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MATCH: A NEW INDUSTRY-FOCUSED APPROACH TO MEDICAL DEVICE DEVELOPMENT

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MATCH (Multidisciplinary Assessment of Technology Centre for Healthcare) is a new collaboration in the UK that aims to support the healthcare sector by creating methods to assess the value of medical devices from concept through to mature product. A major aim of MATCH is to encourage the inclusion of the user throughout the product lifecycle in order to achieve devices that truly meet the requirements of their users. A review of the published literature indicates that user requirements are mainly collected during the design and evaluation stage of the product lifecycle whilst other areas, including the concept stage, have less user involvement. Complementing the literature review is an in-depth consultation with the medical device industry, which has identified a number of barriers encountered by companies when attempting to capture user requirements. These will be addressed by a number of case study projects, performed in collaboration with our industrial partners, that will examine the application and utility of different approaches to collecting and analysing data on user requirements. MATCH is focused on providing advice to device developers on how to select and apply methods that have maximum theoretical strength, practical application, cost-effectiveness and likelihood of wide sector acceptance. Feedback will be sought in order to ensure that the needs of the diverse medical device sector are met.

Background

The Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) is a collaboration between five UK universities funded initially for 5 years by the Engineering and Physical Sciences Research Council (EPSRC), Department of Trade and Industry, Invest Northern Ireland and the National Patient Safety Agency. MATCH aims to support the healthcare sector by creating methods to assess the value of medical devices from concept through to mature product. Although the MATCH research is being done within an academic framework, the emphasis is on working with industry to solve real problems and the deliverables

will be written with industry in mind and feedback will be sought in order to ensure that the needs of this diverse sector are met.

The MATCH approach

One of the major issues addressed by MATCH is that of representing the end-user throughout the product lifecycle and developing methods of capturing user requirements. MATCH is unusual in that it has a multi-disciplinary approach, which includes ergonomists, engineers, clinicians and social scientists, and aims to challenge the concept of what true user requirements are and how these can be appropriately captured. The regulation and reimbursement procedures that govern medical device development can prove a barrier to including the user in the development process, the vital step in satisfying user requirements.

The definition of user requirements related to medical devices is complicated by the disparity in types of devices, their intended function, the relationship to clinical effectiveness and of course the range of users. Satisfying user requirements in medical devices goes far beyond usability and user centred design. Patient safety is an important topic with the creation of the UK National Patient Safety Agency (NPSA) in 2001 and the Design for Patient Safety initiative (Buckle *et al*, 2003). The recommendations made by these programmes for designing safe environments and devices and improving drug packaging will have a significant impact on reducing medical error. Regulations governing medical device development are becoming increasingly focused on improving device design with the aim of improving usability and patient safety, and some standards are being updated to include human factors e.g. the latest revision of IEC60601-1 for medical electrical equipment has a specific section on usability (IEC 60601-1). In addition, a large amount of guidance for medical device development is offered, notably in the USA from the FDA's Human Factors Program and in the UK from the Cambridge Engineering Design Centre. More general advice on inclusive design is available from the Helen Hamlyn Research Centre and the Royal Society for the encouragement of Arts, Manufactures & Commerce (RSA).

In order to meet these requirements and recommendations, industry needs guidance to help apply the most appropriate methods at the most appropriate stages of the product cycle, and with the most appropriate groups of users. Medical devices must fulfill the specific clinical needs of the user in order to be effective, and this may often be at the expense of the experience of the user. Clinicians and device developers may often struggle to see that user requirements should extend past clinical needs. This demonstrates a major issue that differentiates medical devices from many other ergonomics domains, such as the design of work systems or consumer products, and that is the need to satisfy the user both as the operator and the recipient of the device or treatment. Research indicates that in many cases the perspectives of end users differ substantially from the perspectives of device producers and also from professional users. Therefore it is imperative to investigate approaches that capture these differences in a formal and measurable way. Within MATCH, there are currently three user-related research projects in progress: a literature review, industry consultation and empirical research

Literature Review

Three structured literature reviews were performed in order to identify, summarise and appraise the published evidence related to the methods and tools used for the capture of user requirements within the fields of healthcare, social science and engineering and ergonomics. In total more

than 800 papers covering general product development as well as medical devices were reviewed. The engineering/ergonomics literature was primarily concerned with the application of the well established concept of user-centred design and the methods used within it, and a number of recently published articles were identified that described the use of user-centred design for medical devices, specifically with the aim of improving usability in order to reduce medical error.

In general, user requirements are mainly captured during the design and evaluation stage of the product lifecycle. Little published evidence was identified where developers had included the user in other stages of the product cycle such as the concept stage. Users are not usually brought into the developmental process until after the design brief for a new product has been put together as medical device are often technology driven. In order to deliver the needs-driven devices that patients, clinicians and purchasers require end-users need to be embedded into the whole developmental process.

The literature highlights a number of themes that will affect the choice of method for a particular application. These include issues such as the type of users to be studied, the point in the product lifecycle and the cost, time and expertise available as well as issues that are more difficult to identify such as social and cultural considerations.

Although the review provides an indication of the methods that have been used to capture user requirements it is not possible to determine from the literature what the current practices within the medical device industry actually are. Published papers do not necessarily reflect methods in practice: some methods may be so well established that there is no need for further research into their use; methods discussed in the scientific literature may rarely be applied in practice; and current industrial practices may be commercially confidential. Therefore consultation with industry is vital if the work is to reflect and improve on current practices.

Industry Consultation

An in-depth consultation with the medical device industry is currently underway. This aims to discover the positive and negative experiences of a range of medical device companies when applying the methods covered in the literature review and the barriers that prevent users being included in the device development. This is necessary to ground the literature review in the real-world experiences of industry in order to build up a representative picture of what is currently done in a highly diverse industry.

An important aim of this consultation is to understand the differences between large multinational companies and SMEs in their practices, attitudes to and opportunities of meeting user requirements. MATCH recognises that any advice produced for industry must be appropriate not only for dedicated Research and Development teams but also for small-scale device developers working under extreme budget restrictions and without any of the expertise required for assessing user requirements.

A secondary aim of this consultation is to identify areas where medical device companies feel MATCH may be able to provide help, this will ensure that we concentrate on the most relevant areas so that the research undertaken by MATCH is of practical value and receives the acceptance of the medical device sector.

From the interviews conducted so far, with a number of small and large scale medical device companies, a number of themes are apparent:

- Whilst aware of the extensive theoretical guidance, companies still employ an ad hoc approach to capturing user requirements.

- Market push is the main driver rather than customer pull; therefore user needs are not prioritised by companies as a central principle.
- Users are often found by serendipitous methods e.g. ‘trying out’ of initial design ideas on persons who are not the intended user population for the device such as employees.
- Companies often consult advisory panels of specialist clinicians rather than the front-line users of the devices.
- There is a lack of understanding of environmental and system influences on device effectiveness: evaluation is often limited to laboratory assessments
- User requirements are focused on clinical effectiveness and regulatory requirements.
- Companies often use small cohorts of ‘clinical champions’ and these are often used as proxies for patient views. This is recognised as a limitation.
- Companies are often unsure of how to identify ‘un-met’ or ‘ill-met’ clinical need.

Empirical Research

The literature reviews and industrial interviews have identified a number of issues that can prevent medical device companies from fully involving the users throughout the product lifecycle and these will inform the future MATCH research. In collaboration with our industrial partners a number of case studies are now being performed in relation to contrasting medical devices to examine the application and utility of different approaches to collecting and analysing data on user requirements. Specific devices will be compared along the dimensions identified by the industry interviews and literature review and a form of theoretical sampling will be used to select cases to maximise variation.

Discussion

Initiatives such as MATCH to provide support for product/device/system developers face a common problem, that tools for use in product development need to be contextualised, methods invariably need to be adapted for individual cases and specific user issues requires specific methods. However, in order to be useful for prospective development advice on methods and tools has to be generic. The balance between generalisability and applicability is often difficult to achieve and MATCH will be looking to work with industry to try to overcome this barrier.

The MATCH project described in this paper is focused specifically on the provision of advice to device developers on how to select and apply methods and to act on the results. Underlying the success of any kind of ‘industry guide’ is the impetus for developers to adopt the methods described. Medical device development is often technology-led, the ‘user’ may have no voice and, as in all industries, a cost-benefit has to be demonstrated. High profile medical error cases may prove enough to drive up standards related to user requirements. MATCH as a whole will be working on many strands of medical device development, including health economics and the development process, to try to ensure that any advice produced on methods to meet user requirements meets a receptive audience.

References

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