A systems approach to improving patient safety: a focus on medical device procurement processes

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Summary

Although the concept "purchasing for safety" is advocated in both research and policy [1], challenges for its implementation still exist. Recognising that the procurement of medical devices is an integral component of the healthcare delivery system, this project aims to capture the requirements needed to develop a system-based model for a procurement process. This will include consideration of ergonomic and socio-technical issues, operational and financial constraints, and requirements from all involved stakeholders. Firstly, the conceptual framework for such a systems approach is introduced, followed by collected preliminary results which confirm the direction and guidance given by policy documents and literature. The aim is not to provide the final procurement process model, but provide the requirements needed for its development, and suggest the challenges that may exist in embedding it into the healthcare delivery context.

1 Introduction

1.1 The existing challenge

Despite growing awareness that patient safety is related to both device design and user-error [2], there is little research in addressing the challenges involved when introducing devices into the healthcare context. It is in these decisions that procurement plays a large role, as evidenced by previous case studies [3]. Purchasing decisions made on regulation standards alone are not enough to ensure the safety of devices in the user context [4]. Furthermore, the purchase of a single medical device involves engaging various stakeholders as well as balancing different drivers and constraints for a hospital. The challenge is therefore not only to articulate what measures of the medical device truly denote its safety, but to then balance out these requirements among the other factors needed at the time of purchase. Such issues cannot be tackled in isolation, which calls for a need-driven, user-centred, systems approach to the procurement of medical devices.

1.2 Adoption of a systems approach

The concept of "designing systems" to improve healthcare has been advocated in previous publications [5]. A study in the UK provided recommendations for the National Health Service (NHS), calling for a design-led approach to improve patient safety [6]. In line with the conceptual framework presented in this study, this project aims to (1) build a knowledge base based on the NHS context, understand its organisation, user needs, and current purchasing processes, (2) define the requirements needed for improving processes, and, ultimately, to (3) manage risk in the healthcare delivery system via the procurement process. The data presented here form part of the first set of results of the project, which mostly contribute toward stages (1) and (2) of the above. This will provide the basis of a stakeholder-focused procurement system that advocates patient safety, which can ultimately be used to drive design for patient safety of future devices.

2 Methods

2.1 Research methodology

The approach to the inquiry itself is based on qualitative methods of data collection, analysed thematically [7]. Further analysis and identification of risk involves tools from engineering design principles, in line with the conceptual framework presented above.

2.2 Data collection

Data was collected through studies across four hospitals. These included workshops, process mapping of general procurement systems, semi-structured interviews and observations, plus one specific Case Study on infusion systems in conjunction with a National Project*. The results presented here mostly arose from this project but were confirmed by a separate study with a local hospital. The stakeholders included staff

*Collaboration has been established for a national project on Purchasing for Safety of infusion systems.
from Clinical Engineering, Risk, Training and Procurement.

3 Results & Conclusions

3.1 Preliminary findings

A thorough literature review and the advice sought by key national stakeholders confirmed that several factors exist in our current purchasing systems that may be deterring involved stakeholders from focusing on patient safety. Analysis of this review has led to the conclusion that these factors are differentiated by two parameters: (a) the type of hospital analysed and (b) the type of device being purchased. The study was consequently designed in these two work streams. Results presented here reflect the first of these, by keeping the device constant (infusion systems) but examining the procurement issues across four hospitals relating to this one device.

3.2 Results from data collection

In contribution to (1) building a knowledge base of the current procurement and healthcare system, the following processes and their relationships were identified across all four hospitals (see Figure 1).

- **Individual purchasing requirements**: Ease of use, user experience, service support, training arrangements, connectivity to existing equipment
- **Hospital management requirements**: Feedback systems, improvements in communication, life-cycle costing infrastructure
- **National requirements**: National Purchasing guidelines, database on ‘best purchases’, shared experiences across hospitals

Further details of the results summarised here will be expanded, along with the ‘soft’ cultural issues elicited during the studies. The next stages in the project involve the selection of three medical devices to address the second parameter, the device type, since an effective risk analysis needs some level of granularity. It is also planned to investigate further into each of the sub-processes in Figure 1: Standardisation, Evaluation and Purchasing for each of those devices.

4 References


**Interviewed stakeholders include representatives from NHS Purchasing and Supply Agency (PASA), the Association of British Healthcare Industries, and the National Patient Safety Agency.**