective as they are not properly resourced or given priority. Training about safety issues is seen as the way to prevent mistakes. There are a large number of courses on offer, however not all of these are relevant to the staff expected to make use of them.</p>
D	<p>There is an attempt to identify the risk management training needs of the organisation, and the training needs of individuals about safety issues, and to match them up. Such training is well planned and resourced and is available from and for all relevant agencies. Education is seen as integral to individual professional and personal development and is linked directly to other organisational systems, such as incident reporting. The Board and other senior managers understand and value risk management training for staff and encourage people to participate. Preliminary attempts to involve patients and the public in staff training are underway and the organisation is starting to learn lessons from its experiences.</p>
E	<p>The approach to training and education is flexible and seen as a way of supporting staff in fulfilling their potential. Individuals are motivated to negotiate their own training program. Education about safety issues is integral to the organisational culture. Learning is a daily occurrence and does not happen solely in a classroom environment. Patients are involved in staff training to aid understanding of patient perceptions of risk and safety.</p>

Manchester Patient Safety Framework (MaPSaF) – Primary care

09. Team working around safety issues

A

Individuals mainly work in isolation but where there are teams, they are ineffective in terms of risk management.

There are tensions between the team members and a rigid hierarchical structure. They are more like a group of people brought together with a nominal leader and no direction.

B

There are teams but they have been told to work together, and only pay lip service to team working.

People only work as a team following a patient safety incident. Teams get put together to respond to external demands. There is a clear hierarchy in every team, corresponding to the hierarchy of the organisation as a whole. Teams do work together, but individuals are not actually committed to the team.

C

Teams are put together to respond to government policies (e.g. National Service Frameworks) but there is no way of measuring how effective they are.

There is a risk management team. Teamwork is seen by lower grades of staff as paying lip service to the idea of empowerment. There is little sharing of ideas or information about safety issues across teams.

D

Team structure is fluid with people taking up the role most appropriate for them at the time.

Teams are collaborative and adaptable and actively contribute to the risk management agenda within the organisation. There is evaluation of how effective the team is and changes are made when necessary.

Teams may involve those external to the organisation.

E

Team membership is flexible, with different people making contributions when appropriate. Teams are about shared understanding and vision about safety issues rather than geographical proximity. This way of working is just the accepted way in the organisation.

Everyone is equally valued and feels free to contribute. 'Everybody is part of the risk management team', this includes all levels of the organisation from Board members through to those who have day-to-day contact with patients.

Purchasing for Safety Awareness Audit

1. Roles in the purchasing process

Purchasing	<ul style="list-style-type: none"> Obtaining terms of contract from supplier Authorising or signing the PPQ for trust Choosing which device to purchase Placing the order with suppliers
Training	<ul style="list-style-type: none"> Training for staff on device use Trialling of new products
Coordination	<ul style="list-style-type: none"> Coordination of medical device purchase and use Strategic contract planning and monitoring
At ward level	<ul style="list-style-type: none"> Purchasing pumps and devices Purchasing of syringe sets or consumables Purchasing pharmaceuticals Signing off requisition form Filling in a requisition form Identifying that injectable medicine is missing from unit or ward Identifying that pump or syringe drive is missing from unit or ward
On device arrival	<ul style="list-style-type: none"> Picking up the orders from goods in Conducting acceptance tests on new devices Entering devices into a maintenance/clinical engineering asset register Entering devices into a financial asset register Delivering injectable medicines or devices to the unit or ward requesting it Monitoring pumps administering injectable medicines

Involvement of others in purchasing process

	Most of the time	Often	Occasionally	Never	Unsure
Patients					
Nurses					
Clinicians					
Collaborative procurement hub					
Clinical engineering					
Procurement					

2. Resources to help make purchasing decision

An internal medical device policy or set of guidelines covering the purchasing process

Does it include

standardisation?

centralisation?

guidance on device replacement?

A defined list of approved infusion devices

with accompanying documentation?

An equipment library (or equivalent)

Internal register for recording errors

Controls Assurance Standards

Medicines and Healthcare products Regulatory Agency (MHRA): Device Bulletin 98 (01) the Management of equipment in hospitals and the community

Bath institute of Medical Engineering (BIME) recommendations

NHS Purchasing and Supply Agency (PASA) Tendering documents

Collaborative Procurement Hubs recommendations/contracts

National Institute for Clinical Excellence (NICE) guidelines

MHRA Incident Reports for infusion devices

Royal College of Pharmacists guidelines for practice (for training purposes)

Royal College of Anaesthetists guidelines for practice (for training purposes)

Skills for Health guidelines for practice (for training purpose)

National device alerts

Pre-purchase Questionnaire (PPQ)

Other documentation for purchasing

Device specification that considers safety features of new devices to order

Medical Equipment (or Device) Committee

Medical Device Coordinator

Which of the above do you find most useful and why?

3. Managing stock and devices in your trust

Most of the time Often Occasionally Never Unsure

An audit of existing stock to establish infusion device sufficiency and utilisation is carried out

There is a known trust board member or body responsible for medical device management.

When training not given by company, our clinical skills training department has the skills necessary to train staff on new models

Clinical engineering personnel are trained to make decisions on safety of devices and systems prior to commissioning of infusion devices?

Competency based training for clinical staff within the trust is actively assessed

For each new infusion model, relevant training is given (% per department?)

Infusion devices are evaluated by clinical staff prior to purchase

There is a structured evaluation process or form

This process/form is shared with other manufacturers?

Trusts?

CPHs?

When making a purchasing decision, who do you interact with?

Most of the time Often Occasionally Never Unsure

Patients

Nurses

Clinicians

Collaborative procurement hub

Clinical engineering

Procurement

4. Drivers affecting purchasing decisions

Very important Quite important Somewhat important Not important

- Unit cost of device
- Maintenance costs of device
- Safety features
- History of errors with device within trust
- Ease of use
- What staff are used to on wards
- CE marked
- Working relationship with sales representative
- Matching to existing consumables
- Matching to existing equipment in the ward/unit
- Device in standardised list
- Quality of device
- Name or brand
- Supplier image
- Training services given by supplier
- Maintenance services given by supplier
- Maintenance expertise available in-house for device
- Device history globally
- Robustness
- Reliability
- Usability
- After-sales support

Of above, which is the most important and why?

Which is least important and why?

5. Barriers and toolkits

Strongly agree Agree Disagree Strongly disagree

- There is little or no internal support for purchasing for safety
- Implementing purchasing for safety practices would require significant cultural change
- We lack the knowledge/tools for purchasing for safety
- There is no time nor budget to support purchasing for safety
- It is too difficult to think how we can purchase for safety
- There are too many other problems and drivers to think about purchasing for safety
- Purchasing for safety is an unachievable goal

Of above, which is the most significant and why?

Which is least important and why?

6. What would be most useful?

- A national awareness campaign
- Board level trust support
- Set practices as Trust objectives for the year
- Attending conferences on purchasing for safety
- Receiving an assessment form to tick that requirements for purchasing for safety are met
- Training for yourself and colleagues on how to purchase for safety
- Using collaborative procurement hubs in order to assess best practice
- Better clinical training on use of equipment
- Establishing new National Standards & Targets
- Other?

Of above, which is the most helpful and why?

Which is least important and why?

Thank you for your time.

Your Trust

Your Job Title

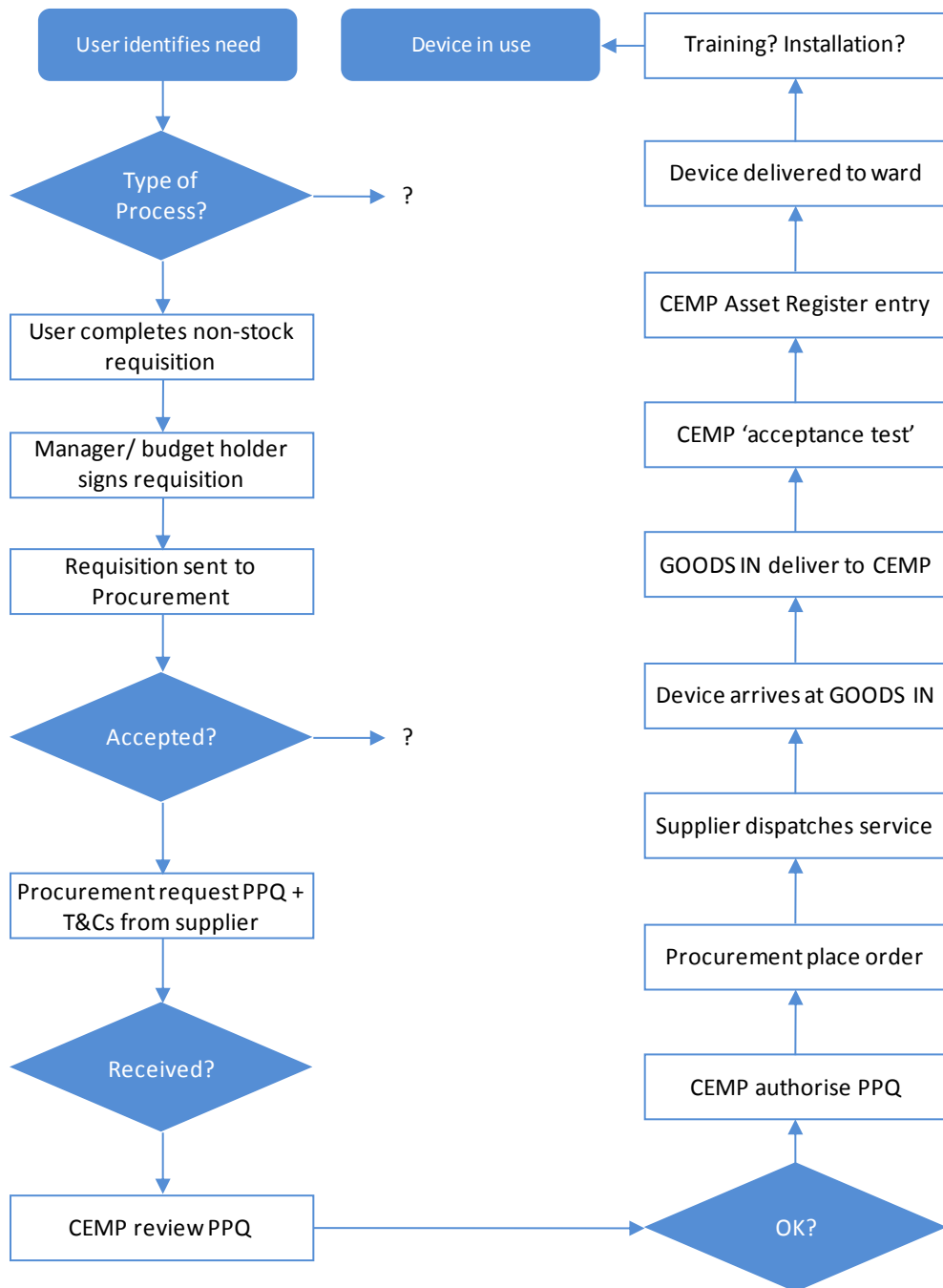
Your role description

CPH? Y N

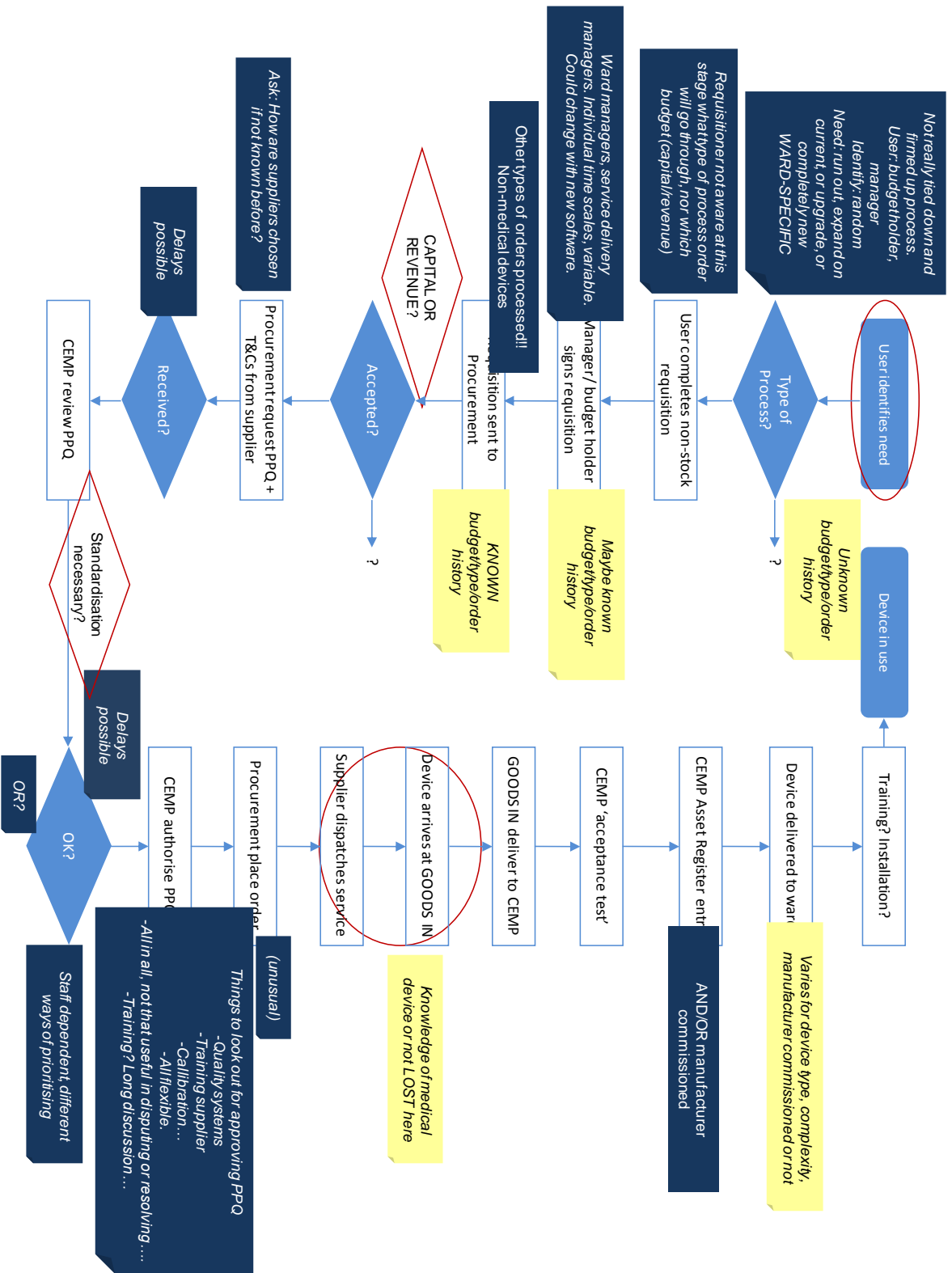
Length of service at trust/site

Length of service in current role

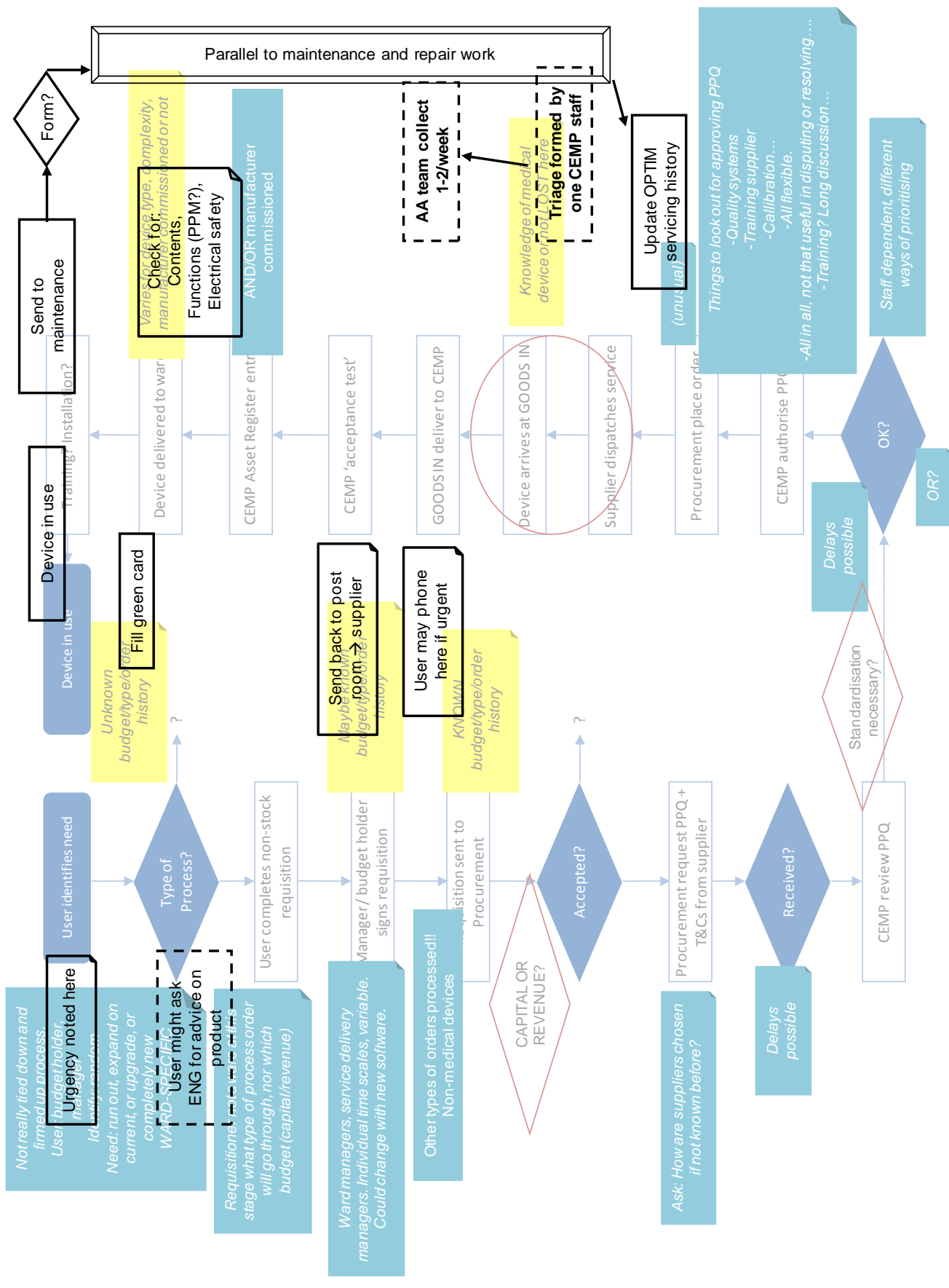
Who would you suggest to speak to next?



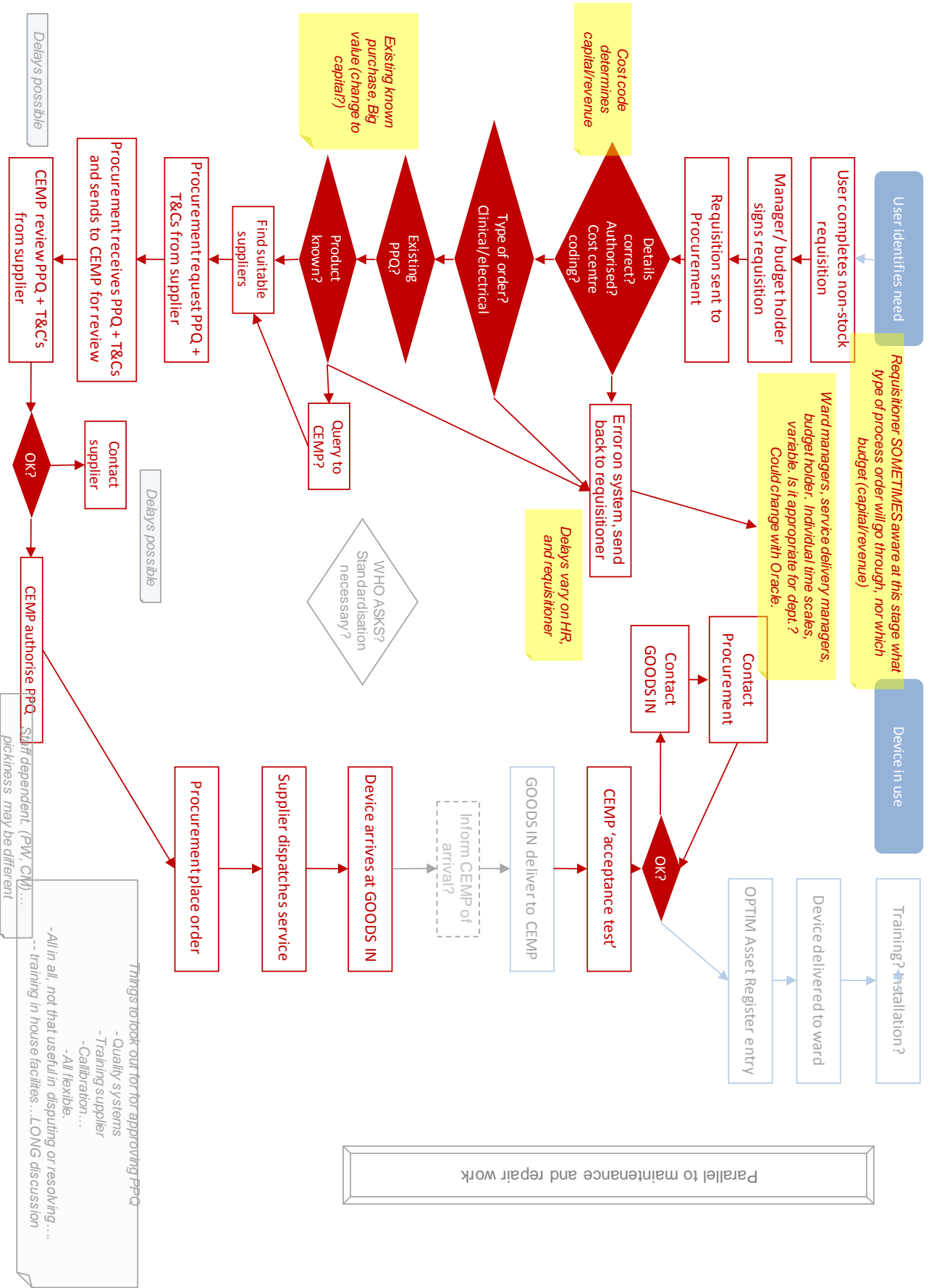
Appendix III Figure AIII_1



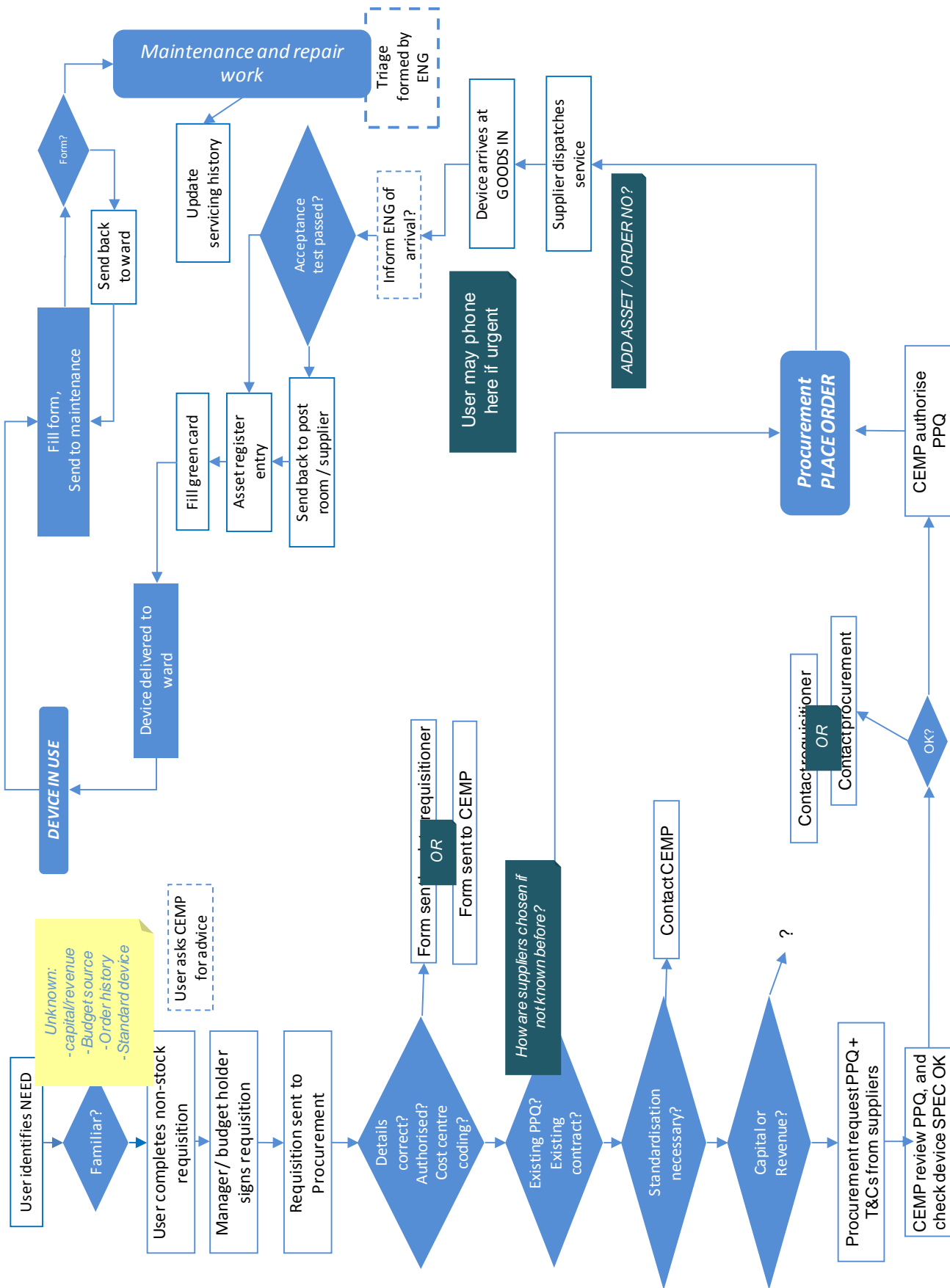
Appendix III Figure AIII_2



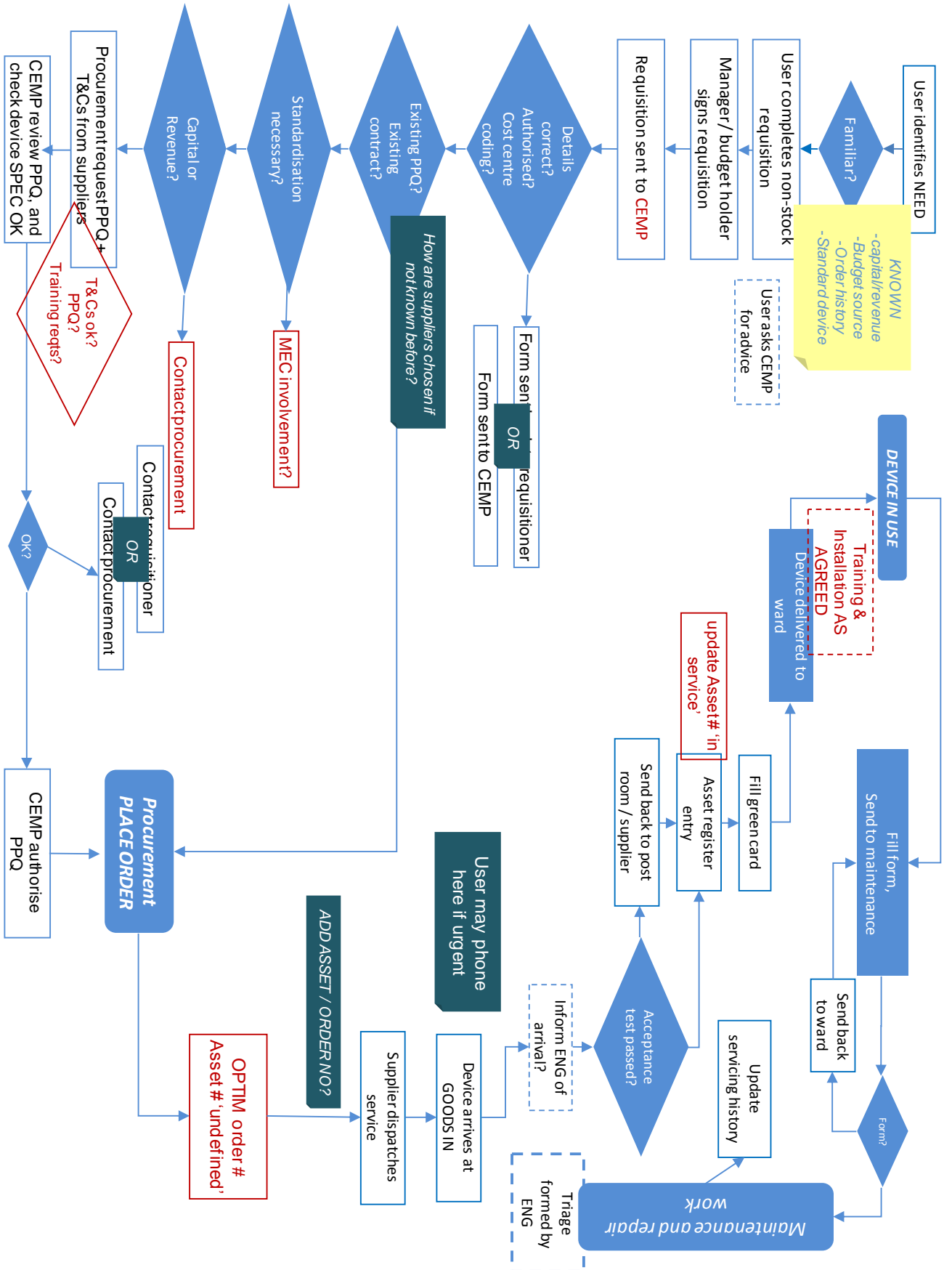
Appendix III Figure AIII_3



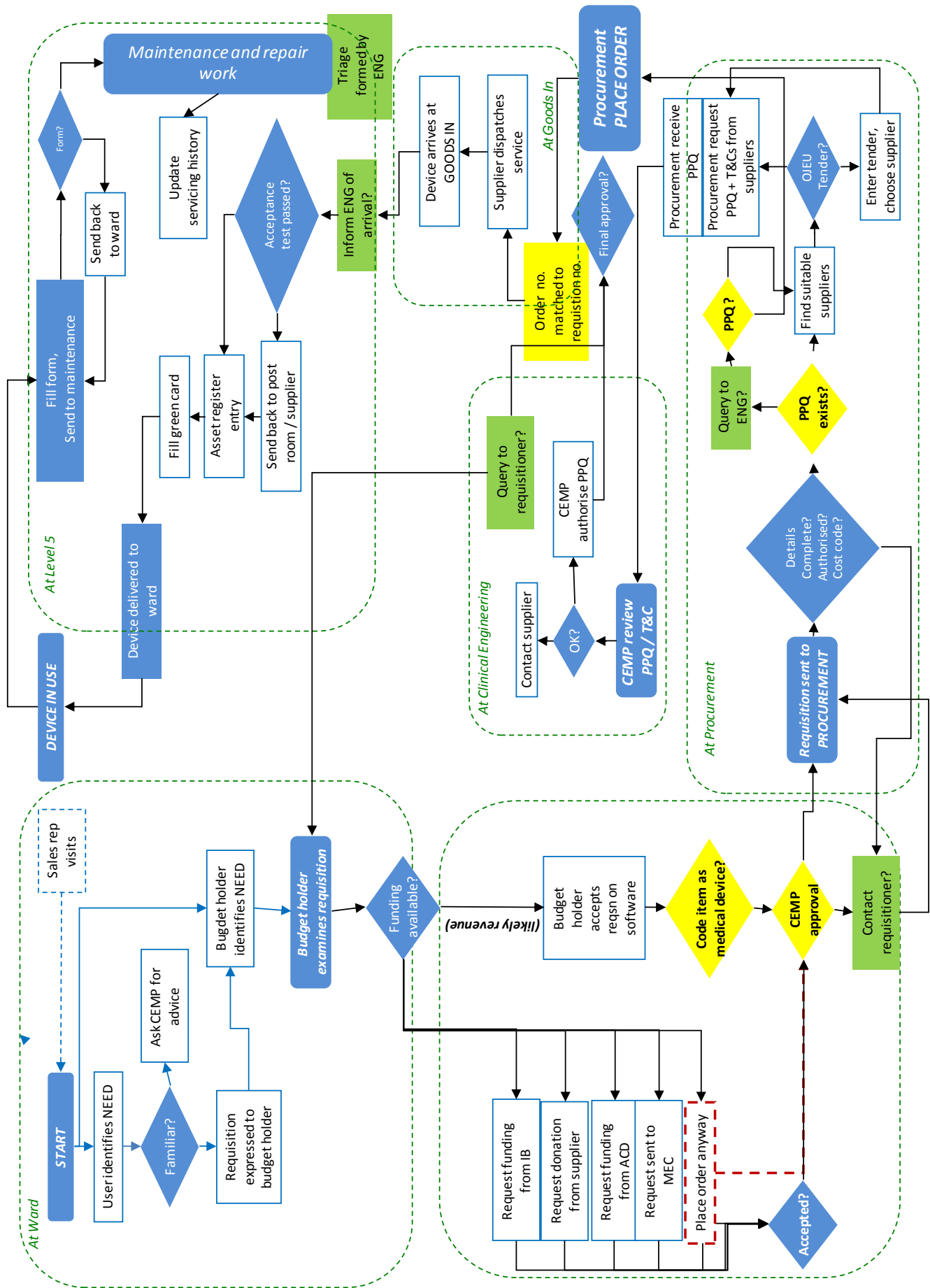
Appendix III Figure AIII_4



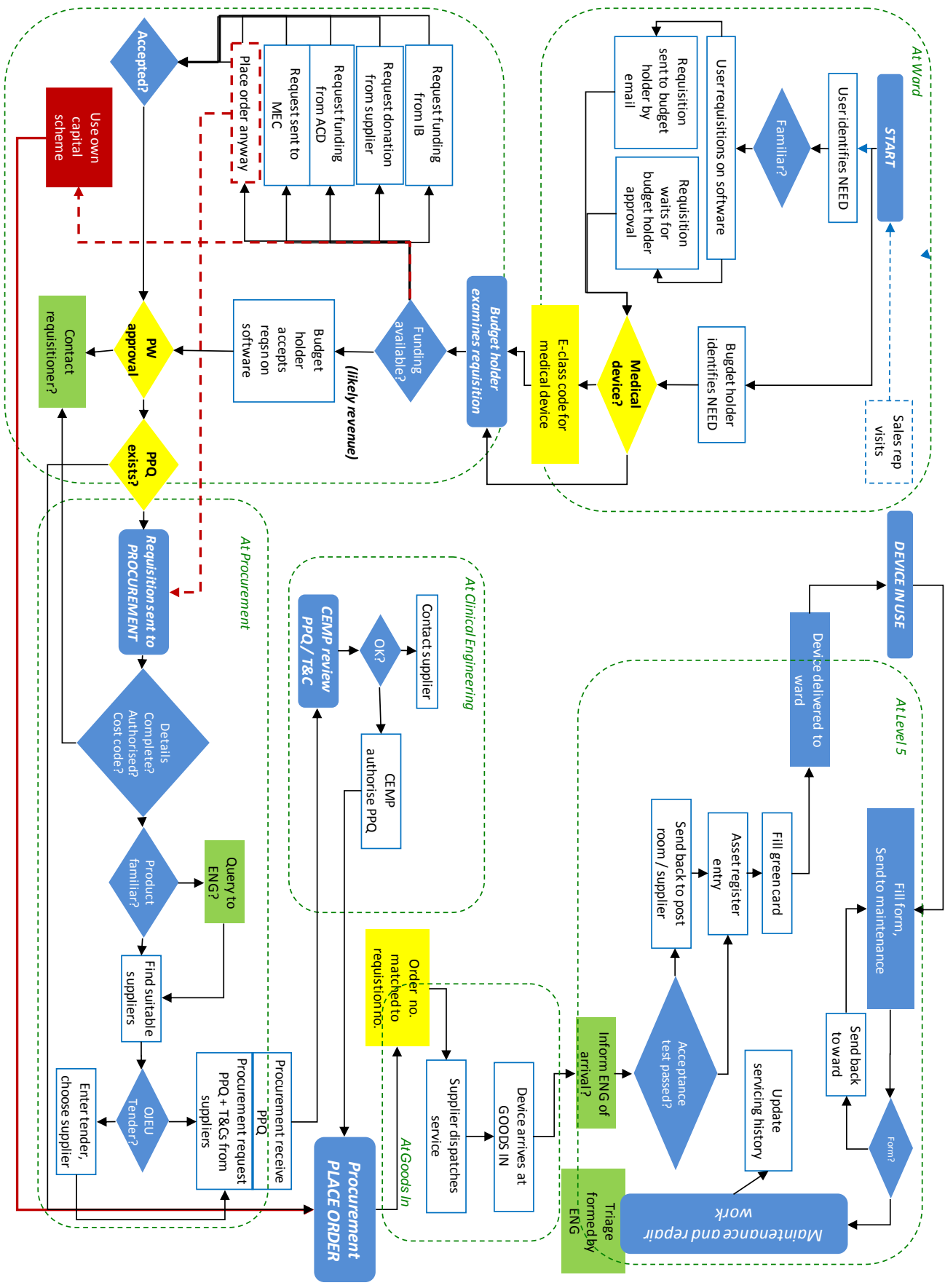
Appendix III Figure AIII_5



Appendix III Figure AIII_6

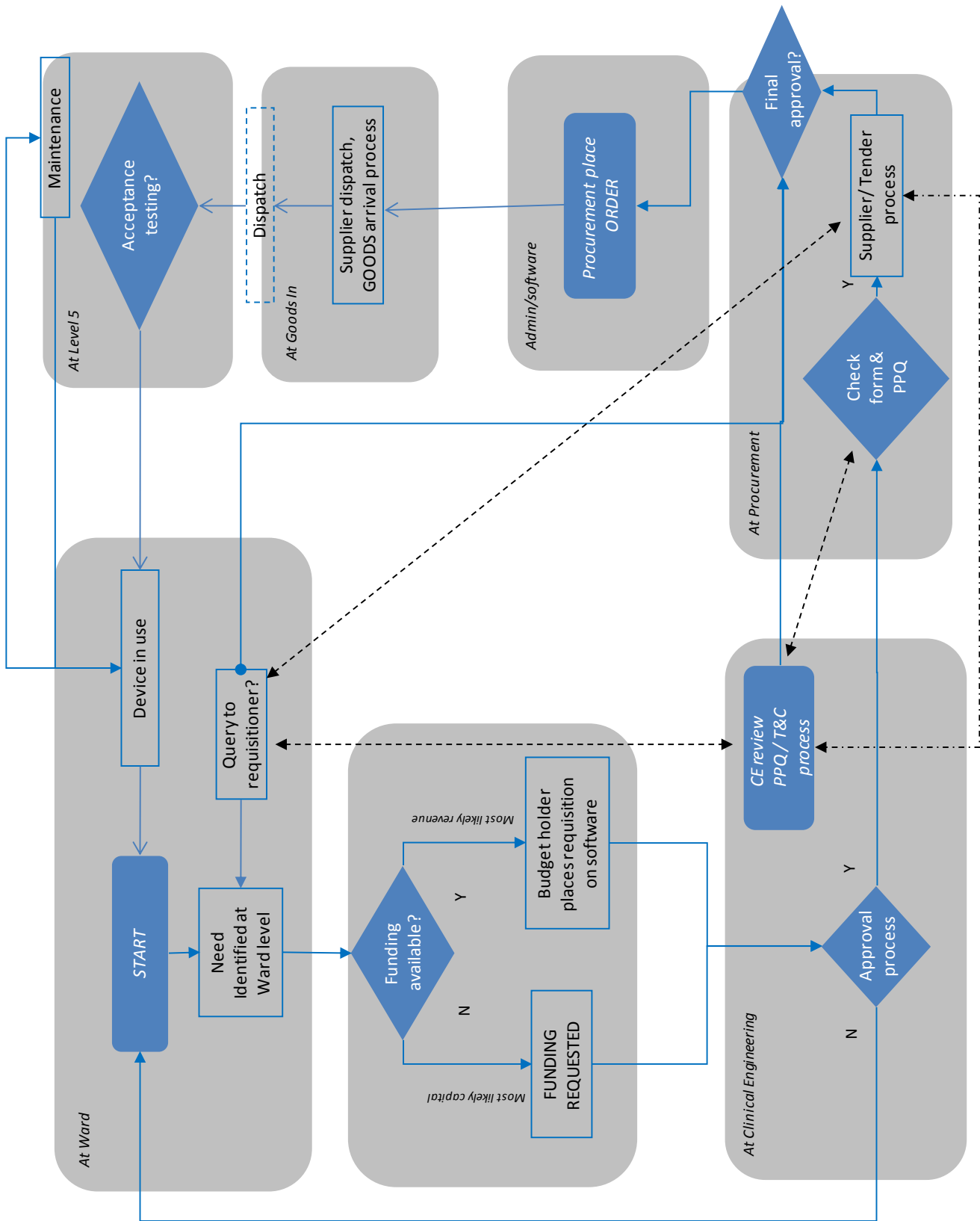


Appendix III Figure AIII_7



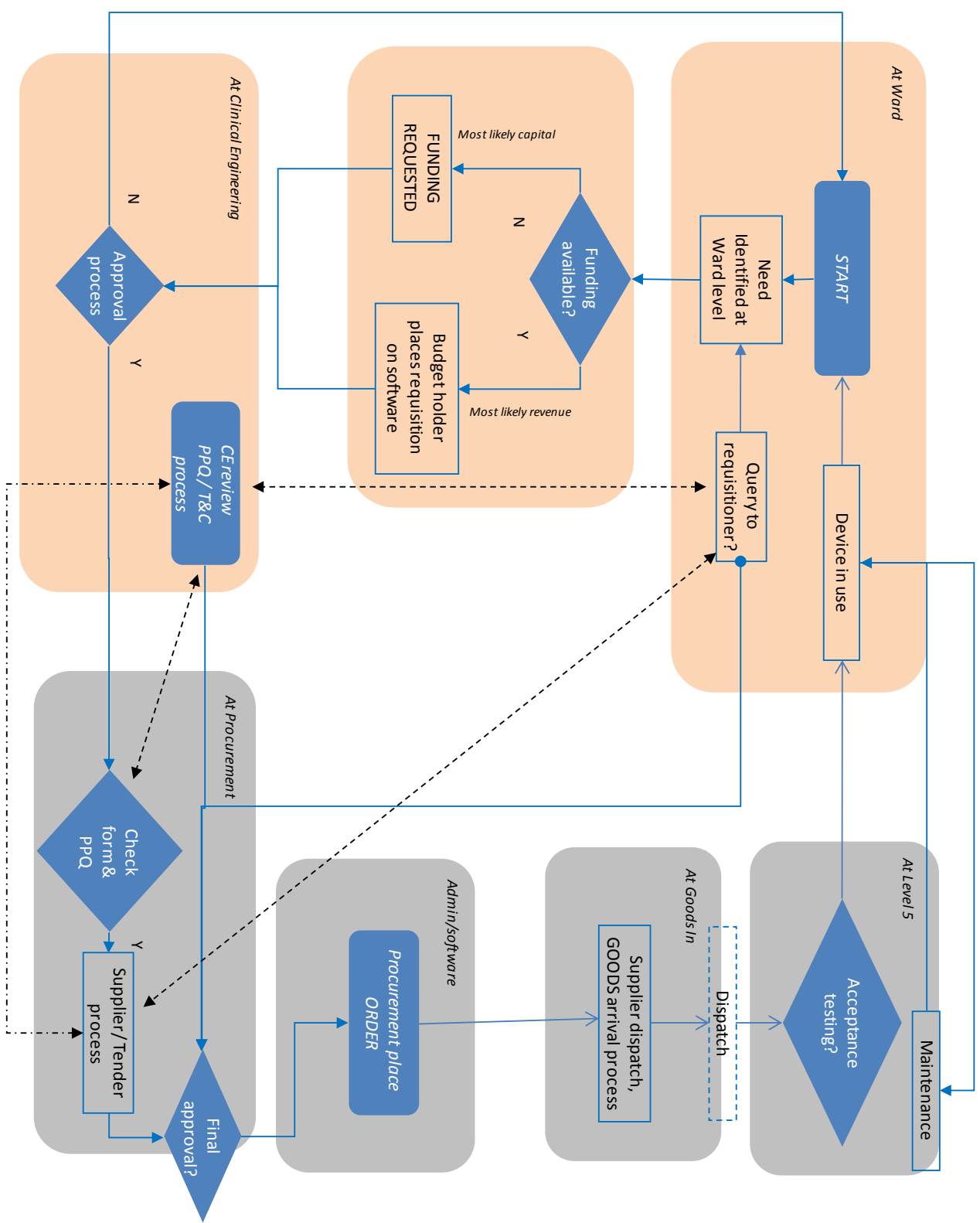
■ Non-addressed risks
 ■ Changes made
 ■ Further changes suggested

Appendix III Figure AIII_8



Appendix III Figure AIII_9

= main areas of risk



Appendix III Figure AIII_10