THE ROLE OF USER REQUIREMENTS RESEARCH IN MEDICAL DEVICE DEVELOPMENT

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Abstract

Aims and Objectives: *This research aims to suggest a concise framework to help in the better conceptualisation and integration of users in the medical device development (MDD) process. The current economic, political and social climate concerning the matter of healthcare delivery has resulted in the emergence of numerous users and user groups for whom the healthcare system has not previously catered for. These users have created ambiguity for the designers and manufacturers of medical devices as the boundaries between their needs and requirements have blurred, outdating current methods of MDD to meet consumer needs.*

Research Design and Methodology: *The research methodology begins primarily with conducting a literature search on the theories relating to user requirements and medical device development. The paper outlines these findings through initially describing users and user involvement and relating them to medical devices. The cross-disciplinary nature of healthcare influenced the investigation into multiple disciplines including; IT, Ergonomics – particularly participatory research, Psychology and Design. These disciplines expose various methods and processes, which are useful to user requirements research. These methods were analysed for their compatibility, and then used to construct a conceptual framework for user involvement in MDD.*

Results: *The research insinuates the true significance of user involvement and hence resulted in the formation of a conceptual framework to aid user involvement in the MDD process. The framework is produced by the amalgamation of relevant methods examined across the disciplines, in a complimentary fashion.*

Conclusion: *The originality of this research lies in its use of a multidisciplinary approach. Previous research claiming multi-methods has dealt with combining two disciplines or methods at a time i.e. Computer supported cooperative work (CSCW) with participatory research (Scandurra et al, 2008) for the needs analysis of healthcare professionals only. Collaboration across disciplines has also been investigated (Johnson et al, 2005), but this was for the purpose of redesign rather than initial designs.*

This framework can help medical device designers to fully access all user requirements through more extensive collaboration right at the start. It reduces the risk of high costs involved in device rejection, usually associated with belated recognition of user needs in the design cycle.

Keywords: *User Requirements, User Involvement, Medical Device Development, Multidisciplinary Research*

1 INTRODUCTION

The healthcare system faces many pressures to change. Changes in population, medical interventions, and new technology opportunities as well as public and political expectations are all contributing factors to this pressure (McKee and Healy, 2002). With these changes, have emerged new users and user groups. Some of these new users play roles that are more distinctive and need more diverse skills than before. For example clinical and communication skills were formally related to the role of a healthcare professional but are becoming increasingly relevant to various healthcare users (Leinster, 2002) including nurses and carers in the home. The role of the healthcare professionals have also changed, their main concern is not only to recall facts, but also to evaluate, assimilate and use new information (Leinster, 2002). With healthcare moving away from its traditional boundaries, away from hospitals (Obradovich and Woods, 1996) and towards patient empowerment and collaboration, the target users for medical devices have changed. This is where the challenge lies. The changing target market has given rise to the need to understand these newly created user groups, as current methods of development of medical devices no longer meet all consumers' needs.

Traditionally, medical devices are often associated primarily with patient users, and although they often are the end users of medical devices, they are not the only users. It is also true that not all patients have the same requirements, although we can assume a subset of similar characteristic needs do exist for all patients. Chronically ill patients who have long term healthcare needs, have a multitude of users involved in their care, all of whom are concerned with the successful operation and use of medical devices for their patients. All these users need acknowledgment and to be taken into consideration when designing a medical device.

The recent analyses of information technologists, social engineers and sociologists has shown that there are several different approaches to studying the role of the users, at any given point in the medical device development (MDD) process. Collaboration of this innovative use of technology with the social sciences has created much disparity in understanding and fully identifying user requirements and the notion of user involvement. Each field clearly comes with its own propositions about how users should and do behave, thus there is both a lack of consensus of what the specific role of the user is, and even more on how and in what ways to fully involve and collaborate with the users deploying the valuable viewpoints from all these disciplines. This ineffective merge results repeatedly in the failure of medical devices as users reject them.

In order to address the user requirements, it is necessary to understand the users in respect to their backgrounds as well as multitude of needs. For the successful capture and integration of the user requirements, medical device development will need to merge with various social science ideas to encapsulate human behaviour and social aspects of the healthcare system - which have a direct impact on the approval of a medical device. Although, the social aspects of healthcare have been explored in other disciplines, they have rarely been the focus of the IT domain. This research considers how users can be involved in device development from a multidisciplinary perspective. Each discipline will be scrutinized on their stance on the role of the user, focusing on methods and theories that look to elicit user needs. These methods and processes will be merged to

compliment the overall process of capturing user requirements in MDD in the form of a theoretical framework, ensuring the success of the medical device.

This research will aim to consider collaboration before the design takes place, aiming to eliminate redesign costs. Johnson et al (2005) recognised the advantage of collaboration between administration, computer scientists, human factors engineering, cognitive scientists, and clinicians to ensure intuitive healthcare applications and proposed a framework for the redesign of healthcare information systems. Although Johnson et al proved redesign could be successful when collaborating across these fields; it was at a notably cost. There will inevitably be a trade off between the methods chosen, as it is evident that certain methods are preferred over others, in terms of feasibility and resource availability. However, the aim is not to use as many methods as possible, but to redefine methods that overlap with others, to understand and hence incorporate elements that are the contributing factors of the method, rather than the method itself. If the contributing elements are significant, this research will produce a concise framework, which will involve users to establish their requirements, during medical device development.

2 METHODOLOGY

The methodological approach on this research paper begins primarily with a literature search that explores the relevant concepts, theories, and research methods on users, user requirements, and medical device development. This includes searching through the disciplines of IT, Ergonomics, Psychology, and Design to appreciate their position on users and user involvement. From this, a conceptual framework of a theoretical solution is suggested which helps in better conceptualisation and integration of users in the medical device development process. The methods will be analysed and compared to assess their contribution to the process of MDD before the necessary elements of user requirements research are put together. This paper will focus on the suggesting a possible framework and justifying the theoretical validation of the framework. This paper forms part of ongoing research, and the framework will be tested and validated in the later stages of this research.

3 USERS

A ‘user' is generally defined as a person who uses something, however for a more specific definition of a user, one must define the type of user for example a computer user or an end user. Users have seldom been considered as a single entity, and have often been categorized into relevant ‘bands’ before their requirements have been addressed, either as technology users, or users of particular medical devices, or consumers of certain products. They have not been visualized as healthcare users in general, nor has there been an underlying truth established of how these users behave.

3.1 User Involvement

Within the parameters of healthcare, there has been movement in the area of user involvement. The NHS in the UK is committed towards user involvement as user involvement is becoming more compulsory (Crawford et al, 2002). The idea of user involvement is a widely accepted principle in the development of usable systems (Kujala, 2003), and is defined as the

'participation in the systems development process by potential users or their representatives and is measured as a set of behaviours or activities that such individuals perform' (Barki and Hartwick, 1989).

This definition is also true in information systems, however when viewed in a subjective psychological state; a user becomes involved when they consider a system to be of importance or significance, or else personally relevant (Barki and Hartwick, 1989). This involvement leads to a more consistent behaviour/attitude towards the system, amongst the highly involved individuals. Users become involved because they intend to use the system for its information outputs, and need their informational requirements to be met so they can perform their job tasks (Foster Jr. and Franz, 2000).

User involvement is perceived to be higher in the earlier stages of system development i.e. analysis and design rather than the later implementation stages (Foster Jr. and Franz, 2000). It is believed to come about in stages (Figure 1: Poulton, 1997), and in terms of healthcare can mean anything from simple information giving to empowerment (Poulton 1997, 1999)

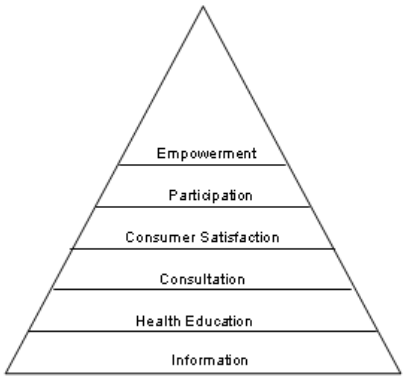

Figure 1. Levels of User Involvement in Primary Care (Poulton.B.C, 1997)

The benefits of user involvement include the improvement brought to the quality of the system, as it is built with more accurate user requirements. There is greater user acceptance, due to the increased understanding of the system (Foster Jr. and Franz, 2000). It brings improvement to users self esteem (Crawford et al, 2002) as well as to user health, reducing inequalities (Fisher *et al,* 1999). Doctors do believe that by integrating patient's views with their own, high standards of care and treatment is attainable (Williamson, 1998).

Fears that lack of user involvement in the design process, could lead to an illogical user interface from the user's point of view exist (Berg, 2001). The extent of user involvement being achieved in reality in the healthcare system was evaluated by Poulton (1999), using two studies. The conclusion showed user involvement to be

limited despite an enthusiasm towards it. Reservations that user involvement may raise patient expectations and hence primary care staffs work load, became a barrier in true user involvement in this case. McKenna and Keeney (2004) asserted that community nurses have not yet reached the lowest level of information giving yet never mind progression to higher level user involvement. Despite the effort towards user involvement, in practise it is still lacking. Irvine (2001) argues that lack of patient respect or recognition of their rights to make decisions about their care, is one of the underlying cultural flaws in the medical profession and the NHS.

Clearly there exists the need to involve users, however the degree of involvement does not determine user acceptance. This is as the degree of user involvement can be perceived differently by the user to that perceived by the analyst that sought the users involvement, hence having an effect on the expected level of acceptance.

3.2 Medical Devices and Their Users

This research is concerned with the user's role in medical device development. A Medical Device can range from simple items like a plaster to complex devices such as heart by-pass machines (Martin et al, 2008) with the end-user being 'a person who uses a medical device for the treatment and/or care of him/her-self or someone else' (Shah and Robinson, 2008). With users of these medical devices ranging from clinicians to the actual persons with disability, or carer's as well as many different types of professional staff (Shah and Robinson 2008, Daraghmi *et al*), it is apparent that the users are as varied as the devices themselves. In terms of device development such users can be employed at any stage of the System Development Lifecycle and may include; designers, manufacturers, doctors, carers, patients, and service users.

Medical devices need to be such that they can be placed in the environment they are meant for, without disturbing the natural balance and expectation of the patient or clinician, as the device is there to aid not hinder their work. Doctors work both in collaboration with their patients, for example during consultations as well as individually. This is where the role of user requirements research is of importance, trying to understand the depth and breadth of the work undertaken in healthcare by its users, before engaging in medical device development to get the mix right. The way healthcare users work, their interactions with others, work environment, time pressures and motivations of the users all affect the success of the medical device. It is necessary through user involvement to get a grasp of these and other pressing issues that affect the efforts of a healthcare user.

4 THE SIGNIFICANCE OF USERS ACROSS VARIOUS DISCIPLINES

The importance of understanding and analysing user requirements has been seen as one of the key factors for the success and failure of innovation (Hyysalo, 2003). Healthcare's increasing complexity makes it difficult to decipher a particular methodology for the healthcare system. Many aspects of healthcare are cross disciplinary and vaguely structured. The system is sensitive due to its patients and the variety of professions involved, which not only adds to the complexity but creates its own array of requirements. Incorporating user requirements

usually means collaborating across disciplines, within and across organisations (Hyysalo, 2003). Investigation into IS methodology alongside different methods of ergonomics, psychology as well as design principles will enable the formation of a framework that is as supportive as possible of all the users involved, no matter what their view. Only by building a system that meets the purpose intended by its users will it be successful (Nuseibah and Easterbrook, 2000). This section will explore methods present in computing and social sciences, which could aid in providing a structure to MDD and its users.

4.1 The IT Perspective

Information Technology is defined as the application of technology to carry out the capture, storage, retrieval, analysis and communication of information. IT has brought on the onset of the information age and the shift towards a knowledge economy (Dwivedi et al, 2002). Present day users are more confident in satisfying their own IT needs, as well as directly driving IT implementation (Kettinger and Lee, 2002) and the move away from a centralised Information System, means more users can get involved. Resistance to change existed, as the user felt removed from the process, with technical terms and jargon limiting their ability to understand the problem or indeed the resolutions (Kettinger and Lee, 2002). Now through better communication (Leonard, 2005) and emphasis on user involvement, users can reach the goal of user satisfaction with IT more successfully.

In terms of healthcare, IT has redefined the structure of healthcare organisation, bringing about new healthcare services, away from traditional management and technology concepts (Dwivedi *et al*, 2002). It has been suggested that Information Technology is the most significant tool that can improve the quality and productivity of healthcare (Whitten et al 2008, Bates 2002, Issenberg 1999) and using IT can open new ways to reach citizens and enhance citizen participation in the healthcare process (Lapao et al, 2007). Technology could make it possible to manage patients in the community as well as provide a step towards engaging patients in managing their own care (Clarke et al, 2004 and Jacobs and Lichteristein, 2003).

There are noticeably many areas in healthcare that would benefit from computerisation, for example; computerised decision support, electronic health records (EHR) systems and computerisation of error prone processes, as well as simulation for skills training in medical education (Issenberg, 1999). Clinical practitioners may be required to make life saving decisions, while attempting to deal with large amounts of clinical data and hence face the challenge of acquiring proficiency in interpreting clinical information so as to attain knowledge and wisdom (Dwivedi et al, 2002). However, investment in technology by the healthcare industry has been remarkably insignificant, producing relatively primitive systems compared to other information intensive industry such as banking and aviation (Bates, 2002). The reason for this absence of technology adoption is primarily the lack of financial incentive (Bates, 2002 and Issenberg, 1999), although complexity of systems, legal issues concerning some collaboration, scales of particular healthcare environments as well issues of privacy and confidentiality do also cause concern (Issenberg, 1999). Further to this, there is the ongoing debate of a

potential dehumanising effect, when using technology for the teaching or practising of medicine (Issenberg et al, 1999).

Despite the argument presented for the much needed adoption of technology in healthcare, and the evident barriers that restrict this development, much has changed in view to the users that could potentially facilitate and even compel technology to be incorporated in the healthcare system. The most valuable thing we can take from information technology is its numerable methodologies, methods, tools and techniques it has made accessible. These methodologies enable the careful planning, management and organisation of routes and pathways to reach a predetermined goal or indeed to enable definition of the goal. The Discipline of Information Systems clearly groups and defines the methodologies and subsets of methods that are divided into business oriented, people oriented, behavioural, ethically sufficient, structured and unstructured. Some are more suitable then others in relation to healthcare.

4.1.1 Soft Systems Methodology

Taking a look at the organisational methodologies in Information Systems, it has a Soft Systems Methodology (SSM) to offer. SSM originates from Action Research carried out by Checkland in the 1990's, and works on the idea that the 'whole' is greater than the sum of the parts (Avison and Fitzgerald, 2003). It deals with 'Soft' problems that cannot be defined in one world view, and has been described as a learning methodology which supports debate on desirable and feasible changes (Iivari, Hirschheim and Klein, 2009).

SSM will be beneficial in identifying the system boundaries and system activities for the complex healthcare system, to establish exactly where the problems lie as it can be applied to a wide variety of areas (Rose, 2006). Its application potential in healthcare has been recognised, with some of its initial ideas applied in the NHS (Checkland, 2000). It provides a very systematic process of inquiry, using the system as an epistemological device to extract knowledge (Rose, 2006 and Holwell, 2000) paying special attention to subjective details. This reflects the interpretive strengths of this methodology. Its position as a learning methodology will allow progression through reflection, throughout the process of medical device development.

However it lacks methods that could deal with the social and more sensitive elements of healthcare (Lane and Oliva, 1998). Further techniques to involve the users still need to be incorporated, as the emphasis of this research thus far has been on the complexity of the changing healthcare system, due to the increase in breadth of the *user* community. In the past SSM has not incorporated other methodologies, being viewed as isolationist (Mingers, 2000) but where SSM lacks in structure, it makes up in the ability to apply relevant methods to a specific problem. Methodologies arising from different paradigms make different assumptions of the problem situation, and therefore can be merged in a complementary fashion to comprehend the depth of the real world (Mingers and Brocklesby, 1997). Given that the healthcare system cannot be judged on one viewpoint alone, SSM could be ideally positioned in assessing the healthcare system, providing a foundation from which opportunity to incorporate multiple views can manifest. This means that the crucial user involvement aspect can

develop within the framework, extending the SSM model to do so. For this we need to seek methods in the social science disciplines, which have a better understanding of human behaviours.

4.2 The Ergonomic Perspective

Ergonomics is a relatively young discipline and is of an applied nature. Its purpose is to enable work systems to function better through better interaction between users and machines (Bridger, 2003). It looks to design with the user in mind, with the set purpose to promote safety, health, well being and efficiency in work conditions, adding arguably to the quality of the product (Erklund, 1997). All these aspects are undeniably essential when dealing with users and the delivery of healthcare. Ergonomic design was introduced initially looking at consequence of poor design – human errors, discomfort, health impairments (Erklund, 1997), and inefficiency (Bridger, 2003). It developed to involve itself in the process of design, and then branched into participative ergonomics (Wilson, 1997).

4.2.1 UCD

User Centred Design (UCD) is a broad term describing design processes in which end users influence how a design takes shape (Abras *et* al, 2004), used for the creation of usable and useful products (Kujala, 2003). It covers a number of methods within it which aim to iteratively involve users at every stage of the product lifecycle (Abras *et al* 2004, Venturi and Troost 2004,) for a clear understanding of the user, task requirements, iterative design and evaluation (Vredenburg *et al,* 2002). Focus on this user involvement is typically during the requirements gathering or usability testing phases (Abras *et al,* 2004). Due to the scope of this research, only the user's role in the requirements gathering phase will be investigated, hence incorporating ergonomic methods relevant to this aim. The aim of UCD is also to save on development time and cost by reducing the need to rework technologies to meet user needs. Fixing a problem in the development phase costs ten times more than if it were to be fixed in the design phase (Johnson, 2005).

4.2.2 Advantages of UCD

User Centred Design enables developers to focus on the users at the heart of the design process (Newell and Gregor, 2000); with the methods ensuring users *are* involved (Abras et al, 2004). Without considering user centred design (UCD) guidelines, adhoc systems were being created, that were quickly rejected or abandoned by users who were dissatisfied (Johnson, 2005). UCD helped designers to understand their users better (Gao *et al*, 2007) and instigated a deeper understanding of psychological, organisational, social and ergonomics factors, which emerge when users are involved at every stage of the design and evaluation of the product (Abras *et al*, 2004). UCD allowed for more needs discovery through multiple iterations in its methods (Gao *et al*, 2007). By embedding user involvement techniques from the start a much better understanding of user needs leads to less cost in later modifications (Shah and Robinson 2006, Johnson 2005) and assures that the product will be suitable

for its intended purpose (Abras *et al*, 2004). Studies of UCD in industry have proved an increase in usability and usefulness of products by 82% and 79% respectively (Vredenburg *et al*, 2002).

4.2.3 Disadvantages of UCD

UCD does have its drawbacks, one major disadvantages being the resource requirement, both financial and human (Abras *et al*, 2004). The need for additional design team members e.g. ethnographers (Costa et al, 2004) who are experts either at these techniques or working with users, can add to the cost. The time allocated for a detailed and thorough investigation using these methods may be greater than expected, as working with users does have an element of unpredictability. The popularity of the techniques of UCD stand at a cost benefit trade-off, and some of the stronger techniques suffer due to their complexity. Management question its value and worth particularly as UCD techniques are often used for short term goals (Gulliksen, 2003), leaving little potential for lifecycle perspective. At the same time, although failing to apply it, organisations do realise the need to increase usability of their products (Nebe *et al,* 2006). Although these disadvantages exist, many are due to the lack of evidence to involve users, when making decisions about services (Crawford *et al*, 2002). If organisations were to recognise UCD's potential value, they would consider investing in the short term, for long term benefits. Lastly, user centred design techniques cannot be used in isolation to capture all user requirements (Martin et al, 2006) and need to be incorporated after a brief is already developed, hence could work well in parts where SSM lacks structure and methods.

4.2.4 Method Selection

It is important to consider which methods are suitable, and most beneficial for any particular point in the medical device development lifecycle. The selection of ergonomic methods does depend upon the purpose of analysis (Stanton *et al*, 2005). The initial stages of requirements gathering, looks to discover work practices in their natural environments and to understand the existing systems. Stages which define a solution would be complemented with different methods, and final stages where changes have been made and need to be assessed for the value and worth they have brought to the users, require use of different methods.

Ergonomics methods have been categorised according to their intention, *behavioural and cognitive methods* being most relevant to medical device development and the field of healthcare. These methods aggregate data sourced from cognitive factors such as; user perceptions, cognitive processes, responses of individuals (Stanton *et al*, 2005), memory, learning and problem solving (Daraghmi *et al*), as users interact with the system. Human factors in medical device design include user's characteristics i.e. physical and cognitive conditions, which are necessary to avoid user related errors. Methods that fall under this category include observation and interviews - the most frequently reported methods (Stanton and Young, 1998) as well as focus groups and user and task analysis.

These methods can also be adapted for application in a macro ergonomic context. Macro ergonomics deals with the overall design of a work system, integrating organisational design and management into its research and practice. This would be a necessary requirement of this research as it is set in a large and complex healthcare system. Other Macro ergonomic methods include field studies, cognitive walk through and participatory ergonomics. The emphasis on participation is such in ergonomics, that it can be found in virtually all ergonomic methods to some degree, with endless application potential in design and analysis (Stanton *et al*, 2005).

4.2.5 User Centred Design and Participatory Research

Participatory Design has often been understood as an approach of UCD (Carrol, 1996), developed as a method to support UCD (Abras *et al*, 2004). It has been argued that UCD methods place users in a reactive role, and can be non participatory (Carrol, 1996). Contended that it is the participatory design approaches which seek to involve users more deeply (Jansson 2008, Crawford *et al* 2002, Kensing and Blomberg 1998) in the design process. Users are involved as core designers, by being empowered to propose, generate and design alternatives themselves. UCD makes user involvement operationalistic, through some of its empirical approaches such as observation, where the users are seen as subjects or cases and not as full participants (Carrol, 1996). This is why the need to discuss participatory research arises, as it appears that Participatory Design and UCD interact in a complimentary fashion (Carrol, 1996), not to be overlooked when assessing the role of the user in MDD, as only by its inclusion, the research will be able to decipher the importance of users as participants versus users as subjects.

Participatory research

Participatory research has been described as the most effective way of conducting context sensitive and user centred quality research. Its distinct features being collaboration, mutual education and results informed action. Early involvement of users has been determined as advantageous by many ergonomists, seen as invaluable to work with users as equals (Kujala 2003), giving participants' empowerment as well as ownership and inclusion that they would otherwise not have had. Designers and users are brought together to envision the context of use, and in turn this leads to more acceptable and accessible service, improving health and quality of life of patients (Crawford et al, 2002). There are two main types of participatory approaches that can be taken. Firstly there is Participatory Action Research (PAR), which stems from Action Research (AR) – looking to involve people in the process of change. The second is Participatory Design (PD) which constitutes democracy and user involvement as key elements.

Participatory Action Research

PAR aims to improve health and reduce health inequities through involving people who subsequently take action to improve their own health (Baum *et al,* 2006). Researchers are seen as facilitators of change here, with power given to the community of interest. It ensures continuation of knowledge building and feedback and gives participants the freedom to make choices.

The many advantages of PAR are that it has helped to develop innovative and engaging ways for staff and community members to work together, overcoming professional dominance to improve strategies and show commitment to democratic principles (Baum *et al,* 2006), with positive and practical outcomes (Whyte 1989). It's collaborative in nature, involving communities and identifying problems important to them and has been increasingly used in health research in the 21st century. Participatory research is acclaimed as beneficial beyond any complications that arise along the journey of its use.

However, PAR is time consuming and can have unpredictable outcomes (Baum *et al*, 2006), with the impracticality of a possible lack of consensus of what the problem is. To carry out such research it will be important to work effectively with people involved, who will have different and competing agendas (Baum *et al*, 2006). In the words of Wadsworth however, 'it is not possible to do any social research without the participation of other human beings' (1998). This said there is still another difficulty - there needs to remain a balance of power between collaborators of the projects. The solution comes in the form of Participatory Design (PD), which developed from PAR and helps to maintain this balance.

Participatory Design (PD)

PD aims to create a shared understanding of the area in focus, and helps to explore conditions for user participation within the design (Kensing and Blomberg, 1998). PD looks to create a design environment where researchers and design professionals are able to learn about user work, considering technologies as well as the organisations, while facilitating users (Abras *et al,* 2004) in taking an active part in the design process.

PD emphasises the importance of mock ups, scenarios, pilot studies and prototypes –collectively known as personas (Grudin and Pruitt, 2002), allowing users to experience the future before making judgement (Kensing and Blomberg 1998, Hyysalo 2003), and allowing them to understand the designers language (Abras *et al*, 2004). Ideally there is a need for users to experience long term exposure to the new technology or process, as this ought to develop empathy, commitment and build a greater understanding in the user (Grudin and Pruitt, 2002). It can also address quality of life and socio-political issues, including values, fears and aspirations (Kensing and Blomberg 1998). Personas should however, be used to enrich existing design processes and enhance user focus, not replace other user centred methods (Grudin and Pruitt, 2002).

In practice participatory design has been met with obstacles. Management across many organisations are concerned with end user involvement contributing to organisational stability. They often turn to participatory design approaches as a quick fix solution to an immediate problem, but fail to implement this as a long term strategy, meaning much of the change is short lived and unsuccessful (Howcroft and Wilson, 2003). There are assumptions that users are involved at the degree they wish, when often this is not the case, leaving the user dissatisfied. User needs are seen as incompatible with each other and even with involvement, resistance still occurs (Howcroft and Wilson, 2003). These obstacles may be evident in the literature, however can be taken forward in a positive light, by ensuring the preconceptions of management do not occur, as well as setting the

standard of participation, to ensure user dissatisfaction with involvement does not impede future application of participatory design.

Participatory Research and the Role of the User in MDD

Participatory Research is particularly relevant to this research because it promotes a socio-technical approach, working towards interaction of 'social' with the 'technical' and cooperation between managers and workers (Kensing and Blomberg, 1998). It considers the system as a whole, ensuring the entire work and technology system is considered, without allowing premature definition of the system. Through participatory design, users can actively contribute to the design, and be understood better. The role of user's and their requirements within healthcare will be more competently addressed and investigated through participation (Hyysalo, 2003). Looking into how and when to involve the users, and which techniques are best for effective collaboration.

The SSM methodology alongside some ergonomic design methods, should theoretically be able to define the problem situation from the viewpoint of all those involved. Good human factors engineering should reduce patient error (Walsch and Beatty, 2002). Furthermore some of the methods specifically looking at usability problems including cognitive walkthrough and task analysis, which eliminate inefficiencies and steps that slow down or confuse the user (Hertzum and Jacobson, 2003). These could prove useful on a number of different stages of development.

However, there is still room to attempt to understand the user and their behaviours. Why users have certain attitudes and why they are inclined to behave in certain ways. Users can be placed where the designers feel fit, but this may not be where the users feel valued or want to be involved. Knowledge of the medical device users needs is important, as they are the primary stakeholders of the technology (Shah and Robinson, 2006). The discipline of psychology can help to bridge the gap between identifying a user and actually really knowing and understanding that user, and what effects their behaviour and choices

4.3 The Psychology Perspective

Analysing the emotional response of the user to products has become increasingly important to improve customer acceptance in the market (Khong and Song, 2003). Health Psychology aims to bring understanding to human behaviours, attitudes, motivations and intentions, as well as the idea of perceived control to impact the way individuals respond to a given system or device.

Health Psychologist, Howard Leventhal, has attempted to define a model that should aid the self regulation of healthcare by patients (Leventhal et al, 1983). The Complete Dual Process Model of Self Regulation, which combines the Health Belief Model and Fear Drive Models.

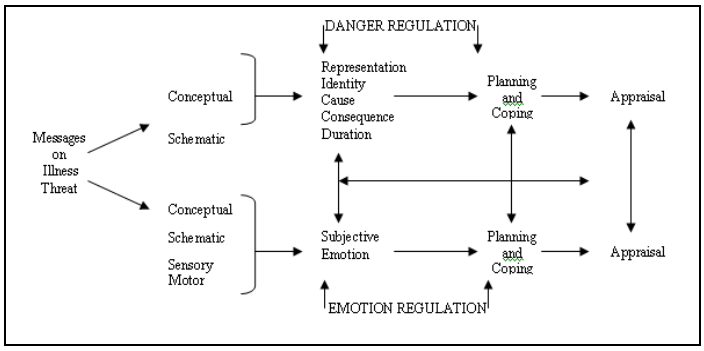

Figure 1. The Complete Dual Process Model of Self Regulation

This model shows that under threat of illness the human mind generates two types of messages. One of which is objective and visualises the threat, processing a system to deal with the threat, the other also generates sensory information, which is translated into fear. The cognitive thought process sums up and analyses previous symptoms, advice from doctors to draw a plan to cope with the threat and hence self regulate their health. Due to both aspects occurring in parallel the fear factor drives the motivation to reach the desired state of good health, with the help of the cognitive thought processes.

Many of psychology theories portray that behaviour occurs in line with expectancy of a certain result. Expectancy Theory defines product satisfaction as the consumers' pleasurable level of consumption-related fulfilment response (Au et al, 2008). This is true for Leventhal's Health Belief Model where an individual changes their behaviour if they want to reduce or eliminate a perceived threat to reach a better perceived outcome, and is premised as an expectancy-value theory (Prentice-Dunn and Rogers, 1986). This idea has lent itself to Leventhal's Model of Self Regulation. The Theory of Reasoned Action (Ajzen and Fishbein, 1980) shows that expectancy of a particular outcome alters ones intention and hence their behaviour, again also correct for the Theory of Planned Behaviour (Ajzen, 1988). Further to these there is Social Cognitive Theory, described as one of the most powerful theories of human behaviour (Venkatesh et al, 2003) which is determined by expectancies and incentives (Rosenstock et al, 1988). The incentive to change ones behaviour could be if their current behaviour poses a threat to their health or well being and needs to be changed in order to reduce the threat.

The input needed by the end user - be it intellectual or physical, needs to be in balance with the benefits the product brings, as this will effect patient motivation in using it. The effort involved by the user cannot exceed the benefit that the information system brings. If too much effort is required, then adherence to the regular and correct use of the system or device may suffer. This idea known as equity theory is sensitive to individual preference, as not everyone perceives an outcome to be equally beneficial (Huseman et al, 1987). In healthcare we can make the assumption that each patient is striving for better health, yet the benefits of the information system and or medical device as perceived by the doctors, clinicians and community nurses may all vary considerably. Equity theory relates to the input/outcome balance, and once again illustrates the fact that the system will need to appeal to various users and their motivations, to stimulate correct and regular use.

In summary, the importance of education and knowledge dissemination, to promote remedial action by patients, has been recognised. The complete model of self regulation shows how important patient knowledge is to aid self regulation, enabling patients' to balance out the fear factor, with a confident attitude and allowing patients to handle the situation unaided or through contacting the right sources at the right time. Leventhal has suggested that for someone to adhere to medical instructions there is a level of motivation involved as well as an emotion related element. It can be further concluded that designing for a healthcare user, specifically the patient, means taking account of their knowledge, fears, judgements, and control aspects. User satisfaction should be now imminent.

4.4 The Design Perspective

Design theorist Patrick Jordan, claims that pleasurable products are used more regularly and that future product choice is affected by pleasure of use (Jordan *et al*, 1996). This research suggests that the pleasure of using a product is not dependant on the task and even a displeasing task can be done by using a tool that is a pleasure to use. The speed in which any impressions are formed about the product, channels any emotions felt during and after product usage. Aesthetics such as visually attractiveness could be the first thing to make an impression, and are just as important as the usability, accessibility and reliability of the product as well as the system of care that is generated by use of that product. Other attributes listed include; performance, features, size, cost, convenience and gimmick. All these attributes need to be checked and tested throughout the process with the users involved to ensure the right messages are coming across from the product and the system of care. Anything ominous to use will be off putting for carers as well as patients, and may upset the required frequency of use. The reliability and performance of the device will pave the future choice of medical practitioners, as will the usability and functionality make the decision for the carer. Khong and Song (2003) tested and proved the hypothesis of Computer Technology Capability having a direct impact on three user belief variables; relative advantage, ease of use and enjoyment to be true. Hence further backing up the need for the reliability and performance of the medical device.

In relation to healthcare, user behaviour can be influenced to accept medical devices by making them more pleasurable to use. Gloyd (2003) makes claims that positive user experience increases patient adherence to medical regimes. Explaining that it is at the design stage that fundamental changes can be made to aid the success of therapy and this is not under the guidance of doctors. Taking a look at designers in that case, it is apparent that they are the first to initiate and conceptualise a design for a medical device. It is in their hands to initially realise the requirements of the user for their end product. Recognition by them in the early stages that users differ across the systems development lifecycle and taking into consideration everyone's needs is essential. If the requirements are defined in the initial stages, it is more likely for the requirements to be met and the users to be happier with the end result. Doerr et al (2008) supports the need to consider usability and user acceptance issues early on in the systems development life cycle phase.

Design theories further conclude the need to assess all types of requirements, as they correspond to the emotional response of the user as ascertained by psychologists. Design methods are in place for the successful capture of these emotional states, before being translated into design features of the product. End user satisfaction is claimed to be critical in the successful implementation of an information system (Au et al, 2008). Integrating these user needs into the design could enable them to be translated into attributes and design characteristics to promote a pleasurable user experience, leading to medical adherence (Gloyd, 2003).

5 THE MERGE

It is evident that regardless of which academic discipline is consulted, there has been extensive investigation on the subject matter of users. It is also evident that there exists an overlap on user requirements research that could be beneficial to explore for healthcare users and users of medical devices. Methodologies arising from different paradigms make different assumptions of the problem situation, and therefore can be merged in a complementary fashion to comprehend the depth of the real world (Mingers and Brocklesby, 1997). This could be a real advantage in assessing the healthcare system as it cannot be judged on one viewpoint alone. Especially given that these users will not only be trying to grasp the concept of a new technology; but may also have personal or critical health issues, that need to be addressed with sensitivity. With such a mix of requirements, it is only logically to address each aspect as thoroughly as possible.

5.1 Similarities

Across the disciplines of IT, Ergonomics, Psychology and Design, there is a notable move towards user involvement. Within IT, more users can get involved due to decentralisation of IT Systems, and Ergonomics has methods in place for user involvement, with an emphasis on how this involvement should be from the very start of product development. All have a preference towards early definition of user requirements, and can see the advantages of this. These disciplines have interpretive strengths in their methods, as well as the scope to learn through iteration. At the same time they realise that these methods may not be utilised at their best in isolation, pointed out as a weakness of SSM as well as an issue when using User Centred Design Principles of Ergonomics. Ease of use of the product is another concern met by all. IT programs aim for efficient systems, reducing complications. Ergonomics methods, keep the user in mind, aiming to make products more usable, with psychology and design principles also supporting the need to increase ease of use, to appeal to users motivations and emotions.

We can use these similarities, to come up with user wants, specifically those of medical device users. However there are differences between these disciplines that must be considered, to understand the extent to which this overlap is possible.

5.2 Differences

There are differences in the way these disciplines address user requirements research. IT methodology has the scope to understand and establish boundaries between users and the system; however IT methods can be insensitive to social/political issues. Ergonomics has different methods available for different stages of product development lifecycle, with a view to iteratively involve users. However these do stand at a cost-benefit trade off. The discipline of Psychology focuses on user requirements through support of education and knowledge. Psychology promotes that user effort relates to the users' expectations and requires motivation, possibly through incentives. The Design discipline has a key difference in view of user requirements, which accrues to pleasure. The emotional response of the user dictates the success of the product.

The differences raised here, are from evidence presented in the literature searched. Although these differences stand, they do not disadvantage the process of collaborating between the disciplines. This is because some of these differences can be eliminated when the disciplines are combined, by complimenting one another. For example the fact that the SSM methodology of IT is different in that it is isolationist, can be complimented through the ergonomics methods, which need a brief and a base, from which to work. IT being insensitive can be complemented through the emotional response ideas present in both psychology and design. In this way the differences between the subjects can be seen as strength, when creating the bigger picture of role of user requirements research in medical device development.

5.3 Advantages

The advantage of establishing the similarities and differences between these disciplines mounts to the overwhelming need to collaborate between these disciplines. As the literature has described these disciplines and their methodologies concerning users, it has become evident that no one method or methodology would be able to fully recognise healthcare user's requirements unaided. This strengthens the need for collaboration between these disciplines for healthcare, proving the necessity for this research. Collaboration to amalgamate corresponding ideas across the disciplines in order to fully understand the role of user requirements research from a single standpoint is needed. The differences bring with them individual strengths that have been integrated within their own specialities for far too long. Lending these expertises to be used with one another will surely strengthen the way user requirements research is perceived.

5.4 The Framework

A possible framework structure is shown in figure 2. This structure takes on board a number of elements from each discipline and is fused to form a single framework.

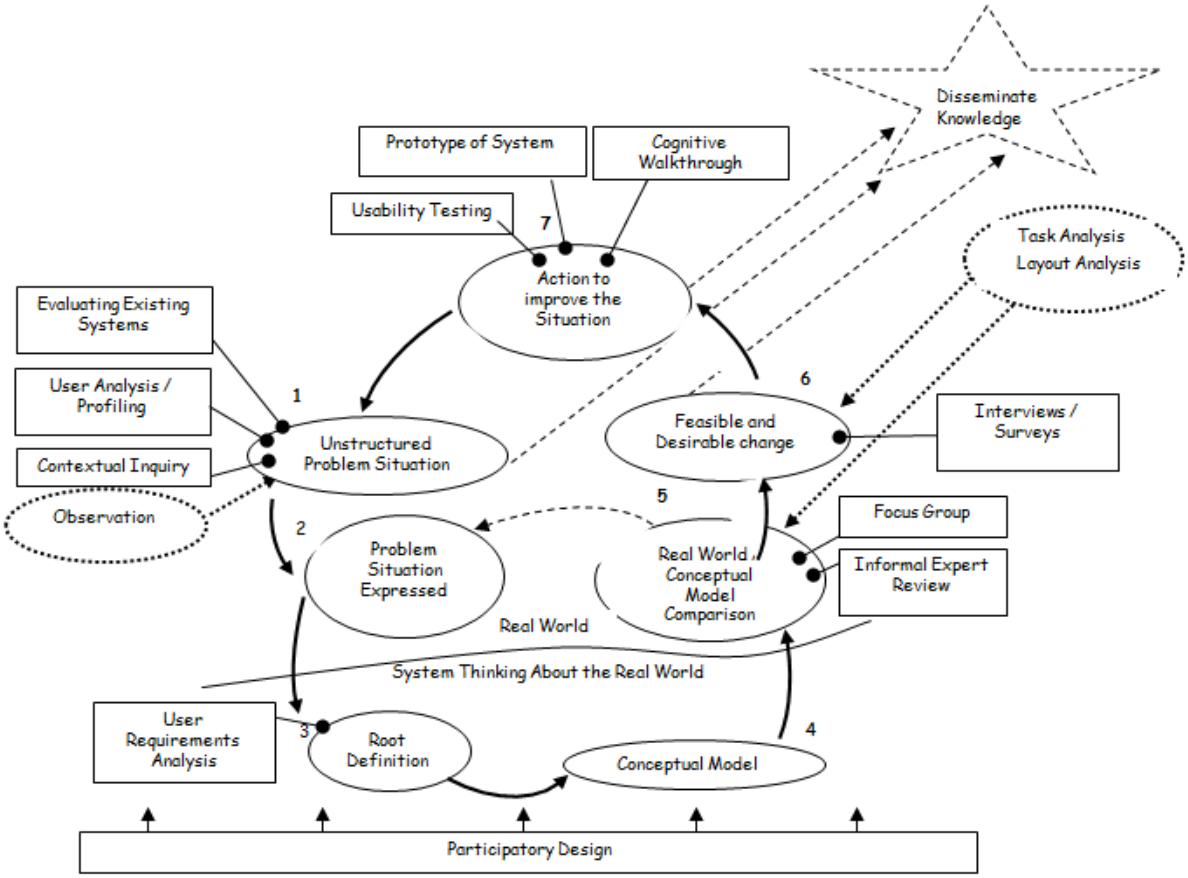

Figure 2. A User Involvement Framework in Medical Device Development

The framework is based on the soft systems methodology (SSM) from the IT discipline, which deals with system understanding of soft problems, indefinable in one world view, and establishes the system boundaries before any structured methods are imposed. It uses the system as an epistemological device to extract knowledge (Holwell 2000, Roswell 1996), and is made up of several iterative steps. Its seven stages are such that they allow the problem to be analysed and expressed using a rich picture method, and enable definition of the problem by working out the relevant systems, taking a diverse perspective on the problem situation (Lane and Oliva, 1998). It goes on to conceptualise a possible solution, and then compare with the initial problem to analyse the feasibility and desirability of the changes. Action is recommended based on these judgements to improve the problem situation.

This process is complemented through use of ergonomic methods, which aim to enhance interactions between people and machines (Bridger, 2003). Behavioural and cognitive methods are used, which aggregate data sourced from cognitive factors such as user perception, cognitive process and responses of individuals (Stanton *et al*, 2005), as users interact with the system. These user centred design (UCD) methods comprising of; observation, interviews, user and task analysis, focus on users at the heart of the design process (Newell and

Gregor, 2000), instigating a deeper understanding of psychological, organisational, social and ergonomic factors (Abras *et al*, 2004) so that designers understand users better (Goa, 2007). They can be applied to a macro ergonomic context too, dealing with the overall design of the work system. Further macro ergonomic methods include field study and experiment and participatory research (PR). PR and UCD interact in a complementary fashion, with participation found in virtually all ergonomic methods (Stanton *et al*, 2005).

These methods overlap into design theory, and are used when considering; usability and user acceptance (Doerr *et al*, 2008), pleasure of use (Jordan *et al,* 1996) and medical adherence (Gloyd, 2003). Design methods are in place for the successful capture of the emotional response of the user, before translating into design and include task and layout analysis as well as observation.

Participatory research also has its routes in psychology as do the cognitive methods of ergonomics. The discipline of psychology contributes to this framework, through supporting knowledge and education as well as user's expectations and motivations in the form of a 'feedback of knowledge' mechanism.

The significance of this model is that it works with an inner process (SSM) as described above, alongside an outer process that draws on methods of ergonomics, design and psychology that complement and aid maximum user participation (figure 3).

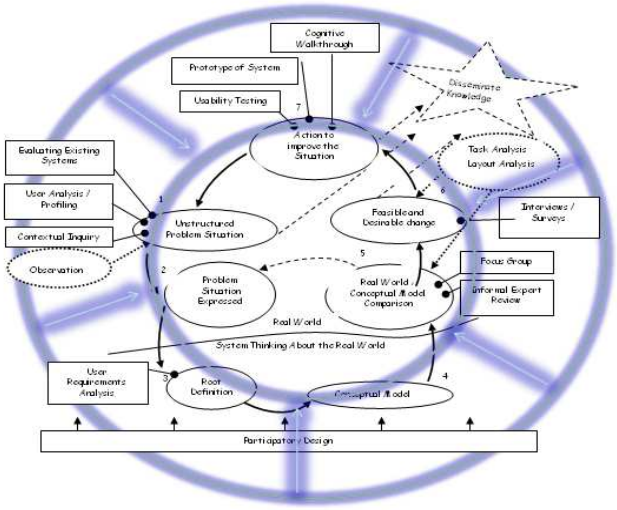

Figure 3. Inner and Outer Process of User Involvement MDD

This outer circle can be used to assess the extent to which users are conceptualised within the process of medical device development, as well as to monitor how thoroughly users have been engaged. This process can be further split into multiple dimensions (figure 4) depending on the types of users that are applied to the process, giving a more detailed outline of user involvement at any time in the MDD process.

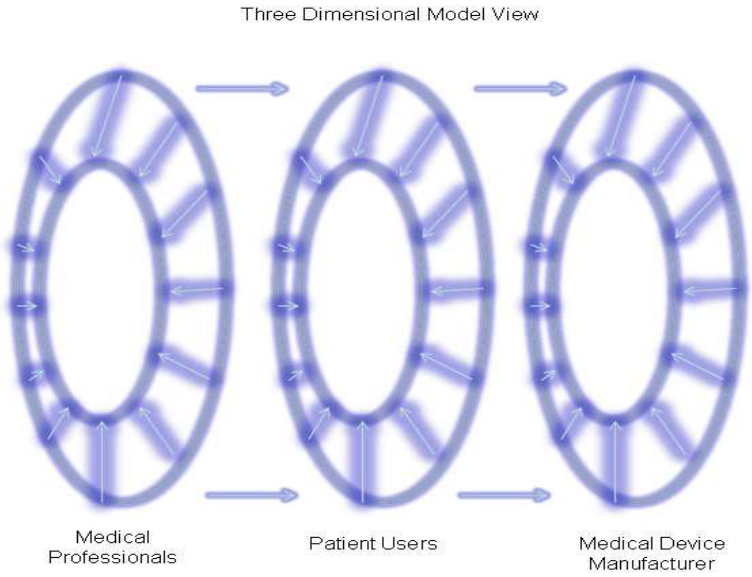

Figure 4. Three Dimensional View of User Involvement

In this way, the framework also eliminates bias between user groups, as the steps and methods are such that they can apply to all users. For example when conducting interviews, both patients and doctors can be interviewed for their response to how they feel the conceptual model fits their requirements. Both user groups can make recommendations, which can be incorporated to influence any changes made in the stages that follow. Similarly, the other user centred design methods, like focus groups, contextual inquiry, and cognitive walkthrough can be used on any user groups, increasing the number and quality of recommendations to make the device usable by all.

6 CONCLUSION

In conclusion, the research has uncovered many elements to the role of user requirements research in relation to medical device development. The research has enabled the recognition of the similarities and differences that exist between disciplines on user needs, and most importantly facilitated an approach whereby these differences can compliment one another for a coherent understanding of user needs.

The research stemmed from the literature search, followed by analysis of the findings to ensure the most fitting methods were used for the construction of the framework. The arguments uncovered on some of the approaches for example SSM having the ability to establish boundaries in a complex system, the need for ergonomics methods to have a base, and the emphasis on participatory research, significantly affected the way the framework took shape. Ideas on human behaviour and cognitive processes established the inclusion of communication and feedback between users at various parts of the process. Translating these ideas into the design of medical devices ensured that user requirements are caught from all angles, and encompassed within the health information system. There is a need for patients to recognise the improvements and the potential these medical

devices bring to the healthcare industry for it to truly progress. The importance of user involvement lies in its potential to increase users' perceived control, leading to user satisfaction of the new system (Baronas, 1988). Fully understanding vital behavioural elements such as these from the beginning can produce much greater success in product acceptance. The underlying requirements of the users can not be undermined, and therefore careful ethical consideration of user involvement is needed.

The resultant framework is theoretically sound. The importance of this work is primarily due to the discovery that multidisciplinary links do exist, and combining them brings a fresh approach to capturing user requirements. Collaboration in the past has been limited to specific numbers and types of methods or scenarios, however here we have a model that can be generalised within the healthcare domain for medical device development. This collaboration will enable the true essence of the problem to be understood better, alongside the people involved.

This paper details ongoing user requirements research. Similarities between medical device users and users in general have helped link work across different disciplines that could aid users in healthcare. Healthcare being a complex environment means that user focus has at times suffered and superficially addressed. The need for a more comprehensive examination of all the users involved in the use and delivery of healthcare is needed to determine how meeting these users requirements has an impact on the success and acceptance of a medical device. In the future, the outcome of this research may change the way designers and manufacturers of devices gather requirements and the way they involve users in development. It may also change the way individuals envision control over their own health.

7 PAPER LIMITATIONS

This is ongoing research, and hence there is currently no data available to validate the practical applicability of the framework proposed.

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