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Maintaining the Standard: Challenges in Adopting Best Practice when Designing Medical Devices and Systems

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Maintaining the standard: challenges in adopting best practice when designing medical devices and systems

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Abstract

Human Factors Engineering (HFE) maintains that a reduction in use error can be achieved through adoption of appropriate design methodology. HFE can be applied across groups, organizations or industries to improve the degree to which a solution delivers safety and usability. There are a large number of resources available to support design; however companies report challenges regarding the adoption of standards and the satisfaction of regulatory controls. We report on a qualitative study involving a range of medical device developers and manufacturers. This identified issues associated with standardizing across the industry and understanding the regulatory intent. For example, there is very difficult for external organizations to assess the rationale underpinning a given design, and standards may not fit well with the reality of design practice. Multiple competing standards confuse the situation and it is not always clear what is required to satisfy regulatory requirements.

Introduction

Within healthcare, there is growing recognition that “human error” is not independent of the broader system within which individuals act and interact. Under this view, errors are not attributed in entirety to the individual involved; rather, they are a consequence of a failure of one or several parts of the system. The EU regulatory system reflects this approach, with manufacturers required to be:

“reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users)”

In the US, the Food and Drug Administration (FDA) requires developers to follow the FDA’s Human Factors guidance and regulations2, and has recently announced an initiative to improve the safety and effectiveness of infusion pumps3. Consequently, when developing healthcare products, manufacturers need to consider users, the tools that they use and the environments in which they live and work. In doing this, there are challenges associated with the adoption of best practice (as defined by standards such as IEC 62366:2007 or guidelines such as ANSI/AMMI HE75:2009). For example, design decisions need to be expressed in a way that a variety of stakeholders can understand. Those who draft guidance need to be in a position to reflect the reality of industrial / healthcare practice. Those tasked with assessing the safety and usability of a product need to understand the rationale behind a given design. This paper explores these issues with a focus on the use of standards to support the interactive properties of infusion devices.

Designing and manufacturing infusion devices is a complex and specialist effort involving multiple design based trade-offs. For example, the choice of numeric entry method may reflect the availability of display real-estate, likelihood of numeric entry error, chance of component failure, match to user expectation, conventions within the hospital environment, availability of standard solutions or precedents set by other devices. Organizations invest time and effort in balancing competing demands and there are various standards and guidelines to support4.

HFE helps incorporate these considerations during the development process. It can also inform those who buy, use and regulate equipment5. Understanding how HFE is applied at both development and procurement stages helps those tasked with developing industry wide guidance or understanding mismatches between suggested and actual practice (for example provision of ergonomic data). This is in the light of questions regarding the degree to which standards, guidance and support reflect the needs of industrial practitioners. For example Gupta found that although HFE was used to identify issues and problems, there was a lack of science based support6. Studies focusing on medical device software have found examples of standards lagging behind regulatory requirements7 or complicated by a lack of international harmonization8.

Assurance of safety and usability may therefore extend beyond the adoption of standardized development process or design solutions. Research has examined the use of graphical and structured depictions to communicate why a device is safe. Examples include the use of Claims, Arguments and Evidence (CAE) or Goal Structured Notation.
(GSN)\textsuperscript{9,10}. The advantage of using these structures is that they allow reviewers to examine completeness, robustness and mistaken argumentation such as circular reasoning. Examples may reference standards, or include analysis to demonstrate safety in use. Where multiple analytical techniques need to be combined, techniques like Questions, Options and Criteria (QOC) can be used to show underlying constraints for User Interface (UI) problems that are novel, complex or difficult to address through user studies.

This paper explores the challenges manufacturers and developers face when adopting best practice for HFE or User Centered Design (UCD) and demonstrating safety in use. Those charged with protecting the public interest aide best practice in this area, for example the US FDA and the UK National Patient Safety Agency - NPSA provide guidance on their websites\textsuperscript{2,4}. In this work we used grounded theory\textsuperscript{11} to explore many of these issues, using the regulation, development, manufacture and deployment of infusion devices as foci. Grounded theory is a method to support the building of theory through qualitative analysis of data. The practicalities and suitability of this method are described elsewhere\textsuperscript{12}. We chose the method as it suited the diverse and complex setting of the healthcare industry.

**Participants**

We interviewed a range of professionals who have an interest in the interactive properties of infusion devices. Table 1 describes the background of the participants. 10 participants were chosen based upon their industrial experience or involvement in UK National Health Service (NHS) safety initiatives. Where participants held senior positions, they maintained awareness of relevant tools and techniques applied within their organization.

**Table 1. Description of Participants**

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Company type</th>
<th>Position</th>
<th>Recording</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCI-01-01</td>
<td>NA</td>
<td>Director of Research Lab, Usability Consultancy</td>
<td>Notes</td>
</tr>
<tr>
<td>MDC-01-01</td>
<td>Global healthcare provider</td>
<td>Patient Safety Advocate</td>
<td>Notes</td>
</tr>
<tr>
<td>MDC-01-02</td>
<td>See MDC-01-01</td>
<td>See MDC-01-01</td>
<td>Transcript</td>
</tr>
<tr>
<td>MDC-02-01</td>
<td>Global healthcare provider</td>
<td>Business Development Manager</td>
<td>Notes</td>
</tr>
<tr>
<td>MDC-03-01</td>
<td>Global healthcare provider</td>
<td>Training and Marketing</td>
<td>Notes</td>
</tr>
<tr>
<td>MDC-04-01</td>
<td>Software consultancy</td>
<td>Team Lead</td>
<td>Notes</td>
</tr>
<tr>
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<td>Software consultancy</td>
<td>Software Development and Usability</td>
<td>Transcript</td>
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<td>MDC-05-01</td>
<td>Global healthcare provider</td>
<td>Human Factors Program Manager</td>
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<td>MDC-02-02</td>
<td>Global healthcare provider</td>
<td>Vice President Marketing</td>
<td>Notes</td>
</tr>
<tr>
<td>MDC-07-01</td>
<td>Local healthcare provider</td>
<td>Chief Executive</td>
<td>Transcript</td>
</tr>
</tbody>
</table>

*Note. MDC = Medical Device Company, HCI = HCI Consultant, MDC-XX-YY: XX = Organization serial – e.g. each organization has a separate serial, YY = Interview number for company. NA = Not Applicable*

**Procedure**

An approach email was sent to participants. Contacts were established in March 2010 and interviews were conducted between April 2010 and October 2010. We used semi-structured interviews based upon a series of core questions (Table 2). Where possible, interviews were audio recorded and transcribed for analysis. In cases where this was not possible, extensive notes were taken. Nine interviews were face to face and two over the phone. One participant was interviewed over the phone and face to face in order to gain additional data (MDC-01-01 and MDC-01-02). Data were transcribed and loaded into ATLAS Ti (Scientific Software Development GmbH). Interviews were analyzed in sequence. We made the final report available to participants to verify that their views were accurately represented. Quotations used to illustrate themes are taken from transcripts, and consequently from three participants, but the analysis underpinning the results is from all 11 datasets.

**Analysis and Conceptual Development**

The first author conducted a process of open coding (breaking data apart and delineating concepts). As successive transcripts were analyzed, the population of codes grew to 132. Codes were abstracted to determine themes and meta-themes. 6 themes were identified (Figure 1), namely: Collaborative Working Practices; Understanding the User and their Situation; Adequate Justification of User Centered Design; Clear Guidance and Support;
Communication of Mandatory Controls and Industry Wide Standardization. The majority of codes related to a single theme; in a minority of cases a single code related to multiple themes. Themes were grouped under two meta-themes, namely Regulation and Design and Development (Figure 1). In this paper, we focus on the Regulation meta-theme and issues relating to Industry Wide Standardization and Communication of Mandatory Controls. Challenges relating to design and development are reported in another paper.13

Table 2. Interview Topics: User Centered Design (UCD) Approach

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Company Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1: Personal Background, Organizational Structure</td>
<td>Practitioner role and responsibility, internal and external relationships and dependencies.</td>
</tr>
<tr>
<td>T2: Fit in Landscape</td>
<td>Known stakeholders, for example relationship with providers of advice on regulatory compliance (in the EU - Notified Bodies - NB)</td>
</tr>
<tr>
<td>T3: Example Product</td>
<td>Example product including interactive properties.</td>
</tr>
<tr>
<td>T4: Awareness of Standards and Support</td>
<td>Awareness, interpretation, utility and relevance of design guidelines and standards, mainly relating to HFE.</td>
</tr>
<tr>
<td>T5: Interface Design Methods</td>
<td>Awareness, interpretation, utility and relevance of UCD tools, details of development process.</td>
</tr>
<tr>
<td>T6: Interface Design Challenges</td>
<td>Mechanisms to prevent input error, interface design drivers / trade offs. Fit within development process.</td>
</tr>
<tr>
<td>T7: Interface Design Assessment</td>
<td>Application of user testing, evaluative techniques, verification and validation. Fit within development process.</td>
</tr>
<tr>
<td>T8: Post Marketing Activities</td>
<td>Training, user documentation, monitoring of device alerts and recalls, opportunities for support, constraints and dependencies.</td>
</tr>
</tbody>
</table>

Results and Findings

Overall, participants were familiar with a range of HFE and UCD techniques and reported that they performed over and above the mandatory requirements. Many faced challenges in understanding what was necessary to satisfy regulatory requirements and were concerned about the abundance of complex and lengthy supporting material.

Industry Wide Standardization

Organizations worked closely with Notified Bodies (NB) (providers of advice on regulatory compliance) to ensure adequate documentation was in place. Those who worked with NB commented that it would be useful to get informal guidance regarding the way in which they should implement usability standards.

[about the NB] “when it comes to the European directive and the usability standard, I think they are still in charge, I also went there to have a course… …there may be the possibility that I can have some feedback from that company before the audit, just to show them what has been done so far, and to show that you are going in the right direction or not, that would be helpful” MDC-04-02

We asked companies about the utility of current standards relating to HFE and their relationship with organizations tasked with generating them. In addition to the concern that usability process such as IEC 62366:2007 may be difficult to implement, companies were also mindful of the requirement for consensus to emerge across the industry when adopting common process or common design solutions. One believed it was the responsibility of customers or procurement organizations to provide the lead and gave an example relating to the standardization of a hardware connector (a common design solution).

[on the adoption of a standard for a new connector] “we as a company are happy to work with any, you know, whatever is adopted we will adapt. So basically it’s very easy for us to say okay, if customers adopt this system, system X, we will buy the connectors for system X and put those onto our sets. We’re quite happy to do that. We don’t want to compete.” MDC-07-01
Developers were concerned about the effect of multiple competing standards, adopted standards being superseded by an alternative solution in the near future, or with issues regarding system wide integration. Translated to the user interface, these issues had the potential to result in inconsistencies across pump design such as varying decimal place location, or a lack of consistency between labeling conventions. In terms of system wide integration, one participant suggested that the use of open standards would help:

[following on from previous quotation] “I mean it wouldn’t have been appropriate for us to take one of those systems, put it in our pump and then say right, that’s the system for our pump and nobody else can use it. Because for something to become the standard and for it to actually work for that to actually be a safe system, you have to have open standards…” MDC-07-01

Communication of Mandatory Controls

We asked organizations how they knew which controls were mandatory. One interviewee suggested that the production of additional standards confuses the situation.

“those standards may ultimately not be mandatory... So you’re left as a participant thinking, well where’s the real advantage, you know, have we moved forward or have we just created more confusion?” MDC-07-01

In terms of working with notified bodies in the EU, where mandatory inspection was required, there seemed to be limited opportunity for a full assessment of the optimality or suitability of a design. For example, it is difficult for any third party to gain a comprehensive understanding of practice within an organization. It is also hard to gain detailed understanding of the technical aspects regarding a given solution. Those tasked with an audit may be limited to checking attributes relating to documentation such as the existence of a given document, date on which it was produced, traceability and control of document revision. Although the Summary Technical Documentation (STED) format produced by the Global Harmonization Task Force (GHTF) allows manufacturers seeking EU approval to provide a standard summary for third party assessment, there are concerns regarding content. For example, a study conducted by the Dutch National Institute for Public Health and the Environment (RIVM) revealed shortcomings in more than 90% of class III device technical files. As the level of scrutiny applied to these files is high, inconsistencies may be as a result of misunderstandings regarding necessary content.

Implications for the Community

For many of the examples we examined, manufacturers provided devices engineered to meet a generic need, but maintained that it is impossible to anticipate all possible combinations of user and usage. Ensuring that consensus emerged across the industry / healthcare environment was seen as a challenge. For infusion pumps, certain programming parameters (Volume To Be Infused - VTBI) may be less likely to be used in some contexts than in others. For other types of medical equipment such as gas cylinders, there are multiple and conflicting international color-coding conventions. For these reasons, there may be subtle factors that influence adoption (or non-adoption) of a given standard. This reasoning may be lost when it comes to procurement or deployment stages.

One potential solution would be to encourage the sharing of assumptions made by those who design equipment and those who purchase and deploy it. Common knowledge can be critical when things go wrong (for example accident investigation), detailing the implications of component failure or when combining several products for novel applications (e.g. systems of systems). It may also be helpful when understanding the potential for confusion to arise as a result of differing design conventions across multiple products. For example, if the majority of manufacturers use a feature known to contribute to use error, specific guidance can be drawn up. In the UK, the NPSA has recently released a Rapid Response Report (RRR), outlining the potential for confusion to arise when setting the rate on ambulatory syringe drivers:

“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.”

Although the presence of post-marketing surveillance and Corrective And Preventative Action (CAPA) makes developers aware of these problems, there is potential for a closer examination of assumed and actual usage (for example inspection of near misses and “unremarkable” programming errors experienced with similar devices).

Conclusion

Our participants, who represent most of the major manufacturers of infusion devices, were aware of the need for UCD or HFE techniques and often went beyond recommended practice. Through this study, we have identified
areas where communication of the tacit knowledge acquired during the design process could benefit a cross-section of stakeholders. For example, providing procurement organizations with the rationale for the user interface having been designed in the way that it has would allow better assessment of the degree to which a solution meets their needs. Although HFE methods have been used to inform procurement decisions, techniques are often conducted in addition to similar tools applied during the development phases. Making procurement organizations aware of HFE activities across the development lifecycle could provide additional benefit. Providing those that produce standards and guidance with similar information would also help match the resources that are offered with the challenges developers face. Providing the regulator with an easily interrogated representation of the way in which design mitigates error and provides for safety in use could help reduce the time taken to get a product on the market (especially for incremental updates). Sharing of information across the industry and open standards could provide for efficiencies across the community as a whole.

Acknowledgments

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References