How does the Healthcare Industry involve Users in Medical Device Development? – Pointers for UbiHealth

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Abstract. This paper introduces the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) and outlines the problem of integrating a user-centred approach for development of medical devices together with the information and communication technology environments in which they are increasingly required to operate. We highlight some of the regulatory requirements that are relevant to user needs consideration in medical device development. Finally, we reveal a range of limitations in the current practice of the medical device industry in the area of user needs capture, based on responses from interviews with MATCH's industry partners.

1   Introduction

The Multidisciplinary Assessment of Technology Centre for Healthcare [1] is a new EPSRC funded Innovative Manufacturing Research Centre (IMRC) involving 5 Universities in the UK (Birmingham, Brunel, Nottingham, Kings College London, Ulster) that aims to support the healthcare sector by creating methods to assess the value of medical devices from concept through to mature product. For MATCH, value assessment has a broad meaning over and above of cost-benefit analysis to the company producing the device. Specifically it includes value to users, whether patients, clinicians or healthcare administrators, and reimbursement agencies such as the UK's National Health Service (NHS) or insurance companies.

As part of MATCH's remit, we have been interviewing our UK industry partners as to their engagement with users during their development of medical devices.

Examples of UbiComp relevant devices in our industry portfolio include:

- Smart implants with location tracking sensors.
- Networked vital signs monitors within hospital wards.
- Personal defibrillators employing telemetry.
- Diagnostic devices that may in the future interact electronically with healthcare information systems.

In addition to its industrial liaison activities, MATCH is currently conducting a structured review of the methods and tools employed by industry and those proposed by researchers to capture user requirements during all stages of product lifetime. The review concentrates on methods and instruments used in three distinct areas: engineering and ergonomics, healthcare, and social science. In particular, human factors as an applied industry-focused discipline has developed a number of user-focused design methods that encourage the participation of the end-user early in the design and development stage. Since these methods consider the inclusion of the 'universal user' as well as the elderly or disabled user they are particularly relevant for the development of medical devices.

2   Vision – An Integrated Approach to User Needs for Medical Devices and Healthcare ICT

Although most medical devices are not computing devices *per se*, a growing number of these are coming to rely on Information and Communication Technology (ICT) whether by means of logging and telemetry functions (e.g. portable or home healthcare devices) or through their deployment in networked hospital wards. In the UK, as the NHS moves over to electronic records, results from all manner of medical equipment (electronic or otherwise) will be required to be submitted to databases as part of the core information system - pharmaceuticals and medical devices are already being recoded as part of the NHS Dictionary of Medicines and Devices [2]. Knowledge-based applications will be responding to the information in these kinds of databases and there is a general expectation that varying degrees of context-awareness and interfaces to enhanced visualisation and collaboration capabilities will become prevalent in healthcare ICT [3]. Pervasive computing ideas should expect to contribute to a safe and efficient healthcare environment with excellent information processing, communication and memory that is suited to the individuals and teams that work in it and those that are served by it.

One key problem is the means by which a user-centred approach can be integrated into all levels of ICT-based healthcare systems. Whereas design of core information systems may already be subjected to user-centred principles, what of the medical devices themselves?

Medical device manufacturers operate within a tight regulatory environment (e.g. from EU Medical Devices Directives) that requires much user consideration during the product lifetime including both development and deployment phases, for example:

- Design controls: as part of Good Manufacturing Process, including design inputs from users, and validation of fitness-for-purpose.
- Observational studies: pre-trial assessment of an innovation/investigative device.
- Pre-market approval or notification: clinical trials as evidence of safety and effectiveness, and adherence to packaging & labelling requirements.
- Post-market surveillance: e.g. Adverse Incident reporting via the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, or Medical Device Reporting (MDR) via the Food and Drug Administration (FDA) in the USA.
- Procedures for maintenance, reuse and disposal of devices.

So in some respects, user involvement at specific stages of device development and deployment may be dictated by regulatory requirements (although it is worth noting that these are not yet globally harmonised). In addition, a large amount of guidance is offered, notably in the USA from the FDA's Human Factors Program [4] which recommends standards such as ANSI HE74-2001 and has produced guidance documents such as *Do It By Design*. In the UK, in addition to regulatory advice, useful guidance for medical device development is offered via the Cambridge Engineering Design Centre's *Design for Validation* approach [5]. More general guidance on usability that is suitable for assistive and medical devices is available via the *Inclusive Design* effort from the Royal Society for the encouragement of Arts, Manufactures and Commerce (RSA) and others involved with the EQUAL network [6,7,8], and from the Design Council's *Humanising Technology* programme [9].

However, whilst much guidance exists in theory, MATCH's interviews with the medical device industry are revealing a quite adhoc approach to user issues. So far, from a small number of pilot interviews, limitations that we have discovered include:

- Market push being the main driver rather than customer pull, so that the user needs are not prioritised as a central principle.
- Need for confidentiality resulting in early assessment iterations being conducted in-house e.g. on employees.
- Serendipitous methods by which users are found e.g. 'trying out' of initial design ideas on acquaintances who are not in the intended age group for the innovation.
- Use of advisory panels of clinicians (e.g. specialist physicians) that do not include the front-line users of the device (e.g. ward nurses) or hospital administrators.
- Difficulty in 'pinning down' of expert opinions, suggesting lack of skills in this area.
- Devices that worked in a hospital lab setting but are not ergonomic in the clinician's working space, or are not well suited to a busy environment.
- Manufacturers having to pre-empt user requirements in the context of changing work practices e.g. increased use of outreach teams (who would be involved in responding to alerts generated by monitoring devices, for example).
- Manufacturers clearly identifying the need for reducing time-to-market and lowering costs, but highlighting help with complex regulations and conducting clinical trials as priorities rather than improvement of approaches to user needs i.e. they are not explicitly asking for guidance in human factors.

We expect to build a clearer picture from further interviews and comparison with forthcoming literature survey results.

3 Conclusions and Expectations for the Workshop

Medical devices need to relate to healthcare ICT but human factors approaches are not currently well integrated. Although regulations require user issues to be addressed at various stages of development and deployment of devices, the impression from interviews with manufacturers is one of an adhoc approach and there appears to be some limitations to improvement of practice. Since it is likely that a growing number

of devices will be relating more directly to information systems in the future, it is essential that user needs research within UbiHealth addresses integration of the approach to both devices and systems, and that ways can be found for this research to have a bearing on real-world practice. Computer science, in particular the fields of human-computer interaction, computer supported cooperative work and more recently ubiquitous and pervasive computing, has already shown the way in the embracing of ethnomethodologies, scenario-based design, and usability engineering for capturing user requirements in the design of healthcare systems and interfaces. Many of these techniques are also applicable to device development.

As a multidisciplinary research effort, MATCH is keen to network with the pervasive computing community. We would be most interested to discuss aspects of human factors research related to the rapidly changing healthcare environments in the UK and internationally, with a focus on medical devices and how they should fit into development of pervasive systems.

Short Biographies

Dr. Michael Craven is a MATCH Senior Research Fellow at the University of Nottingham, engaged in healthcare research and industry liaison. He has experience in electronic engineering and computer science teaching and research, including design of assistive and surgical simulation devices and software, and collaborative virtual environments. He obtained a BSc in Physics (1987) from the University of Bristol, an MSc in Modern Electronics (1989) and a PhD in the area of neural networks (1994), both from the University of Nottingham. He is a member of the IEEE Engineering in Medicine and Biology and Product Safety societies.

Dr. Jennifer Martin is a MATCH Research Fellow at the University of Nottingham, engaged in healthcare research with a focus on user requirements. Her background is in human factors, including low-carriage equipment design for the Ministry of Defence. She also has experience in health-services research methods involving evidence-based systematic reviews. She obtained a BSc in Human Biology (1997) and PhD in the area of ergonomics (2001), both from Loughborough University.

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