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

CJ Vincent & A Blandford

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.

Keywords: Interface, User Computer; Purchasing; Medical Device Design.

Highlights

- Purchasing provides an opportunity to shape the usability of medical devices.
- In the purchasing processes studied, the assessment of usability was limited.
- The processes studied emphasised functional requirements.
- We identify tools that can account for broader (social) circumstances.

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.

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 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.

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 Figure 1.

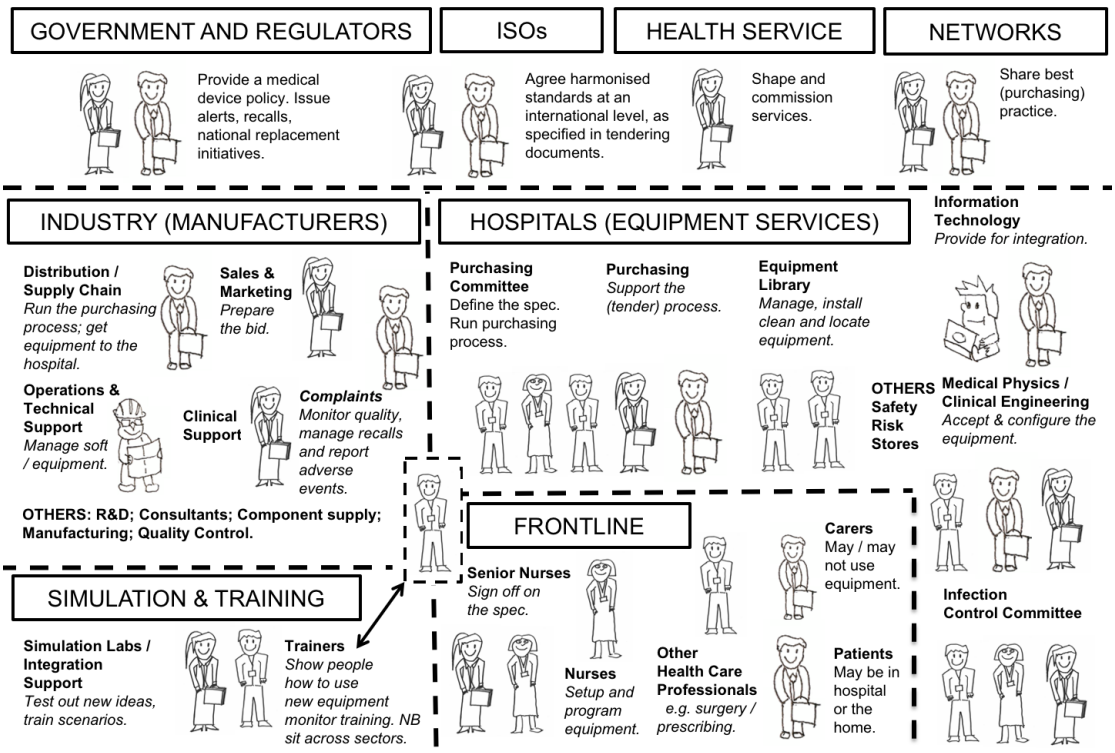


Figure 1: Purchasing stakeholders

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 and colleagues (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 Optimise Medical Device Design” (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. (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.

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 feedback is often subjective and may sit uncomfortably with broader purchasing processes. When it comes to integrating usability assessment with formalised processes, the current situation reflects other public sector purchasing exercises that prioritise accountability over effectiveness. For example, Pollock and Williams (2007) describe the comparisons made during a software procurement exercise as resulting in a schism between subjective and formal testimonials: decisions based on personal assessments contrasted with the need for a "stabilised form of accountability" where legislative requirements require an objective stance.

A similar account is provided by Hussain and Taylor (2007), who focus on the introduction of information systems within the UK National Health Service. They found a tendency for a functionalist agenda to prevail amongst those responsible for enacting change. This provides a systematic approach to discovering what are seen as stable and objective requirements. It involves a reduced need to engage with stakeholders in lieu of a formal, rationalistic and procedural method.

A functionalist agenda may be at odds with the need to perform a comprehensive assessment of usability. For example, it generally fits a stable world view and an objectivist approach (generalizable requirements can be discovered and stated precisely), whereas aspects relating to equipment usability may be subjective, unstable and require consideration of multiple aspects of a work system.

Smith and Carayon (1989) propose that to provide a safer and more productive workplace it is important to develop a holistic view of the work system, in terms of interactions between people, technology, tasks, organisations and environment. This has culminated in SEIPS (the Systems Engineering Initiative for Patient Safety), a framework for understanding the structures, processes and outcomes in healthcare (Carayon, 2009; Carayon et al., 2006; Carayon and Smith, 2000; Carayon et al., 2014). Approaches such as SEIPS have been applied to work system design (Carayon et al., 2006) and to evaluating work systems in terms of patient safety (Carayon et al., 2014), but not, to date, to supporting purchasing decisions.

By understanding how purchasing is currently happening in hospitals, we aim to better understand how to consider usability during equipment evaluation and how this type of evaluation can be integrated with existing practice.

Aim and objectives

The aim of this study was to identify common issues and practices in purchasing based on the experiences of those involved in selecting, buying and using equipment, with a view to identifying ways in which those involved in purchasing can be better informed when reasoning about interactive medical devices (e.g. during assessment and evaluation). A qualitative study was conducted in order to understand purchasing decisions in a rich and nuanced way, with a focus on the usability of infusion devices. This included:

- how purchasing occurs;
- the factors that shape purchasing decisions;
- why decisions are made in the way that they are; and
- perceptions, cultures and values relating to the above.

Methods

A qualitative interview study involving UK National Health Service (NHS) staff and equipment suppliers was conducted based on the following procedure.

Data gathering

The study involved semi-structured interviews with 20 participants across 4 hospitals, 1 community service provider, 2 universities and 1 equipment provider (see Table 1). Participants across multiple sites were approached in

parallel. Interviews focused on building an understanding of practice and identifying opportunities for support. Participants were approached via regional Clinical Research Networks (CRNs) or based on their role in the management or provision of hospital equipment.

Ethical permission was obtained from a university departmental research ethics committee. Additional permissions were obtained as per the Health Research Authority (HRA) process for a qualitative study involving staff in the NHS (i.e., research governance was granted by the healthcare trusts that were involved in the study).

The study was based on two alternative interview scripts, so that questions could be chosen based on the circumstances of the participant (Tables 2 and 3). The scripts were created using guidance on planning semi-structured interviews in qualitative studies (Blandford, 2013). The choice of script was based on the extent to which the participant had been involved in the purchasing of infusion equipment. For script 1 (purchasers), interviews addressed 7 topics, based around the equipment lifecycle, with an emphasis on evaluating equipment usability during purchasing (Table 2). For script 2 (device users), the interviews addressed 5 topics, with less emphasis on purchasing and more on the experience of use (Table 3). This second script was created when it became clear that it would be valuable to interview equipment users who had minimal involvement in the purchasing process but could present other perspectives on the circumstances surrounding the introduction and use of equipment.

The scripts contained a default plan for the interviews, but the topics could be covered in a different order, depending on how participants responded.

Table 1: Participants

Ref	Topic guide	Reference	Organisation	Profile	Involvement in purchasing
1	1	Ergonomics-1	University-1	HCI / Ergonomics researcher (senior)	M
2	1	Ergonomics-2	University-1	HCI / Ergonomics researcher (senior)	M
3	1	Manufacturer-1	Equipment Manufacturer-1	Infusion pump provider (marketing) (senior)	H
4	1	Manufacturer-2	Equipment Manufacturer-1	Infusion pump provider (marketing)	H
5	1	Health Service Manager and Accademic-1	University-2	Health service researcher (senior)	M
6	1	Equipment Library Manager-1	Hospital-2	Equipment library	H
7	1	Equipment Services -1	Hospital-2	Equipment services (senior)	H
8	1	Device Trainer-1	Hospital-1	Device trainer (senior)	M
9	1	Equipment Services-2	Hospital-3	Equipment services	H
10	1	Equipment Sevices-3	Hospital-3	Equipment services (senior)	H
11	1	Equipment Library Manager-2	Hospital-3	Equipment library	H
12	1	Hospital Purchasing-1	Hospital-3	Purchasing services (i.e. tendering)	H
13	1	Equipment Services-4	Hospital-4	Equipment services (senior)	H
14	2	Frontline-1	Hospice-1	Community practitioner (team lead)	L
15	2	Frontline -2	Hospice-1	Staff nurse	L
16	2	Frontline -3	Hospice-1	District nurse	L
17	2	Frontline -4	Hospice-1	Hospice manager	L
18	2	Frontline -5	Hospice-1	Staff nurse	L
19	2	Frontline -6	Hospice-1	Staff nurse	L
20	2	Frontline -7	Hospice-1	Staff nurse	L

NOTES: Frontline1-7: Worked for provider of NHS community services; Interview with Ergonomics 1 and Ergonomics 2 conducted at same time. Interview with Manufacturer 1 and Manufacturer 2 conducted at same time. Column "Involvement in Purchasing: L = Low: very little or no involvement, M = Medium: some involvement but not current, H = High: recent and regular involvement (at the time of the interview).

Table 2: Interview topics for those involved in purchasing (topic guide 1)

Topic	Description	Mapping to aim and objectives
T1: Personal Background	Interviewee role and responsibility.	-
T2: Example Purchasing Project	Example purchasing project including: trigger, who was involved, intended user, need for new equipment.	How purchasing occurs
T3: Process	Awareness, interpretation, utility and relevance of purchasing guidelines, process and authority.	How purchasing occurs
T4: Budget and Selection	Cost, leasing, purchasing options.	The factors that shape purchasing decisions; why decisions are made in the way that they are
T5: Advice on Equipment Usability	Awareness of sources of support re device usability.	The factors that shape purchasing decisions; why decisions are made in the way that they are
T6: Introduction of Equipment	Phased v incremental introduction, length of process.	The factors that shape purchasing decisions; why decisions are made in the way that they are
T7: Agreement, Reconciliation and Expectations	Reaching a consensus, trade-offs, outcome v expectation, what did / did not work well.	The factors that shape purchasing decisions; why decisions are made in the way that they are; perceptions, cultures and values

Table 3: Interview topics for those affected by purchasing decisions (topic guide 2)

Topic	Description	Mapping
T1: Personal Background	Interviewee role and responsibility.	-
T2: Devices Used	Example of an infusion device that they used; naming conventions; context of use; alternative devices.	-
T3: Involvement in Purchasing	Experiences of being involved in the purchasing of the infusion device, and/or recollection of introduction.	how purchasing occurs;
T4: Suitability of Equipment.	Likes / dislikes, needs, issues, comparisons with other equipment.	perceptions, cultures and values
T5: Networks and Advice	Awareness of sources of support and advice; influences on selection.	the factors that shape purchasing decisions; why decisions are made in the way that they are; perceptions, cultures and values

Informed consent was obtained from all participants. Where participants agreed, interviews were audio recorded and transcribed for analysis. When interviews were recorded, the audio recorder was clearly visible to participants. Alternatively, notes were taken. Pictures of equipment or purchasing documentation (e.g., questionnaires) were taken, with permission of those who were involved. These were suitably redacted (e.g. personal data removed) and used to support analysis.

In total 20 participants were interviewed, in 13 cases the interviews were audio recorded and in 7 cases the interviews were noted. Interviews ranged from 9 minutes to 2 hours in length, the average interview length was 37 minutes. This number of participants was chosen in line with established best practice (i.e. determining when saturation had occurred). In common with other studies (Guest et al., 2006) we found saturation occurred in fewer than 12 interviews.

Analysis

Audio data was transcribed; transcriptions and interview notes were loaded into NVivo (QSR International, Victoria, Australia). Data was analysed using thematic analysis, a qualitative method designed to support the identification, analysis and reporting of themes (Braun and Clarke, 2006). This method was chosen as it is independent of theory and offers a flexible and accessible approach to the rigorous analysis of qualitative data. In terms of trustworthiness (as defined by (Krefting, 1991)); the researcher established confidence by conducting interviews in a way that encouraged honesty; presenting sufficiently descriptive data to support comparison; and explaining sources of variability.

The first author led a process of inductive coding. Over progressive interviews the set of codes was combined, revised and simplified (as in phase three of (Braun and Clarke, 2006)). Member checking occurred both during and after the interviews. For example during some interviews findings from previous interviews were checked with the interviewee. Post study a draft of the analysis was distributed to participants to check that their views were accurately represented. As part of this process, potential for variability was addressed through a consensus approach, as per recommendations in the qualitative research literature (Glaser and Strauss, 1967). As part of the analysis, codes were abstracted to determine core categories and themes. As successive transcripts were analysed, the population of codes grew to 122. These were mapped to three themes as presented below. A mapping between the codes and the results section is provided in the supplementary data.

Results

The codes mapped to three themes: **how evaluation occurs** (e.g. equipment could be selected on the basis of harmonised standards); **how usability is assessed** (e.g. feedback could be collected from equipment users during on-site evaluations) and **why equipment was replaced** (e.g. equipment could be replaced as a result of national alerts). These themes were not mutually exclusive but provide an account in line with the objectives of the study. A mapping between these themes and the set of codes is provided in supplementary data.

How evaluation occurs

If a formal tendering exercise was conducted, it involved assessment based on engineering standards. These were contained within the purchasing specification. The use of standards provided a recognised way of judging the suitability of equipment, as defined by purchasing regulations. Those writing the specifications were mindful of this, in that they were working with the hospital's procurement team to ensure compliance:

"the input from procurement was also very important as to what would be appropriate, what wasn't, what we could ask for, and we couldn't ask." (8)

For usability, international standards IEC 62366 or IEC 62366-1 (application of usability engineering to medical devices) could have applied; however, there were concerns that this type of practice was not being recognised:

"well, I know there are very good companies that do spend the time, and you'd like to think they had the commercial advantage, but if their products aren't being evaluated for those advantages, then they quite possibly aren't." (1)

Participants often referred to the need for a generic CE (Conformité Européene) mark, which is a high-level indication of compliance with the essential requirements of the European device regulations:

"It has to be CE marked, obviously, it has to be CE marked, and once it has got the CE marking you know it complies with those standards" (9)

Although the CE marking process provides assurance that the device meets European requirements (relating to performance and safety), a purchasing team would not necessarily have access to the underpinning documentation used to gain the CE mark, or the texts of the standards documents. In addition, as the process of certifying to such standards is detached from the healthcare context, it may not anticipate site-specific concerns, and it focuses on the safety of the device rather than acceptance by front line staff.

The criteria used to select equipment are therefore functional, generic in nature, focused on safety, and may not anticipate site-specific concerns. For example, frequently specified standards included ones relating to electromagnetic compatibility (EMC), electrical integrity, biocompatibility, fluid ingress, and in some cases environmental protection. These are not criteria that ensure the device is easy to use or fits with the practices in a hospital.

How usability is assessed

Purchasing practices generally included a mechanism by which local needs could be taken into account. This was because, even if the manufacturer had applied a usability engineering process, there was no guarantee that it would take account of the circumstances of the ward or department. Participants reported that purchasing involved an on-site evaluation. This could work in a number of ways; for example, staff could learn about the pumps as part of a presentation and then provide feedback:

"we had suppliers in, they gave presentations, we rated those; we had the products in, we evaluated those" (1)

Evaluation could also involve trialling equipment and completing surveys based on experiences of using it. In examples relating to the purchasing of volumetric pumps (taken from two of the four participating hospital sites), the number of staff involved was typically large (e.g. 150) and evaluation took place in a training room, away from the ward.

For these procurement exercises, surveys were scored by front line users. The scores were based on the extent to which they believed the pump met criteria relating to functionality, for example "clear display of volume infused…." This type of feedback was necessary in order to fit with other parts of the purchasing exercise (e.g. to combine it with selection on the basis of cost or technical specification).

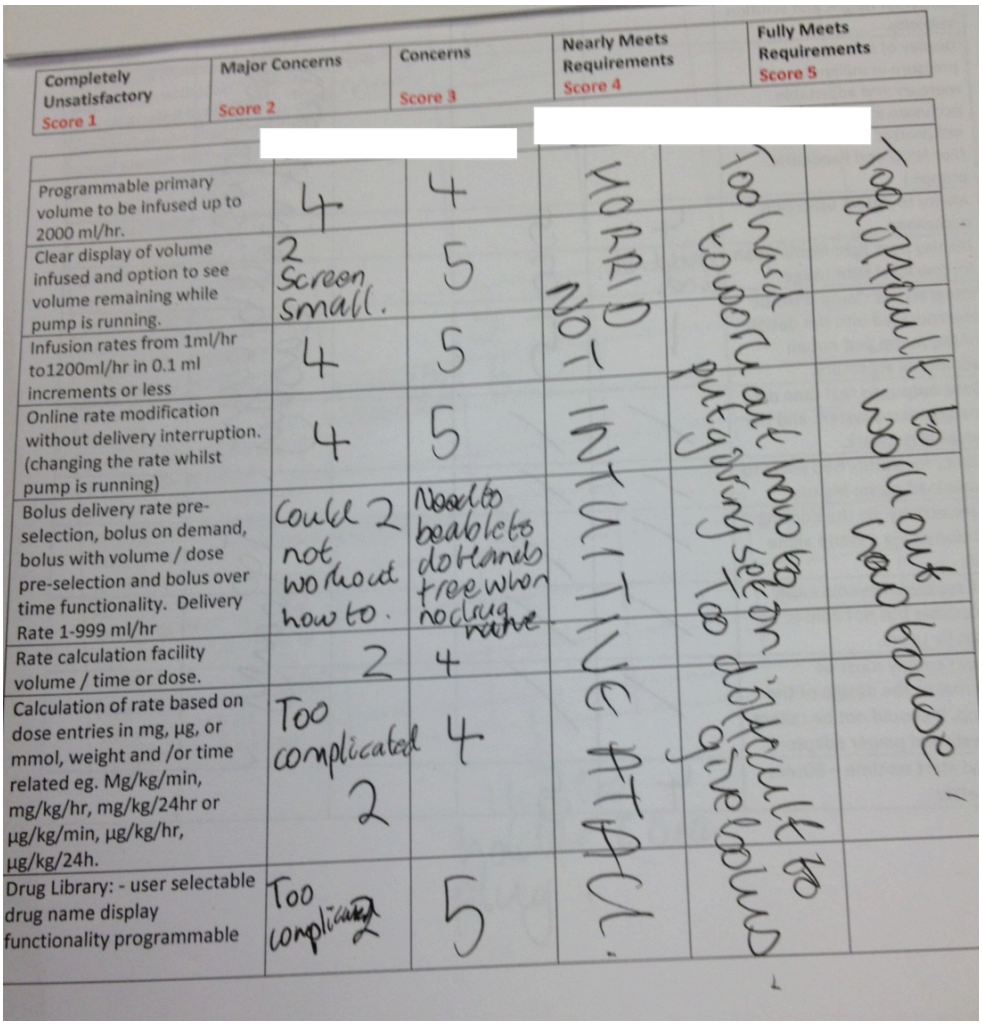
The use of a score gave the impression of an objective process:

"those comments would, I know they are very subjective, but we try and use them in an objective way for…. that shows that exceeds a four, so we took it on board, but but but yeah it is very difficult to quantify" (13)

"So they'll bring them in for a week, work with them and then feed back to them, and put some kind of weighting on what they feel is, you know, how they feel." (6)

However, despite the numerical value and accompanying rationale giving the impression of objectivity, feedback was likely to have been subjective. For example staff may have been familiar with a particular brand, be responding from numerous perspectives or anchoring their response variably (e.g. easy to use compared with existing equipment or easy to use compared with their mobile phone?)

There was a tension between what was often seen as subjective feedback, shoehorned into a process that needed to give an impression of objectivity. For example staff were supplementing the formal evaluation criteria with their own insights, using long textual narratives, or substituting scoring criteria with verbal labels (Figure 2).



Completely Unsatisfactory Score 1	Major Concerns Score 2	Concerns Score 3	Nearly Meets Requirements Score 4	Fully Meets Requirements Score 5	
Programmable primary volume to be infused up to 2000 ml/hr.	4	4			
Clear display of volume infused and option to see volume remaining while pump is running.	2 Screen small.	5			
Infusion rates from 1ml/hr to1200ml/hr in 0.1 ml increments or less	4	5			
Online rate modification without delivery interruption. (changing the rate whilst pump is running)	4	5			
Bolus delivery rate pre-selection, bolus on demand, bolus with volume / dose pre-selection and bolus over time functionality. Delivery Rate 1-999 ml/hr	could not work out how to. 2	Need to be able to do hands free when no drug name			
Rate calculation facility volume / time or dose.		4			
Calculation of rate based on dose entries in mg, µg, or mmol, weight and /or time related eg. Mg/kg/min, mg/kg/hr, mg/kg/24hr or µg/kg/min, µg/kg/hr, µg/kg/24h.	Too complicated 2	4			
Drug Library: - user selectable drug name display functionality programmable	Too complicated 2	5			

Figure 2: Survey that has been adapted

There were also questions about who to involve when assessing usability – e.g., junior nursing staff versus senior staff – and the extent to which specialist staff should be involved (e.g. those in intensive care). Surveys had to be kept to a manageable length; this constrained the number and type of criteria that could be applied. There was a perception that some of the feedback provided during on-site evaluation was of limited value, for example:

"until you get a product out into the workplace you don't fully appreciate what are going to be the difficulties" (8)

There was also a concern that equipment purchased for one area was being trialled in another (e.g. the Intensive Treatment Unit - ITU):

"they will do a trial in ITU, which is the worst place to do a trial, because patient nurse, it's one to one, on a ward it's one to eight" (6)

There were often multiple, conflicting views on what constituted usability, many ways of defining it, and constraints in terms of how usability could be evaluated, where and by whom. What was in the interests of one part of the hospital and/or trust might not be in the interests of another. It was challenging to combine the many and varied influences during device evaluation, although some participants suggested that they were well placed to do this:

"As ergonomists, we're very good at managing people coming together, and trying to make sure that their views are represented. So, that's… you don't go into ergonomics unless you've got the ability to cope with divergent views – because you're going to get them." (1)

Why equipment gets replaced

One impetus for changing equipment (and evaluating new equipment) was the need to replace devices that were known to have poor usability. This could occur at a local level (through professional judgement), or as a result of national alerts or recalls. Due to the timing and focus of the study (on infusion device purchasing), participating hospitals had recently had experience of a national recall, which resulted in one purchasing process featuring strongly in the interviews. This featured a syringe driver that was replaced due to concerns about ease of use. This followed the release of a Rapid Response Report (RRR) from the National Patient Safety Agency (since disbanded). The report outlined concerns including the potential for confusion when setting the rate on ambulatory syringe drivers. It called for a "purchasing for safety initiative" which would address this problem:

"While the majority of syringe drivers and pumps used in healthcare have rate settings in millilitres (ml), some older types of ambulatory syringe drivers have rate settings in millimetres (mm) of syringe plunger travel. This is not intuitive for many users and not easy to check." (NPSA, 2010)

Healthcare providers recognised this alert and initiated replacement of the equipment in question. Following the replacement, staff were generally positive about their experiences of using the new equipment; however, the situation was complicated by the limited number of pumps on the market:

"if you want a small syringe pump for this purpose there is currently one available which is really very regretful, but it's a niche market… …So essentially we had one pump in the market, but we were able to use the tender spec to at least clarify what we required" [8]

As the replacement was unavoidable, there was little decision to be made about the interactive properties of the device. Despite purchasers going through a formal tendering process (e.g. including involvement from working groups representing front line interests), the choice of pump was a given. The user group in question was palliative care nurses. On the one hand, staff were getting a replacement which was seen to offer many advantages. On the other hand, purchasing did not involve meaningful choice.

In this case it was also apparent that many of the front line staff had not been involved in the purchasing of this device. Most thought that they should have been involved:

"I think nurses [should] have a bit of a say in it because we're the ones that sort of have the sharp end of the stick and are using them all the time. And quite often we're just told, this is what we're having and we don't get involved" [20]

Reasons for a lack of involvement could include: not being around at the time of the evaluation; the decision being driven by the "engineering department"; the hospital trust not adopting a holistic approach (and therefore not consulting with the frontline staff) or the equipment needing to be replaced in a very short timeframe.

Discussion: Usability evaluation during the purchasing process

An idealised view of the purchasing process assumes a two-way relationship between hospitals and medical device manufacturers. Hospitals shape equipment design though purchasing practice: if hospitals seek to buy equipment that is easy to use, it provides motivation for manufacturers to invest in usability and improve the design of technology from a user-centred perspective. If there is only one type of device available, or user feedback is avoided, this two-way relationship breaks down.

In our study, we found that purchasing is driven by engineering standards, and that the emphasis is on functional requirements rather than those relating to social or organisational needs. In SEIPS terms, purchasing was conducted with a focus on some parts of the work-system but not others. Changes in infusion pump technology were not "balancing" the elements of the work system. Whereas SEIPS advocates a holistic approach and multidisciplinary involvement, this study identifies practices that are closer to a Taylorist view, which

acknowledges the need to get the right tool for the job but also seeks to standardise work and diminish the autonomy of the worker.

An alternative view, that takes into account social circumstances, is Barley's (1986) account of "technology as an occasion for structuring," in which technology is treated as a social object rather than a physical one and is conceptualized as a process rather than an entity. According to this perspective, true evaluation can only occur in an organisational setting (or proxy of one), as technology alters institutional roles and patterns of interaction. For example, the introduction of a new type of syringe driver might require new operating procedures, which could in turn impact on broader practices such as prescribing.

This highlights a need for tools that allow those involved in equipment evaluation to conduct an assessment not only of the suitability of the equipment, but of the combination of equipment, staff and organisational circumstances, before and after the replacement. This assessment would be shared across members of the organization and serve to strengthen links, should there be a need for follow-up support and advice. In this way, the pump replacement would act as more than a replacement of technology: it would support a refinement of the organisation surrounding the technology.

Although there was an acknowledgement of the need to factor in the social circumstances of technology use (of which usability was a component), the formal purchasing process made this very challenging. This is not the first time that such a tension has been observed. For example, Pollock and Williams (2007) describe the purchasing processes as "dragging" the choices surrounding the procurement from an informal domain to a formal one. In acknowledging the role for cultural sociological accounts, they suggest a "grey area" that opens up between rationalist and sociological approaches. They identify a need for tools to bridge this gulf. There is a tension between a view of the purchasing process as expressing formal and objective criteria as defined by a statement of economic, managerial and engineering intent (e.g. rigid adherence to a tendering specification) and a view that good purchasing decisions cannot be detached from the organization setting.

Although collectives such as purchasing committees are working together in selecting a pump for purchasing, the overall method is systematic and functional. For example, the group focuses on forming a technical specification. Buying is characterised by adherence to this specification, fixed rules and a hierarchy of authority. On the one hand, the formal approach provides a decision that is accountable and objective; on the other hand, it can be insensitive to the organisational context and fail to truly represent the needs of users.

There is a need to revisit what the purchasing process means. The current situation is reminiscent of the waterfall process of software development (Benington, 1983), where those writing a specification need to produce the most detail early on in the process, when they know the least. As many of our participants observed, there is no way of knowing the true relationship between technology and the organization until after equipment has been deployed. A

different approach is required where requirements are developed iteratively, amongst teams. For example the inclusion of HF / usability specialists on purchasing committees and use of systems models such as SEIPS could help broaden the focus and move beyond a purely functionalist agenda.

In this case additional tools are required to empower groups to understand how equipment is really used in practice, facilitating a closer match to the circumstances of use. There are numerous techniques that can be used to build a better understanding, sensitise to multiple perspectives, and represent informal accounts (see Table 4). They are exemplified by the approach of soft systems methodology (Checkland, 1981), which utilises rich pictures (pictorial summaries of findings from interviews, reports etc.), and has been applied in various public sector improvement projects (Flood and Carson, 1993).

The process might also be facilitated by tools that can be applied with flexibility and rigour and represent multiple perspectives. One example is multi-attribute utility models that formalise the tradeoffs between product characteristics such as cost and safety. The technique was originally applied in the 1970's and has been used in many domains, including inventory ordering for blood banks (Kenney, 1972). In applying this technique, there is scope to consider a broader range of subjective criteria, which would address some of the issues identified in this study.

Table 4: Examples of approaches that can represent 'social' requirements

Approach	Addresses	Resources	Comment / limitations
SEIPS; Consideration of the sociotechnical system	Focus on single parts of the work-system / evaluation in isolation	http://cqpi.wisc.edu/seips-main.htm	Need to consider how modelling efforts can be integrated with purchasing process
Including HF / HCI professionals on purchasing committees	Lack of awareness of HF / HCI	NA	Need to make HCI knowledge and process available and effective at the right time
Develop models to combine objective and subjective influences	Functional approach	Multi-attribute utility theory e.g., (Pecchia et al., 2013) .	Trade-offs regarding safety may be unacceptable
Use tools that support a statement of social requirements	Limited input regarding usability	Soft Systems Methodology (Checkland, 1981).	Subjective influences may not be an acceptable input
Illustrate how multiple requirements inform the selection process and illustrate trade-offs	Rationale for decision unclear, not accessible to a range of staff	Design Rationale. (Moran and Carroll, 1996).	May not scale to broader system models
Increase the fidelity / realism of the context used to conduct the evaluation	Wrong assumptions	Simulation (Lamsdale et al., 2005)	Limits to fidelity of simulation

Limitations

Limitations to the study include issues of generalizability, in terms of generalising across purchasing contexts and activities. Because we were aiming to understand the realities of practice without bringing preconceptions of what we would find, no *a priori* framework was used to generate the interview topics. Given the complexity and variability of purchasing practices across health service organisations, we cannot be certain that we have identified the full range of practices. We aimed to achieve coverage by working with individuals across eight organisations, including four hospitals and a hospice. Findings were broadly similar across these different organisations; however, there might have been different findings for other combinations of device, context and condition. Further work could study how consistent the purchasing process is and address these issues of generalizability. At the time of conducting the work it was difficult to recruit those who had direct experience of infusion device purchasing and had knowledge and experience in HF / HCI, reflecting the limited number of people with this dual expertise. Given this limitation future work could engage purchasers with mock purchasing scenarios and then allow them to be consulted with a human factors focus. It could elicit if and how human factors issues affect their decision-making.

Conclusion

This study has highlighted the need to supplement the current formal process with greater consideration of the social circumstances surrounding use of technology. We have proposed approaches that can be applied with flexibility and rigour, to support systems thinking and represent multiple perspectives.

In shifting the emphasis in purchasing, from one where the solution is determined through rigid specification to one that is sensitive to user needs at a local level, there is potential for future purchasing to leverage the benefits of diversity in practice, rather than seeking to overcome them (e.g. encouraging consultation and discussion to inform change, rather than attempting to shoehorn user views into an inflexible framework). In this case, staff would involve themselves in a co-evolution of equipment and practices, aligned with the broader management and functioning of the health service, rather than having solutions imposed on them.

Conflict of Interest Statement

Employment: The first author is currently employed by product and service design innovation consultancy PDD Group Ltd.

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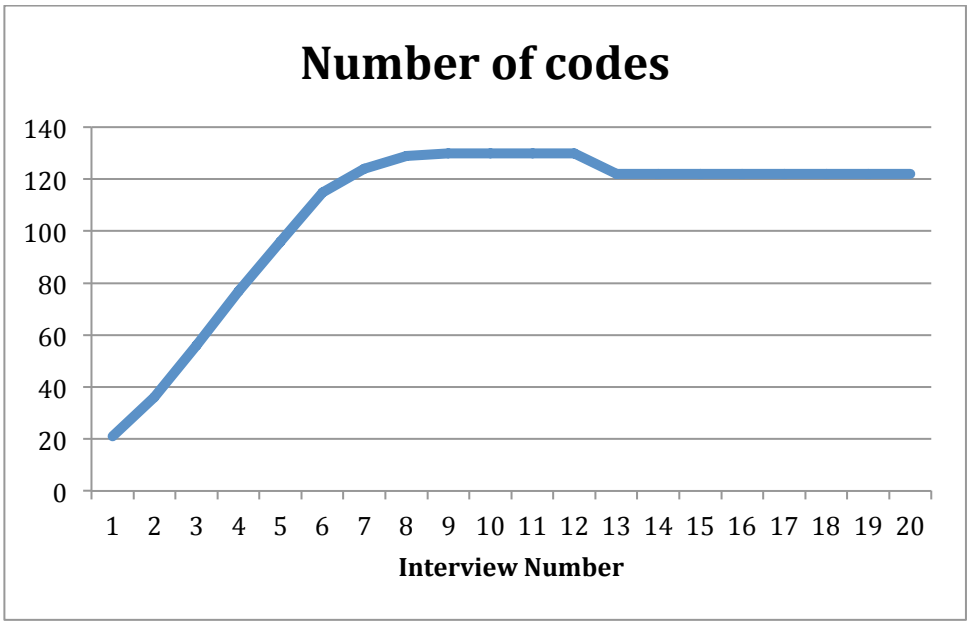
Supplementary data



Codes ordered by frequency of occurrence. Under "category", we list the themes; some codes are not reported in this paper.

Name of code	Category
Whole life and systems view	How evaluation occurs
Blur between health service and commercial support	-
Equipment replacement	Why equipment gets replaced
Hospital organization	General background
Shortcomings of equipment	Why equipment gets replaced
Collectivism or winner takes all	-
Complexity and scale	General background
Integration of equipment	-
Purchasing process	How evaluation occurs
Rules, regulations and policy	How evaluation occurs
Safety	Why equipment gets replaced
Standardization of equipment types	Why equipment gets replaced
Substance of user input	How usability is assessed
Discrepancies around cost and transparency of cost	-
Front line interest and involvement in purchasing decisions	How evaluation occurs
Management of equipment	-
Savings and economy	-

Name of code	Category
Training	-
Availability of equipment	Why equipment gets replaced
Big bang v phased	-
Clinical engagement	How usability is assessed
Conflict between stakeholders and need to involve them	How usability is assessed
Dose Error Reduction Systems (DERS)	-
Evaluation metric	How evaluation occurs
Focus is broader than usability	How usability is assessed
Going through the motions	-
Liability and litigation	-
Tradeoff	How usability is assessed
Unexpected outcome	-
Bias	-
Blur between technical and clinical evaluation	How usability is assessed
Capacity	-
Conflicts of interest	-
Cost benefit analysis	-
Disconnects	-
Fixed timescales	Why equipment gets replaced
Hands are tied	-
Hierarchy	-
Making cost transparent	-
Senior versus junior feedback	How usability is assessed
Servicing	-
Unusual process	-
Bureaucratic process	-
Capital v revenue	-
Common language or lack of common language	-
Configuration	-
Customization	-
Device risk levels	-
Disconnect between purchasing and the front line	How usability is assessed
Drug device combinations	-
Dynamic process	-
Education	-

Name of code	Category
Equipment often purchased based on feedback from intensive care	How usability is assessed
Forced decision	Why equipment gets replaced
Hospital management	How usability is assessed
Human Factors as education	Discussion
Incidents	-
Lack of evidence	-
Leasing versus buying	-
Level playing field and fair play	-
Match between pump and practice	How usability is assessed
Obvious decision	Why equipment gets replaced
Project management	-
Regret	-
Scenarios	-
Sharing knowledge	-
Workarounds	-
Accidental overdose	-
Being seen to put the user first	-
Blur between equipment providers	-
Catch 22	-
Charity	-
Confusion	-
Denial	-
Destructive testing	-
Differences between volumetric pumps and syringe drivers	-
Difficulty of change and time of change	-
Failure to learn	-
Future proofing	-
How open	-
In situ updates	-
Innovation	-
Internal v external process	-
Internal versus external purchasing process	-
International differences	-
Isolating parts of the hospital	-
Lean and sig sigma	-
Lock-ins	-
Management of transition	-
Manufacturer bias	-

Name of code	Category
Move towards private provision	-
Nature of evidence	-
Need for usability evaluation	-
No need to overcomplicate things	-
Patient first	-
Positive versus negative framing	-
Predictability of failure	-
Quality of tendering process	-
Reconciliation of equipment	-
Reducing redundant equipment	-
Relationships	-
Replication of effort	-
Resilience	-
Scaling of process depending on device type	-
Senior buy in	-
Service rather than device	-
Show and tell	-
Simulation	-
Standardization of the UI	-
Supply chain	-
Technical spec v usability	-
Time to develop products	-
Training as a way to address safety concerns	-
Unintended delivery	-
Utilization	-
Variability of users	-
Variations in practice	-
What the pumps are being used for	-
Wider political changes	-
Cost of fragmentation	-
Preventative measures	-
Reducing length of stay	-