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# How do health service professionals consider human factors when purchasing interactive medical devices? A qualitative interview study

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ABSTRACT

We present findings of a UK study into how those involved in purchasing interactive medical devices go about evaluating usability, the challenges that arise, and opportunities for improvement. The study focused on procurement of infusion devices because these are used by various professionals across healthcare. A semi-structured interview study was carried out involving a range of stakeholders (20 in total) involved in or impacted by medical device procurement. Data was analysed using thematic analysis, a qualitative method designed to support the identification, analysis and reporting of patterns. In principle, health service purchasing was found to accommodate consideration of equipment usability. In practice, the evaluation process was driven primarily by engineering standards; assessment of local needs did not accommodate substantive assessment of usability; and choice was limited by the availability of equipment on the marketplace. We discuss ways in which purchasing could be improved through techniques that account for social circumstances.



## 1. Introduction

Poor usability is frequently cited as a contributory factor in incidents involving medical devices (AAMI/FDA, 2010). There are many potential sources of pressure for delivering products with acceptable usability, including regulatory requirements, international standards, and the needs of the market.

The decision about procurement of a medical device is a key point in shaping usability, both directly and indirectly. Firstly, the local procurement decision will affect staff and patient experience as the selected devices are typically used for several years. Secondly, feedback about user requirements has the longer-term potential to inform manufacturers about user needs and to raise the importance of usability within the development process. To better understand how usability does and could feature within procurement processes, we need to better understand how purchasing really happens, how equipment usability is assessed within that process, and what tools might help to support usability assessment within procurement. This paper reports on a UK study investigating how those involved in purchasing evaluate the usability of medical equipment, the challenges that arise and opportunities for improvement.

We focus on how those involved in the selection of infusion devices (volumetric pumps and syringe drivers) reason about equipment usability. ISO standards define usability as effectiveness, efficiency and user satisfaction (IEC, 2015); however, for this study we did not work with any *a priori* definition of usability. We worked with those involved in purchasing as they are aware of the stakeholders involved and are familiar with how equipment is evaluated. Whether or not they had a background in HF/HCI, we sought to better understand their views on usability and how they take this into account in procurement.

The focus on volumetric pumps and syringe drivers was chosen as infusion devices are widely used for the administration of medication, fluids and nutrition, across a range of both hospital and home contexts, by a diverse range of users. Since most organisations aim to standardise their equipment of any given type, the procurement of infusion devices is at an extreme of complexity for those involved in the decision.

## 2. Background

It is widely accepted that interactive medical equipment should be usable and fit for purpose (Zhang et al., 2003), but it is also recognised that there are challenges in assessing usability in an

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organisational setting (Maguire, 2001). For example, although health service staff require decisions based on "the best possible evidence" (Pecchia et al., 2013), the factors that contribute to safety, usability and overall fitness for purpose may be based on opinion, numerous and difficult to scope. The User Interface (UI) is a case in point, as it supports safety critical operations, but the views on fitness and suitability vary, may be conflicting, may be based on only part of the work system and are hard to detach from the organisational setting. Improved usability can contribute to the quality of patient and staff experience (Liddell et al., 2008) as well as improving safety, cost, time and reliability (Cassano-Piché et al., 2010; Gandillon, 2013), but we know little about how these improvements can happen in practice and how integration occurs across the different elements of a work system.

In this section, we review key background studies on purchasing and usability: who is typically involved; how usability has previously been used in purchasing; and approaches to considering usability within purchasing.

### 2.1. Who is involved in purchasing

Others (Hinrichs, 2009; Keselman et al., 2003; Nemeth et al., 2014; Phillips et al., 2007) have provided an overview of the groups involved in purchasing and how they relate to one another. In the UK, infusion devices for general use are often selected by a purchasing committee (e.g (Freemantle et al., 2011)), working closely with a purchasing department. This committee typically represents a range of interested parties: for example, end users, power users, trainers, pharmacy staff, and those responsible for the management and maintenance of the equipment. In addition, the purchasing department may work with external bodies such as regional or national purchasing groups. A case for procurement might also be made at a national level (e.g (Phillips et al., 2007)), or as a result of changes to legislation (Ford and Phillips, 2008). In this case a range of law making bodies, standards agencies, government departments, regulators, charities and special interest groups could be involved in defining what is and is not an acceptable solution. An overview of those involved in purchasing is provided in Fig. 1.

### 2.2. The role of usability in purchasing

Usability evaluation or Human Factors methods have been applied to scope efforts and reduce buying options (Ginsburg, 2005; Turley et al., 2006; Zhang et al., 2003). They have also been used to collect input from a wide array of stakeholders, support multidisciplinary communication and support reconciliation of viewpoints (Johnson et al., 2005; Keselman et al., 2004; Namshirin et al., 2011). Johnson et al. (2005) highlight the variety of those involved, including nurses, doctors, pharmacists, biomedical technicians, quality improvement staff, unit managers, patients, trainers and accountants. This emphasises that the consideration of usability needs to accommodate multiple perspectives and adopt a holistic approach. Namshirin et al. (2011) illustrate how a multidisciplinary approach (including usability evaluation) applies to the selection of smart infusion pumps (i.e., pumps with safety features designed to prevent an accidental overdose of medication). They suggest that by involving a range of stakeholders and considering the variety of front line needs, hospitals can choose equipment that implements appropriate safety measures to reduce the potential for drug and dose errors. Although this appears to be a good example of collaborative evaluation, other studies have highlighted some of the challenges in procurement.

One such challenge is that hospitals might not adopt a multidisciplinary approach at all. For example, Trbovich et al. (2011) studied 29 hospitals buying smart pumps in Ontario, Canada, and found that many were not involving multidisciplinary teams. Even if a multidisciplinary approach is adopted, the right people might not be involved. For example, in the US, there have been reports of administrators dominating infusion device purchasing and financial requirements being prioritised over clinical preferences (Nemeth et al., 2009). In a similar study, also based on US practice, Keselman et al. (2003) focused on patient safety related requirements and found that although multiple sections of the hospital contributed to the specification and selection process, communication was limited and administrative staff were ultimately responsible for purchasing decisions. These staff tended to equate patient safety with technical aspects rather than device usability or Human Factors. The same study found that expressions of user need were filtered through questionnaires supplied by the manufacturers, passed on to administrators. Gosbee et al. (2001) report on a panel session on usability evaluation in a hospital context which identified issues including there not being the right training in place, a lack of management buy in, limitations in resource and difficulty integrating usability testing with existing purchasing processes. In other cases the assessment of technology has been held up by disagreement amongst clinical professions, and differences in opinion over evaluation methodology (Cook, 2012; Cook et al., 2012; Kinsella, 2013; Kinsella et al., 2012).

These issues are not limited to the hospital context: medical device manufacturers can also face constraints in including Human Factors practice (Money et al., 2011). The situation on the supply side may change following the recent issue of FDA guidance on "Applying Human Factors and Usability Engineering to Medical Devices" (FDA, 2016), which focuses on design rather than purchasing. This guidance sets out the content of a Human Factors Engineering/Usability Engineering report and outlines techniques that can be applied (e.g., contextual enquiry, interviews, task analysis, heuristic analysis, cognitive walkthrough and simulated use testing) (FDA, 2016). Such a report can be requested as part of a regulatory submission in the US; however it does not give assurance that the assessment will provide balanced consideration of all work elements such as people, organisations, technology, tasks and the environment. The focus of regulatory submissions (across legislatures) is on safety, rather than user experience. Also, tests for safety conducted prior to marketing, based on particular assumptions about use, do not necessarily mean that a device is suitable for a given hospital context (Blandford et al., 2014).

The lack of consideration of equipment usability often leads to problems; for example, newly introduced equipment has resulted in workarounds (Koppel et al., 2008), increases in workload (Patterson et al., 2005; Saleem et al., 2005), a lack of acceptance (Carayon et al., 2010) and the avoidance of safety features (Trbovich et al., 2011). For example, Lee et al. (2012) analysed log files and found a high incidence of "door open" alarms that could only have resulted from workarounds or violations in practice. Rajkomar and Blandford (2012) observed the use of infusion devices in an Intensive Care Unit (ICU) and found a frequently used function (volume reset) embedded under multiple levels of menu hierarchy: a mismatch between the way the device was designed to be used and local protocols resulted in poor usability. These are examples of misalignments across the work system: the task and technology are at odds with one another.

### 2.3. Approaches to considering equipment usability

Even if usability evaluation is promoted, it can be hard to realise it in practice. Although there are many methods for studying the intersection between medical technology and practitioner cognition (Schraagen and Verhoeven, 2013), applying usability evaluation rigorously and exhaustively is not straightforward. Usability