

USER INVOLVEMENT IN MEDICAL DEVICE DEVELOPMENT: AN EMPIRICAL STUDY

A thesis submitted for the degree of Doctor of Philosophy

By

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DEDICATION

This thesis is dedicated with all my love to;

My parents: Zia Hussain Shah & Nagina Kausar Shah,

My husband Arfan Shah,

&

My beautiful son Zain.

Their support and encouragement made this achievement possible.

Anila Shah

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DECLARATION

The following publications have been produced as a direct or indirect result of this the research discussed in this thesis.

Journal Article

Clarke, M., **Shah, A.** and Sharma, U. (2010), 'Systematic Review of Studies on Telemonitoring of Patients with Congestive Heart Failure: A Meta-Analysis', *Journal of Telemedicine and Telecare*, 17(1), pp. 7-14

Conference Paper

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ABSTRACT

Changes in population, medical interventions and new technology opportunities, as well as public and political expectations, are all contributing factors to the pressure facing the healthcare system to change. Healthcare in the UK is beginning to move away from its traditional boundaries, for example hospitals and towards patient empowerment and collaboration. Consequently the target users for medical devices have also changed, with new users and user groups emerging. Further to this user involvement is emphatically becoming a part of healthcare delivery in the UK, recognised for bringing improvement in the quality, acceptance and in turn success of a medical device. The changing target market has given rise to the need to understand the newly created user groups and finding new ways to elicit their requirements has become vital for the success of medical devices.

This research intends to draw upon and capture the importance of user requirements research, by investigating the early stages of Medical Device Development (MDD) giving particular attention to the conceptualisation of the user within this process. The research shall assess the possible links between user requirement elements, to benefit the healthcare system and investigate how user requirements methodologies that have been proven in other fields can be successfully deployed in the medical device development lifecycle. User requirements methodologies identified within the disciplines of information technology, ergonomics, psychology and design theories relating to medical device design, will be collectively assessed for their capacity to collaborate.

The research methodology began with undertaking a systematic review of the literature, which facilitated the construction of a single theoretical conceptual framework of user involvement in medical device development, representative of a superior model of user requirements capture. To validate this framework empirical research followed. This was divided into exploratory, explanatory and interpretive data collection phases, with a view to extract; *what* the current process of MDD is in industry, *why* and *how* users are currently deployed in MDD, and the users perceived experience of involvement.

The exploratory study showed that manufacturers were aware of their users and extracting the user requirements effectively was seen as the main competitive differentiator. However, manufacturers were not always aware of the best methods to capture user needs, especially with business objectives and obligatory requirements repeatedly taking precedence over optional user involvement methods. The explanatory study showed that not every department has an equal role to play in terms of user involvement in terms of methods to elicit requirements. However there was consensus across the departments to acknowledge their customers and their feedback to ensure they feel valued. Further to this communicating information to potential new devices users was carried out well in advance of the product coming to market. The customer focus was something not only addressed in the design of the device, but the service that followed. The interpretive study emphasised the importance of understanding the user's needs and to understand that these needs do change over time. Educating users on disease and self-management was considered important, but realisation by patient user of their responsibility was vital in the successful use of a medical device.

The original contributions of this study include its endeavour in taking a multidisciplinary approach to account for users and user involvement methods, and apply to specifically the early stages of the medical device development process. The research developed naturally to transcend and collaborate between these theories, as well as represent various voices within the research to really emphasise the multidisciplinary and multi-user approach it took. This research made a further innovative contribution by developing a framework to the problem of inadequate user involvement in the medical device development process. This could prove very beneficial for medical device manufacturers considering user involvement may become a regulatory requirement, meaning all medical device manufacturers would need to incorporate and document user involvement by law.

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1 CHAPTER ONE: *Introduction and Overview*

1.1 Introduction

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 Medical Device Development (MDD) to meet consumer needs. This research addresses the issues relating to the acceptance of medical devices by today's healthcare users and reflects on user requirements methodologies to extract user needs more accurately. This research intends to suggest a concise framework to help in the better conceptualisation and integration of users in the medical device development process, in an attempt to ensure new devices meet the user's requirements more thoroughly to aid their success.

The healthcare system is made up of multiple interactions of various users. The research methodology relates to this research, attempting to attend to the issues surrounding the complexity of capturing the requirements of such a diversity of users and their variety of needs. These social interactions need to be accounted for, through interpretation of their subjective meanings, ensuring at the same time that the uniqueness of humans is recognised. The research methodology takes on an interpretive perspective, accounting for subjectivity, descriptions, interpretations, beliefs and emotions through this research. Qualitative methods are used to ensure capture of these characteristic ideas of interpretivism through the empirical investigation. The purpose is to discover and analyse the function of user requirements methodologies in the process of medical device development.

The research shall assess the possible links between user requirement elements in order to benefit the healthcare system and to see how user requirements methodologies that have been proven in other fields can be successfully deployed in the medical device development lifecycle. This can be done by identifying user requirements methodologies within the disciplines of; information technology, ergonomics, health psychology and design, to distinguish how they can be merged effectively. Areas where the methodologies are similar and overlap can be brought together more concisely, and dissimilar areas can be analysed and

incorporated in a complimentary fashion where possible to form a single framework, representing a superior model of user requirements capture.

This chapter starts by looking at the research background and problem situation, followed by stating the main aim and objectives of this research. A brief overview is then given of the proposed methodological course of the research.

1.2 Research Background and Motivation

Changes in population, medical interventions, and new technology opportunities as well as public and political expectations are all contributing factors to the pressure on the healthcare system to change (McKee and Healy, 2002). Healthcare is moving away from its traditional boundaries, away from hospitals (Obradovich and Woods, 1996) and towards patient empowerment and collaboration, meaning that the target users for medical devices have also changed. With these changes, new users and user groups have emerged. 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). 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.

The rapidly increasing proportion of older people in modern society has its unavoidable implications on healthcare (Bhachu, Hine and Arnott, 2008), effectively increasing the load on the healthcare system. The government's '*Partnership for older People Project*' has deployed £60 million, in a move to keep older people in their homes and out of hospitals and residential homes. Phil Hope (www.dh.gov.uk, 2008a) indicated that within 20 years there would be double the number of over 85's and a quarter of the population would be over 65 years old. This will also imply a rise in the number of chronically ill patients, placing demands on the current healthcare system that it simply cannot meet. 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. Consequently, although medical devices have primarily been associated with

patient users, and although they often are the end users of medical devices, they are not the only users. All these users need to be firstly identified and then acknowledged and taken into consideration when designing a medical device.

The recent analysis 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 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's 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 the development of devices 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 reduce redesign costs. Johnson, Johnson and Zhang (2005) recognised the advantage of collaboration between administration, computer scientists, human factors engineering, cognitive scientists, and clinicians to ensure intuitive healthcare software applications and proposed a framework for the redesign of healthcare information systems. Although they proved redesign could be successful when collaborating across these fields; it was at a notably cost. There will inevitably be the need to compromise 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.

The direct beneficiaries of this research will be the manufacturers and designers of these medical devices, as by providing consumer specific design requirements, it is less likely the device will fail. The indirect beneficiaries of this research are the clinicians and patients, as it is their input and involvement which will be recognised and become part of the process of development. The importance of this work is primarily due to the multidisciplinary links bringing a fresh approach to capturing user requirements. Users are involved and considered from a multidisciplinary perspective which will not only enable all users to be distinguished and appreciated for their requirements, but will also enable the component parts of the healthcare system to be better understood. The importance of user involvement lies in its potential to increase user's 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. In addition it could lead to social acceptance to the governments focus on medical devices, ensuring their considerable effort in involving users is not futile. In the future the outcome of this research may change the way clinicians are assigned patients, and may also change the way individuals envision the control over their own health.

1.3 Aim and Objectives

1.3.1 Aim

The main aim is to establish a role for medical device users through proposing and validating a concise framework which encapsulates and integrates the user more distinctively throughout the medical device development process and at the same time discover and analyse the importance of user requirements methodologies within this process.

1.3.2 Objectives

1. To capture the significance of users through the synthesis of existing methodologies in information technology and social science subject areas, by conducting a literature search.
2. To examine the current process of medical device development in industry through empirical research, to explore and define the role of the manufacturer of medical devices
3. To examine the end users perspective, on current level and perceived benefits of involvement, to explore and define the role of end users in using / developing medical devices.
4. To produce an innovative process of user-involved-medical-device-development.

1.4 Research Methodology

The philosophical stance of this research is constructed as follows; first and foremost an epistemological position is taken as this research leans more towards the social sciences and social interactions of the user with the system, believing that there is not one objective truth that needs to be discovered, but that it can be constructed through social interactions. Subsequently, the research stance that follows is constructivism, whereby truth and knowledge is said to be constructed by individuals through their interaction with the world (Gray, 2009), in this case with the process of medical device development and the experience of using medical devices. Following this, the theoretical position of interpretivism is taken, with the belief that the social world exists in a world of social interaction, and needs to be interpreted in order for it to be partially understood, recognising both the distinctiveness of humans, and grasping the subjective meaning of social interactions (Bryman, 2008). The phenomenological approach is the most fitting following interpretivism as subjectivity, descriptions, interpretations, beliefs and emotions are all accounted for (Denscombe, 2008). Qualitative research methods will hence be used, as they would better meet the aims of the underlying philosophical position of this research.

The research methodology begins primarily with conducting a literature search on the theories relating to user requirements and medical device development. The cross-disciplinary nature of healthcare influenced the investigation into multiple disciplines

including; IT, Ergonomics and Participatory Ergonomics, Health 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 amalgamated in a complimentary fashion to construct a conceptual framework for user involvement in MDD. This is followed by the conducting of empirical research, which is split into three phases, and is used to both validate the framework as well as further discover aspects of practical user involvement from the view of various users. The first phase is the exploratory phase, which looks to investigate and discover the process of medical device development from its practical standpoint by exploring current practice and knowledge in the field. The next two phases provide supplementary information, the explanatory phase includes an in-depth case study in industry and the interpretive phase conducts an in-depth case study on telecare devices. This is followed by analysis and a refined design of the user involvement framework for medical device development, which ultimately recommends the role users and user requirements methodologies have in the medical device development process.

1.5 Thesis Outline

The thesis will be broken down into seven Chapters.

Chapter One: Introduction and Overview

This chapter introduces and provides background to the issues this research addresses as well as stating the aims and objectives this research will address. This is followed by a description of the research methodology, as well as a thesis outline.

Chapter Two: A Review of the Literature

This chapter combines all relevant user related ideas and principles found in the literature. It begins with a discussion on users and user involvement, before discussing user related methodologies within the disciplines of information technology, ergonomics, psychology and design, and how these principles can be used to further enhance design of medical device technologies.

Chapter Three: Conceptual Model

This chapter presents the theoretical conceptual framework, which was produced from the amalgamation of the theories and ideas which arose from the literature search. This chapter

will focus on taking each segment of the framework, and work to refine the model and clarify what is involved in each step, for the users in question.

Chapter Four: Research Methodology

This chapter presents the approach of the research; initially describing the research philosophy, followed by the chosen research methodology and subsequently producing the research framework for this study. The data gathering instruments used in conjunction with the methods applied at each of these phases are described. This chapter also addresses issues relating to the credibility of this research.

Chapter Five: Data Collection

This chapter explains how the research was conducted, against the planned research phases described in the previous chapter. Execution of the exploratory, explanatory and interpretive phases is described. Specifics of how the chain of evidence was constructed for each of the case studies are presented here, together with final details on the sample sizes, instrumentation, interview administration and analysis.

Chapter Six: Empirical Data Analysis

This chapter analyses all of the empirical work conducted, and is broken up by research phase; exploratory, explanatory and interpretive. The themes of analysis are first outlined, followed by coding schemas, followed by the themed analysis. This chapter concludes the findings and constructs a final user involvement framework for medical device development in light of the evidence collected.

Chapter Seven: Conclusion

This chapter looks to conclude this research, by summarising the progress made while achieving the aims and objectives of the research. The different threads of the argument are drawn together followed by a discussion on the extent to which the research aims and objectives were met. This is followed by expressing the contribution this research has made to knowledge, practical recommendations, its limitations as well as any further research possibilities.

2 CHAPTER TWO: *A Review of the Literature*

2.1 Introduction

This chapter combines all relevant user related ideas and principles found in the literature. It begins with a discussion on users and user involvement, before discussing user related methodologies within the disciplines of information technology, ergonomics, psychology and design, and how these principles can be used to further enhance design of medical device technologies. These ideas will be discussed and analysed to form a framework which expresses the role of user requirements research within healthcare.

The literature search aims to fully identify the multidisciplinary aspects of this research by firstly addressing each area of focus individually, before reconciling into a single context. Information technology, psychology, ergonomics and design ideals will be scrutinized on their stance on the role of users and user involvement in device development, focusing on theories, methods and methodologies that look to elicit user needs. These will be further merged to reflect the relevance of user requirements research in the healthcare system and more specifically medical device development.

The chapter is concerned with illustrating the strengths individual disciplines can bring to user requirements gathering, and how through combining strengths across disciplines, any weaknesses can be minimised if not eliminated. This can be done through providing an insight into all the methods, tools and techniques these disciplines have to offer which relate to user needs, followed by the collaboration of the relevant user related techniques into one theoretically sound user model. It is necessary to primarily understand the concept of what a ‘user’ is, and the meaning of user involvement before examining the differing schools of thought on the subject.

2.1.1 Users

A ‘User’ is generally defined as a person or thing that uses (Collins, 2007), 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. This may be as it has long been recognised that in order to build a good system, certain characteristics of people need to be accounted for, so that the system can take advantage of

those characteristics, rather than work against them (Rich, 1983). Coming closer to the present day, not only do system developers look to extract people characteristics, but try and engage in End User Development (EUD), where the end user is empowered to adapt systems themselves (Lieberman *et al.*, 2006). This is especially in relation to the emerging information society (Lieberman *et al.*, 2006).

This section of the review addresses users by looking at the current view of the user in IT and healthcare, the concept of user involvement, followed by a more specific focus on medical device users.

In terms of Information Technology (IT) users, everyone is a potential user of IT, and manufacturers of IT products are belatedly recognising that all users are not experts. Concern to make technology easy to use and compatible with the user's skills exist, since key components of IT are not leading to the desired level of satisfaction amongst users (Khong and Song, 2003). It has been recognized that even the best designed information systems are not used, if they are not aligned with users' motivations and commitments (Malhotra and Galletta, 2004).

The healthcare user has been seen to be taking a more consumerist approach when seeking healthcare (Lupton, 1997), and the definition of this user does not only include 'patients and their carer's, but can include members of the general public, community and voluntary organisations and healthcare professionals' (Wright *et al.*, 2007). The conservative government argue that healthcare should take on a free market model, through which increased competition will ensure optimal quality, consumer choice and price (Lupton, 1997). Policy makers and healthcare professionals recognise the importance of the patient or client as consumer, of the patient coming first (Gilleard and Higgs, 1998) and of patient's rights (Lupton, 1997). Healthcare users are being seen as individuals who want to be involved and empowered, in order to get improvements in the practices of care (Gilleard and Higgs, 1998).

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 (Simpson and House, 2002) as user involvement is becoming more compulsory (Crawford *et al.*, 2002). It is believed that patient involvement leads to more acceptable and accessible services, and research by Crawford *et al* (2002) showed the effects of user involvement; increases the self-esteem of contributing patients. There was a noted improvement in quality of healthcare

delivery and people's health according to 75% and 46% patients questioned respectively. Despite evidence of patient satisfaction supporting the need to involve users, there is limited evidence on the impact this has on services (Fudge, Wolfe and McKevitt, 2008).

There is notably a move towards exploring the parameters of user involvement to some degree by both the healthcare system and information technologists, given existing shortcomings in relation to users in these areas. User involvement done correctly could provide a clearer understanding of the user needs and requirements to make more effective systems. In order to understand user requirements it is necessary to understand the user in this research as it is evident that a healthcare user falls within the categories of technology user, end user, consumer and potentially much more.

2.1.2 User Involvement

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, p.53)

This definition is certainly 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 Hatwick, 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, 1999).

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, 1999). It is believed to come about in stages (Figure 2.1: Poulton, 1997), and in terms of healthcare can mean anything from simple information giving to empowerment (Poulton 1997 & 1999). Participatory design is an evolving technique, which has been used with great variations, from merely making use of access to workers skills and experience, to actually acknowledging their interests in the design outcomes, and supporting them (Kensing and

Blomberg, 1998). An evaluation of literature by Kujala (2003) found generally a positive attitude towards user participation looking at the following user involvement approaches; user centred design, contextual design, participatory design, ethnography and task analysis. User centred design and participatory design are similar in that they call for direct contact with the users early on in the development process (Gibson and O'Donnell, 2008), with the best results when researchers and the community collaborate as equals (Macaulay *et al.*, 1999). This will be further discussed within section of ergonomic design.

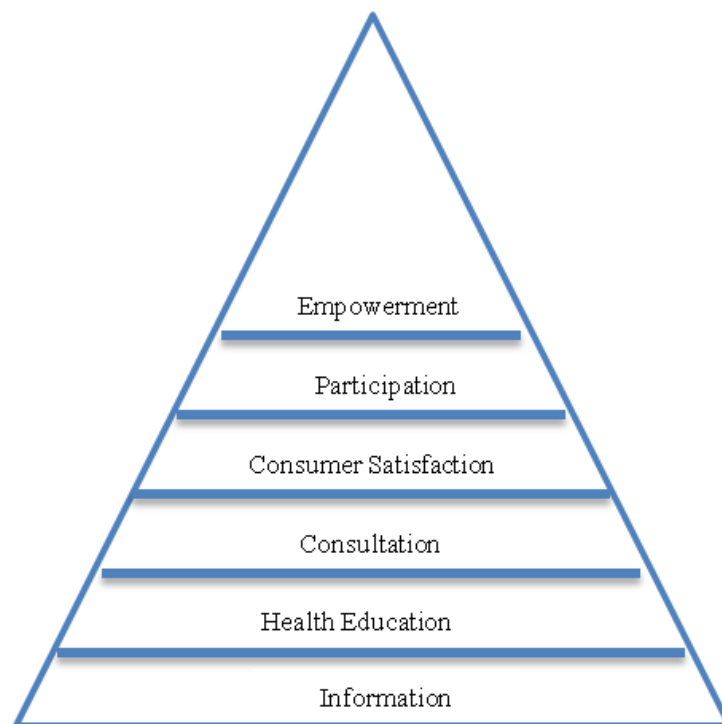


Figure 2.1: Level of User Involvement in Primary Care (Poulton, 1997)

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, 1999), as well as increased user participation in organisational decision making. It brings improvement to users self-esteem (Crawford *et al.*, 2002), as well as to users' health, reducing inequalities (Fisher, Neve and Heritage, 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 pursued the users involvement, hence having an effect on the expected level of acceptance.

2.2 Medical Devices and Medical Device Users

This research is specific to the user's role in *medical device* development. A 'Medical Device' means

'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, or for compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means'

(European Council Directive 2007/47/EC, p. 23-24)

Hence, the complexity of a medical device can vary greatly (Maisel, 2004), from implantable life sustaining devices to minimally invasive surgical techniques (Lee *et al.*, 2006) to less sophisticated devices, such as bedpans and gloves. 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 (Daraghmi, Cullen and Goh, 2008), make it apparent that the users and users' needs are as varied as the devices themselves.

Safety, reliability and comfort are becoming increasingly critical in medical device design. With the increasing functional complexity, ignorance over design requirements in the design stages leads to the majority of failures of medical devices (Chen *et al.*, 2005). Therefore although there are virtually an endless number of applications in IT for healthcare management services and as medical devices, levels of satisfaction may still be low. Any generalisation of the user requirements of the medical device embracing such a wide range of users can lead to user dissatisfaction amongst any number of the users involved, which may lead to the devices' clinical failure. Additionally the user's knowledge, experience and cultural background may play a significant role in the effective use of a medical device (Chen *et al.*, 2005), so must be taken into consideration during the process.

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, and individually e.g. documentary tasks (Luff *et al.*, 1992). Consultation is a social task, and use of devices which distract the doctor from what the patient is saying, detracts from this social interaction and brings about obstacles in the actual activity and value of consultation (Luff *et al.*, 1992).

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.

One way of differentiating the main users of medical devices is by using two major categories which are widely employed in healthcare; primary and secondary care. Primary care describes community based health services, which are often the first point of contact, and sometimes the only point of contact for a patient with healthcare services. The Department of Health states that a primary care service is predominantly provided by the

following professions; general practitioners, community and practice nurses, community therapists, pharmacists, optometrists, dentists and midwives. Primary care also allows greater continuity of care, especially with regards to long term illnesses. NHS Primary Care Trusts, the major mechanisms through which primary care is provided, aim to improve healthcare via preventative and other interventions. Secondary care is a more specialist service provided on referral from primary care thus a medical specialist does not have the first contact with the patient. The patient is referred via a primary care service provider, who will be seeking further specialist consultation, for example on a particular healthcare issue.

In the context of this division of services, the end-user is ‘a person who uses a medical device for the treatment and/or care of him/her-self or someone else’ (Shah and Robinson, 2008). In terms of device development such users can be employed at any stage of the System Development Lifecycle and may include; medical professionals, carers and patients. These users will be described in the section below. There are of course other users including; designers, manufacturers, installation, maintenance and service providers. These users will not be explored in the literature, as they quite often are the ones addressing the end users’ needs and are considered the target audience of this research.

2.2.1 Types of Medical Device Users

2.2.1.1 Medical Professionals

Doctors, physicians and specialists all need to use medical devices in the care of patients, often to aid their judgement in patient diagnosis and treatment options. As the doctors’ requirements are quite often complex, there is little or no room for error on the part of the technology. For example a heart monitor reader needs to enable the doctor to view the information so that patterns, correlation and discrepancies can be determined. Hence the software programme as well as the hardware is important, the options to skew and filter the information for it to be useful data are important, as are the setting options to take readings. Human Computer Interaction aspect will also be important to enable efficient operation of the device. In comparison the user requirements of a patient for the same device will be quite different; as how the readings and visual display are presented will not be of immediate concern. Using the example of a heart monitor, what will be more apparent is how comfortable the patient is, when attached to the different plugs and nodes. Does it restrict their movement or daily activities and is it heavy or obtrusive to carry around?

2.2.1.2 Carers and Community Nurses

The next major group of users that are widely on the increase are carers in the community, community nurses and carers in residential homes. The increase is mainly due to the shift towards primary care; taking pressure away from hospitals in an attempt to enable patients to take responsibility in managing their own care, and thus experiencing a better quality of life for longer. The elderly in particular are recipients of this shift in nursing care to the home environment (McGarry, 2008). McKenna and Keeney (2004), in their study showed a need for community nurses to work more closely with members of the public. There are views that the NHS will not change, and if it does it is nursing that will change it (Lilley, 2008). The importance of nursing is apparent, however there is also the role of family members and other carers not under instruction by the hospital that partake in home caring, they too classify as users of the system. A community support structure in this way is seen as protective of people's health (Fisher, Neve and Heritage, 1999). Usability for them may be just as important as or more important than for the patient, depending on the extent the patient can self-manage their health.

2.2.1.3 Patients

Patients as users are quite often the end users, described as medical end users in some cases (Ferguson, 2002), due to their ability to direct and control a great deal of their medical care. The patient user has differing needs and issues related to medical devices in comparison to other users. For example the usability of the equipment from the patient's perspective varies significantly to that of the doctor's. How comfortable a heart monitoring device is or the comfort and ease with which patients can monitor their vital signs, is of greater importance to the patient than the doctor. Sometimes the patient, as an end user does not use the device directly. In the instance of a pacemaker, once installed the main requirement is for the device to be unnoticeable. So it is evident that user's requirements also vary in accordance to their needs and health situations.

Defining the users was indicative of this research, as it is apparent that there are a vast number of users involved in the use of medical devices, and each would have at least some potentially differing needs. The main users with differing needs are the patients and the healthcare professionals who are experiencing the shift in healthcare delivery and hence will be used to measure the importance of user involvement in the requirements gathering phase of development, to benefit designers' vision of the device.

Having established who the users actually are, the next step is to define their roles in the delivery of healthcare or use of a particular medical device. The role of the user is in some cases dependant on which context they are being perceived in and by whom. The roles can be broken up looking at users from the perspective of different disciplines; including Information Technology, Ergonomics, Psychology and Design to see how these ideas can be reflected in the design in accordance with their individual theories. The perceptions of each discipline when collaborated should give a much broader base from which user requirements can be gathered and assessed, giving a better understanding of the user. Alongside increasing our ideas about the user requirements it is important for the user to be involved in any healthcare program that aims to benefit them, as user needs emerge and are only defined gradually, meaning they are articulated to and by the users themselves (Hyysalo, 2003).

2.3 User Requirements Methodologies

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). There is hence a need to build a framework which captures the needs of all the users involved, and can deal with the scope, breadth and perspective of multiple users with different and sometimes conflicting views needs and levels of involvement in the system. Only by building a system that meets the purpose intended by its users will it be successful, and identifying stakeholders and their needs to enable analysis is the first step (Nuseibah and Easterbrook, 2000).

Healthcare is becoming more complex (Plsek and Greenhalgh, 2001) making 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 Information Systems (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.

2.4 The Information Systems Perspective

2.4.1 Introducing Information Technology

Information Technology is defined as application of technology to carry out the capture, storage, retrieval, analysis and communication of information (Dwivedi *et al.*, 2002). IT is technology used to support human processes (March and Smith, 1995) and includes areas of processes and information systems. IT practice includes the development - largely a design activity, as well as operation and maintenance of IT systems (March and Smith, 1995). Information Communication Technology (ICT) is a term which extends upon information technology and includes communication and telecommunication. It has brought on the onset of the information age and the shift towards a knowledge economy (Dwivedi *et al.*, 2002).

March and Smith (1995) argued that for IT research to progress, IT systems need to be seen within their context of use, i.e. their environment. Information system combines information technology and people using the technology to support operations, management and decision making. In an organisation, an information system provides processes and information useful to its members, helping it toward a more effective operation. It looks at the interaction between people, data and technology.

The terms information technology and information communication technology will be used interchangeably in the discussion with respect to healthcare that follows. This will be followed by information systems methodology that could be used to address the complexities of the healthcare system within its social context.

2.4.2 Information Technology and Healthcare

Information Communication Technology (ICT) has within the last 10 years redefined the structure of healthcare organisation, bringing about new healthcare services, away from traditional management and technology concepts (Dwivedi *et al.*, 2002). Using IT can open new ways to reach users and enhance user participation in the healthcare process (Lapao, Santos and Silva, 2007), suggested as the most significant tool, that can improve the quality and productivity of healthcare (Whitten *et al.*, 2008; Issenberg *et al.*, 1999; Bates 2002). In terms of data between clinicians and researchers it allows reliable and speedy delivery of information (Traher, 2000) and the necessity of this is more apparent in situations of mass casualty incidents (Gao *et al.*, 2007) and with the move towards Remote Patient Monitoring. 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, Jones and Larkworthy, 2004; Jacobs and Lichterstein, 2003). New technologies in medical education, for example simulators for skills training, address issues in current medical practise where instruction time and patient availability are limited. Trainees gain greater experience than using real patients, producing clinicians with better diagnostic skills, potentially reducing the numerous and sometimes intrusive diagnostic tests (Issenberg *et al.*, 1999).

There are noticeably many areas in healthcare that would benefit from computerisation, for example; computerised decision support, electronic medical records and computerisation of error prone processes (Issenberg *et al.*, 1999). 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; Issenberg *et al.*, 1999). Complexity of systems, legal issues concerning some collaboration, scales of particular healthcare environments as well issues of privacy and confidentiality do also cause concern and resistance to technology adoption (Issenberg *et al.*, 1999). Further to this, there is the on-going 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. Present day users, are more confident in satisfying their own IT needs as well as directly driving IT implementation (Kettinger and Lee, 2002). 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. 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).

The most valuable thing we can take from information systems 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 (Avison and Fitzgerald, 2003). 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 than others in relation to healthcare.

2.4.3 Information Systems Methodologies




This section will attempt to summarise the available IS methodologies, in order to justify the use of the chosen one in this research. There are many advantages to each methodology; however the limitations which make the methodologies inaccessible for this research, will be highlighted in order to make clear their exclusion.

The discipline of Information Systems (IS) categorises the methodologies as follows; process-oriented, blended, object-oriented, rapid development, people oriented and organizational-oriented methodology. The process-oriented and blended methodologies are very structured in their approach. Approaches include; Structured Analysis, Design and Implementation of Information Systems (STRADIS) and Structured Systems Analysis and Design Method (SSADM), and are geared towards very well structured problems which have clear objectives, but are unclear of user requirements (Avison and Taylor, 1997), hence have the ability to extract such requirements. The reason for not using these methodologies is because in healthcare systems the problem is not clearly defined in many cases, and this needs to be addressed through the methodology chosen. This is also true for the rapid development approaches. Object oriented methodology - Object Oriented Analysis (OOA), focuses on analysis and is geared towards programming languages. People oriented methods like Effective Technical and Human Implementation of Computer Based Systems (ETHICS) relies heavily on users to design their own systems (Avison and Fitzgerald, 2003), with the multitude of users in healthcare it may become impractical to bring all the different views together. The organisational oriented methodology approach looks to assess a problem situation where the problem is unstructured and has either unclear or conflicting objectives. The most well-known is Checkland's Soft Systems Methodology (Checkland and Scholes, 1990), which will be made use of in this research for the reasons described below.

2.4.3.1 Soft Systems Methodology

Taking a look at the organisational side of healthcare, Information Systems offers a Soft Systems Methodology (Figure 2.2). Its basis comes from Action Research carried out by Checkland in the 1990's (Checkland and Scholes, 1990). The systems ideas were carried out in client organisations, i.e. in a human activity system not a laboratory setting, with the analysts as participants. SSM 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 from a single viewpoint, and has been described as a learning methodology which supports debate on desirable and feasible changes (Iivari, Hirschheim and Klein, 1998). This is an ideal methodology to be applied in this research; firstly as healthcare is a 'soft' problem, and secondly in respect of analysing the user's roles, as it is evident the user is involved expressly at the initial stages of product development (Foster Jr. and Franz, 1999) and not implementation, which is the key area addressed by SSM. SSM also recognises that the perspective of the individual will affect their view of the problem situation (Avison and Taylor, 1997).

2.4.3.2 The Seven Stages of SSM

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). The rich picture is made up of a number of symbols including; crossed swords  representing conflict, an eye  representing an external interested party, an arrow  representing directional relationship and a thinking bubble outlining a major concern (Checkland and Scholes, 1990). The rich picture uses the terminology of the environment, the people involved, controlling bodies, and sources of conflict between departments or users (Avison and Fitzgerald, 2003). Building a picture on all areas of the systems helps to understand the system and identify problem areas.

It goes on to conceptualise a possible solution, and then compare with the initial problem to analyse the feasibility and desirability of the changes. For example a problem identified could be a conflict between two departments and the solution could be developing a system which redefines departmental boundaries (Avison and Fitzgerald, 2003). Action is recommended based on these judgements to improve the problem situation. Table 2.1 provides explanations of what each step entails. It is noteworthy that this methodology does

not prescribe implementation solutions, and is more concerned with understanding of the problem.

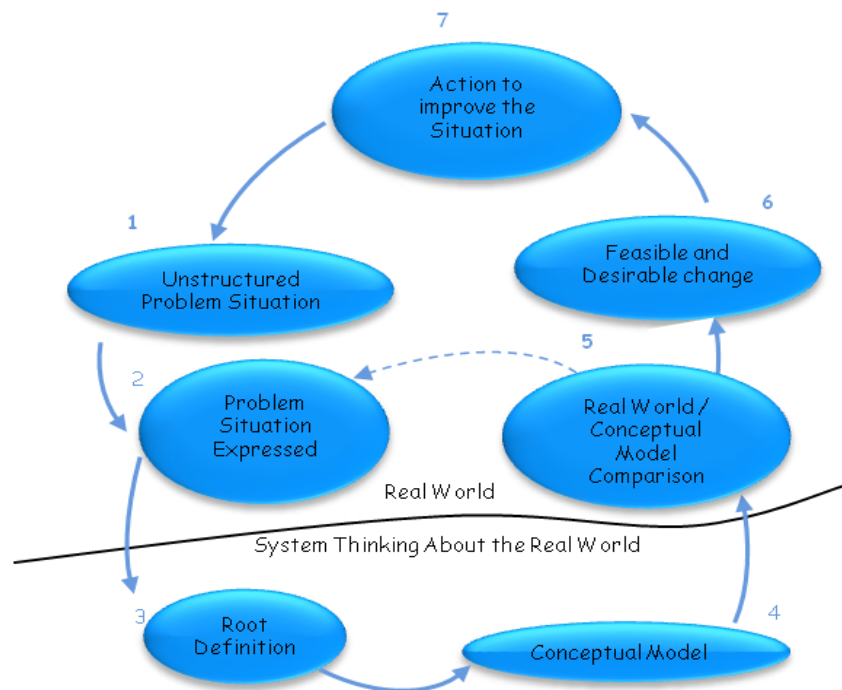


Figure 2.2: The Seven Stages of the Soft Systems Methodology (SSM) (Checkland, 2000)

Stage	Explanation
The Problem Situation Unstructured	The first two stages are engaged in discovering the problem situation, using the people in the problem situation. A rich picture is then constructed as a formal annotation of the problem.
The Problem Situation Expressed	
Root Definition	Relevant Systems within the rich picture are visualised by analysing possible problems, conflicts of interest. A CATWOE checklist will ensure all system elements are included.

	<p>Customers – the Beneficiaries of the system</p> <p>Actors – the roles of running the system</p> <p>Transformation – system inputs converted to outputs</p> <p>Weltanschauung – world view , perspectives given in defining the system</p> <p>Owners – the roles of monitoring and taking appropriate action</p> <p>Environment, the constraints on the system</p>
Conceptual Model	This stage will conceptualise what the system defined in the root definition stage will do. There can be a conceptual model for each root definition.
Real World / Conceptual Model Comparison	Comparison of conceptual models against the problem situation, as well as against the views of the stakeholders, leading to a list of recommendations.
Feasible and Desirable Changes	Analysis of proposed changes, that is feasible and desirable.
Action to Improve the Problem	Recommendation of actions to help the problem situation.

Table 2.1: The Seven Stages of SSM Explained (Checkland, 2000)

2.4.3.3 Strengths of SSM

SSM has the potential to be applied in a wide variety of areas (Rose, 1996). Its application potential in healthcare has been recognised, with some of its initial ideas applied in the NHS (Checkland, 2000). SSM is needed to understand the system and establish the boundaries before any structured methods are imposed. It provides a very systematic process of inquiry, using the system as an epistemological device to extract knowledge (Holwell, 2000; Rose, 1996). It pays special attention to the subjective details, reflecting on the interpretive strengths of this methodology. SSM practices participative interventions (Rose, 1996), which stems from the core ideas of Action Research that brought about the development of SSM (Checkland, 2000). People took part in bringing about the change as participants not

observers. This methodology clearly has scope to deal with user involvement and the flexibility to incorporate methods that could aid successful user involvement.

2.4.3.4 Weaknesses of SSM

The Soft Systems Methodology does not come without weaknesses, including being viewed as isolationist (Mingers, 2000) in that it does not draw upon work in other disciplines. It is also noticeable that there are no specific tools and techniques relied upon through the methodology, although these can be incorporated if need be in the particular information system project. Another weakness is that SSM does not consider sensitivity on social-political issues (Lane and Oliva, 1998). It lacks in self-reflective conscientious application and as with any tool, the skill and experience of the researcher determines the limitations of the methodology (Rose, 1996).

2.4.3.5 Potential of SSM

Where SSM lacks in structure, it makes up in the ability to apply relevant methods, tools and techniques specific to the particular 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.

2.4.4 *Summary*

In conclusion SSM will be beneficial in identifying the system boundaries and system activities for the complex healthcare system, to establish exactly where the problems lie. Its position as a learning methodology will allow progression through reflection, throughout the process of medical device development. Its ability to incorporate user participation will be beneficial for the aims of this research. However it lacks methods that could deal with the social and more sensitive elements of healthcare. This drawback creates a gap in the literature from the IT perspective, as it shows that IT theories or methodologies cannot work in isolation where healthcare is concerned.

Further techniques, to involve the users still need to be incorporated, as the emphasis 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, but does has within it the scope to do so. This has unsurprisingly been the case wherever humans have needed to interact with technology, and computer science rapidly developed the subject area of human-computer interaction (HCI). In order to understand the human elements of interacting with a computer, IT could no longer define the characteristics and factors to singularly influence the design of applications with which users needed to interact. It drew upon social science subject areas like cognitive psychology to define the multidisciplinary subject of human computer interaction - looking at human behaviours, computer systems design, social and organizational context of the user as well as drawing upon cognitive and organisational psychology (Preece *et al.*, 1994).

In the same way for medical device development, the user is the most significant element for which the device is made, meaning the social elements need to be addressed from outside the paradigm of IT. The complexity here is that the users are multiple and so are the interactions between users and the technology, which must be reflected in the approach taken to understanding their requirements. 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.

The Gap

The gap in the literature on the IT perspective is its failing to impress on how this IT methodology will accommodate the social and sensitive aspects of healthcare. It offers a methodology but not methods that could aid the execution of each step in the methodology.

2.5 The Ergonomic Perspective

2.5.1 Introducing Ergonomics

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, wellbeing 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).

This section details user centred design, and presents an argument for the use of its methods, when eliciting users in MDD. The argument for participatory research follows, as it directly links with user involvement, discussed and concluded earlier as an essential element for the success of medical devices.

2.5.2 *User Centred Design*

User Centred Design (UCD) is a broad term describing design processes in which end users influence how a design takes shape (Abrás, Maloney-Krichmar and Preece, 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 (Venturi and Troost 2004; Abrás, Maloney-Krichmar and Preece, 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 (Abrás, Maloney-Krichmar and Preece, 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, Johnson and Zhang, 2005).

2.5.2.1 *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 (Abrás, Maloney-Krichmar and Preece, 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, Johnson and Zhang, 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 (Abrás, Maloney-Krichmar and Preece, 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, Johnson and Zhang, 2005) and assures that the product will be suitable for its intended purpose (Abrás, Maloney-Krichmar and Preece, 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).

2.5.2.2 Limitations of UCD

UCD does have its drawbacks, one major disadvantages being the resource requirement, both financial and human (Abrás, Maloney-Krichmar and Preece, 2004). The need for additional design team members e.g. ethnographers 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. 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.

2.5.2.3 UCD Methods

Table 2.2 lists the possible methods and processes that UCD equates to.

Method	Description
Prototyping	A preliminary version of the product is made to be tested, so any changes can be made before manufactured commercially. (Grudin and Pruitt, 2002)
Heuristic Evaluation	Evaluators (not end users) compare the device interface to usability principles ‘heuristics,’ in order to identify any problems with the design of the device. (Johnson, Johnson and Zhang, 2005)
Informal Usability Testing	Usability users perform a number of tasks which are typical to the device, to measure how effective it is. (Kaufman <i>et al.</i> , 2003, Kushniruk and Patel, 2004)
User Analysis / Profiling	This is the process of identifying potential users of a system and their attributes. Profiling aims to meet customer needs by collecting information about them. (Johnson, Johnson and Zhang, 2005)
Evaluating existing systems	Drawing conclusions of the characteristics of the current system. (Stanton <i>et al.</i> , 2005)
User Requirements Analysis	This encompasses those tasks that go into determining the needs or conditions to meet for a new or altered product, taking account of the possibly conflicting requirements of the various stakeholders, such as beneficiaries or users. (Maguire and Bevan, 2002; Vredenburg <i>et al.</i> , 2002)
User Interviews	Facts and opinions sought in a formal meeting. (Myers, 2007)
User Surveys	A series of questions aimed at collecting people’s attitudes on a particular product / concept. (Roberts, 1999)
Informal expert review	The product is reviewed by an expert in the area. (Vredenburg <i>et al.</i> , 2002; Stanton <i>et al.</i> , 2005)
Participatory	This is an approach to design that attempts to actively involve the

Design	end users in the design process to help ensure that the product designed meets their needs and is usable. (Howcroft and Wilson, 2003; Grudin and Pruitt, 2002)
Task Analysis	Task analysis seeks to examine a particular task and to break it down into the actions, decisions and/or cognitive processes that are necessary to complete it. By studying a task in detail, areas that are inefficient, unsafe or unsatisfactory can be identified. (Johnson, Johnson and Zhang, 2005)
Iterative Design	Is a cyclic process of prototyping, testing, analyzing, and refining a work in progress. (Nielsen, 2003)
Contextual Inquiry (Field Studies)	This is where the opinions of the user are combined with conducting the task, by observing the user in their own living environment. The developer asks questions throughout the use of the device, to ask the how and why of their use of the device in an attempt to gain insight to make it more efficient. (Dekker, Nyce and Hoffman, 2003)
Focus Groups	This is a form of qualitative research in which a group of people are asked their attitude towards a certain product / concept. (Morgan, 1996)
Cognitive Walkthrough	Is a usability inspection method used to identify usability issues in a piece of software, testing ease of use for new users? The system is simulated and tested for possible problems during task accomplishment. (Kaufman <i>et al.</i> , 2003; Johnson, Johnson and Zhang, 2005)
Ethnography	Ethnography observes the user in their natural environment, and then interviews separately the involved personnel to get further insight to their observations. (Dekker, Nyce and Hoffman, 2003)

Table 2.2: User Centred Design Methods

2.5.3 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, with certain methods being more appropriate than others to meet this purpose. Further stages which entail defining 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, Cullen and Goh, 2008), 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 (Chen *et al.*, 2005). Methods that fall under this category include observation and interviews - the most frequently reported methods (Stanton and Young, 1998), focus groups and user and task analysis.

2.5.3.1 Behavioural and Cognitive Methods

2.5.3.1.1 Observation

Observation is a core approach for an ergonomist (Stanton *et al.*, 2005), almost certainly as it feeds data into other methods relevant to user requirements gathering. Indirect approaches of observation for example ethnography or contextual inquiry will be more beneficial, in a busy healthcare environment. Ethnography observes the user in their natural environment, and then interviews separately the involved personnel to get further insight to their observations. Contextual Inquiry is a shortened, more focused version of ethnography which may be more beneficial to product development when considering the practical constraints (Martin *et al.*, 2006) for example the time factor, as ethnography can involve months of observation if not years. Contextual Inquiry is a more intrusive technique however, and in a busy healthcare environment it can be inappropriate to ask questions as tasks are being performed.

2.5.3.1.2 Interviews

Interviews can also take a variety of forms, and are adopted according to the type and purpose of analysis they contribute towards, be that complementary to an observation technique, or separately with experts or lay users of the system. From completely

unstructured to semi structured or completely structured. They allow for the rich exchange of information between the researcher and participants (Myers and Newman, 2007).

2.5.3.1.3 Focus Groups

Focus groups are a research technique which collects data through the interaction of a group, under the researcher's defined topic (Morgan, 1996). This can be an extension of individual interviews, or used in combination with interviews and surveys. Here people may share similar views and discuss these views to reach a consensus on the issues.

2.5.3.1.4 User and Task Analysis

User and Task Analysis, has borrowed from ethnography, unobtrusive observation and participatory observation (Hackos and Redish, 1998). User and task analysis is the process of learning from ordinary people by deeply observing them in action, and fundamentally framing the problem in terms of the human activity in context. These are structured methods which help compose a rich understanding on who the users are and how they behave in their natural environments to assist in design, as observation not assumption leads to successful design (Hackos and Redish, 1998). These methods also relate to cognitive psychology, on how people think and behave. People are viewed as active parts of the system, and require even greater study and understanding, as they are the less predictable and less understood element of the system (Hackos and Redish, 1998).

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.

2.5.3.2 Macro-ergonomic Methods

2.5.3.2.1 Field Studies

Field study is based on realism, looking at users within a real environment, not a laboratory setting, being one of the oldest most classic means of studying organisations (Stanton *et al.*, 2005). This gives greater confidence in the usefulness of the results. However observation may take place for a long time before any real cause-effect relationship can be established.

Sometimes these natural occurrences need to be observed many times before the causal factors can be identified.

A useful technique to follow up on a field study, after any change has been suggested or made, is a field experiment. In field experiments, ergonomists act as change agents, observing outcome of changing particular variables in the environment, to get a more focused reaction. The way this change is implemented can affect the result. With artificial changes, user perceptions on the outcome of this change may affect their behaviour as users may alter the ways they respond to it i.e. the placebo effect.

2.5.3.2.2 Cognitive Walkthrough (CWT)

Cognitive Walkthrough is an analytical usability inspection method, similar to task analysis. It takes the perspective of the user, through gathering a thorough understanding of the user's interpretation and mental model that influences product exploration (Stanton *et al.*, 2005), and applies to the task scenario in order to identify usability problems.

2.5.3.2.3 Participatory Ergonomics

These are principle methodologies, which embrace the involvement of people, in planning and controlling a significant amount of their own activity (Stanton *et al.*, 2005). There are three different approaches to this involvement, firstly parallel suggestion i.e. collaboration. Here workers work to solve problems and generate ideas to influence the routine operation of the organisation. Second is job involvement, which involves designing work to better motivate job performance. Increasing job involvement by engaging employees more completely in their work and making work a more meaningful and fulfilling experience, can enhance organisational efficiency (Brown, 1996). Finally, the high involvement approach, which works to ensure the lowest level in the organisation, has a sense of involvement, through greater information, knowledge, rewards and power. Studies have shown high involvement to achieve highly in terms of productivity and employee retention (Guthrie, 2001).

Participation can be found in virtually all other ergonomic methods to some degree, with endless application potential in design and analysis (Stanton *et al.*, 2005). The emphasis on participation is such in ergonomics, further investigation into the literature was undertaken to evaluate its value within the context of this research.

2.5.3.3 User Centred Design and Participatory Research

Participatory Design has often been understood as an approach of UCD (Carroll, 1996), developed as a method to support UCD (Abrams, Maloney-Krichmar, and Preece, 2004). It has been argued that UCD methods place users in a reactive role and can be non-participatory (Carroll, 1996). Contended that it is the participatory design approaches which seek to involve users more deeply (Jansson, Mortberg and Mirijamdotter, 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 operationalises user involvement through some of its empirical approaches such as observation, where the users are seen as subjects or cases and not as full participants (Carroll, 1996). This is why the need to discuss participatory research arises, as it appears that Participatory Design and UCD interact in a complimentary fashion (Carroll, 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.

2.5.3.3.1 *Participatory research*

Participatory research has been described as the most effective way of conducting context sensitive and user centred quality research (Gibson and O'Donnell, 2008). Its distinct features being collaboration, mutual education and results informed action (McCaulay *et al.*, 1999). 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 (Gibson and O'Donnell, 2008) as well as ownership and inclusion (Kujala, 2003) 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).

2.5.3.3.2 *Participatory Action Research*

There are a number of participatory approaches that can be taken. There is Participatory Action Research (PAR), which stems from Action Research (AR) – looking to involve people in the process of change (Jansson, Mortberg and Mirijamdotter, 2008). It aims to improve health and reduce health inequities through involving people who subsequently take action to improve their own health (Baum, MacDougall and Smith, 2006). Researchers are seen as facilitators of change here, with power given to the community of interest (Walter, 1993). It

ensures continuation of knowledge building and feedback and gives participants the freedom to make choices.

The many advantages of PAR include its part in helping 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, MacDougall and Smith, 2006), with positive and practical outcomes (Walter, 1993; Whyte, 1989). It's collaborative in nature, involving communities and identifying problems important to them (Walter, 1993) 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 (Gibson and O'Donnell, 2008)

However, PAR is time consuming and can have unpredictable outcomes (Baum, MacDougall and Smith, 2006), with the impracticality of a possible lack of consensus of what the problem is (Walter, 1993). To carry out such research it will be important to work effectively with people involved, who will have different and competing agendas (Baum, MacDougall and Smith, 2006). In the words of Wadsworth (1998) however, 'it is not possible to do any social research without the participation of other human beings'. 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.

2.5.3.3 Participatory Design (PD)

Participatory Design (PD) constitutes democracy and user involvement as key elements. It aims to create a shared understanding of the area in focus (Jansson, Mortberg and Mirijamdotter, 2008), 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 (Abrams, Maloney-Krichmar and Preece, 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 (Abrams, Maloney-Krichmar and Preece,

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 presumptions 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.

2.5.3.3.4 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’ (Walker *et al.*, 2007) 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 (Grudin and Pruitt, 2002). 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.

2.5.4 Summary

Evidently ergonomics seeks to maintain better interaction between users and technologies. Its user centred design methods combined with participatory design would certainly aid this

research in seeking the role of the user in the advancement of medical technologies. Using methods which allow users to take a level of control will help establish if, when and how the users are needed in the development process of new technologies, in this case medical.

A selection of methods were described, and it is important to select the correct method in any given point of the process, yet most studies validate using data from a variety of sources, by combining methods (Stanton *et al.*, 2005). Participatory design methods are emphasised to be used in parallel with UCD methods, and although healthcare providers will be encouraged to involve more patients, notably they will still be the ones held accountable for the decisions they make (Crawford *et al.*, 2002).

Although we have defined the role of the users and at which points of the medical device development lifecycle they can be involved, 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 are these the same points where the users feel valued or even 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.

The Gap

Ergonomics methods offer tools to incorporate users, yet need a brief established before they can be put to use. Further to this the ergonomics perspective assumes all users will be willing to participate, without accommodating for the users intentions and behaviours.

2.6 The Psychology Perspective

It is important in medical device development to fully understand the users, and 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.

The area of psychology this research will primarily draw upon is that of health psychology, being the most recent development concerning the use of psychology theories for an understanding of health. Health psychology focuses upon; the promotion and maintenance of health and the cause and treatment of illness. The educational, scientific and professional contribution of psychology is used to address these aspects of health and illness. It is particularly relevant as health psychology draws upon social cognition theories (SCT) which emphasise beliefs and attitudes, as well as stage theories which look at change and progression. Both of these areas are particularly relevant in medical device development, as change and progression is the aim of new device development and consideration of users' beliefs and attitudes is fundamental in ensuring product acceptance.

McKeown (1979) in his examination of health and illness through the twentieth century drew him to the conclusion that individuals' behaviour influences the cause of their illness (McKeown, 1979, *cited in* Ogden, 2007). Health behaviours have played an increasingly important role in the past century and seem to be important in predicting mortality (McKeown, 1979, *cited in* Ogden, 2007) and the longevity of an individual. Numerous studies have been done to prove the relevance of behaviours and to predict health related behaviours by health psychologists. An example is the work by Belloc and Breslow testing mortality and longevity in relation to seven behaviours (Belloc and Breslow, 1972; Belloc, 1973; Breslow and Enstrom, 1980, *cited in* Ogden, 2007). These behaviours include; sleeping 7-8 hours a day, not smoking, eating breakfast daily, maintaining recommended weight, no smoking, no alcohol, regularly exercising and no snacking between meals. Over a ten year period the results confirmed the correlation between these behaviours and mortality.

Health psychologists predicting health behaviour largely emphasise 'beliefs' throughout work. It sets the idea that for a medical device to succeed the individuals' perception of the device – attitude and beliefs, behaviours relating to its use and adherence to the subsequent medical regime, could have a significant impact on the health status of the patient. Respectively the medical device cannot be seen in isolation, but would be better addressed in the context of its use, and with consideration of the factors that influence the success of the device in the specified environment.

2.6.1 Cognition Models

Cognition models such the Health Belief Model - HBM (Rosenstock, Strecher and Becker, 1988), considers the predictors and precursors to health behaviours. In the HBM 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).

The Health Belief Model (figure 2.3) shows that motivation to act, is stimulated by a reminder (cue for action). This could be from the external environment, for example flu virus. The patients vulnerability to the possible health threat and perceived severity will allow them to make a judgement of the action to take (Leventhal, Safer and Panagis, 1983). It does not however tell how to change belief or alter the actions to take or take into consideration the social context of these cognitions. The HBM suggests that behaviour is a rational consideration of the costs and benefits of behaviour by an individual.

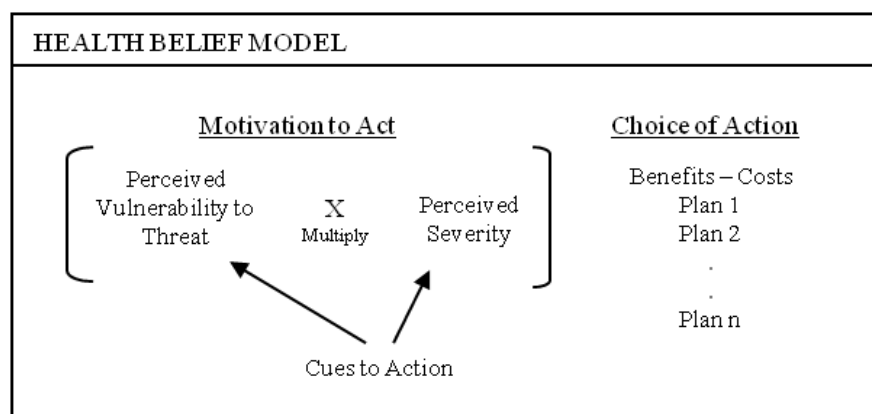


Figure 2.3 Health Belief Model (Leventhal, Safer and Panagis, 1983)

The Fear Drive Model - FDM (figure 2.4) is an emotional process that does follow through to the action stages, until the fear is removed. This model translates knowledge into action, in a sequential order of events (Leventhal, Safer and Panagis, 1983).

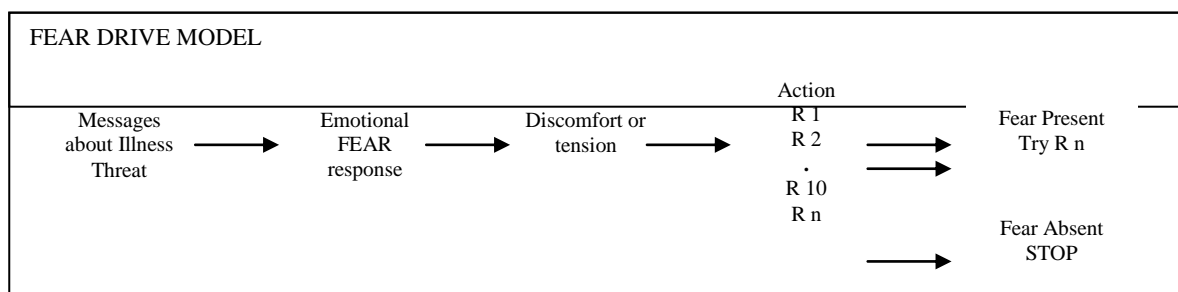


Figure 2.4: Fear Drive Model (Leventhal, Safer and Panagis, 1983)

Health Psychologist, Howard Leventhal, has attempted to define a model to aid the self-regulation of healthcare by patients. Combining these two models; HBM and FDM produces the Complete Dual Process Model of Self-Regulation (figure 2.5). The Dual Process Model

looks at patients' motivations to act. It is explained through the combination of two particular contexts in which we interpret information; the emotional context (intensive component) or the cognitive context (directive component). We interpret subjective information at the emotional level, and at the cognitive level we interpret the objective information. This means that the clarity and the quality of a message can have an impact of how information is interpreted, and in the medical context will relay how the individual wants to respond to the given medical instruction or recommendation. Given that the aim is for maximising the positive user experience and ensuring as much health advice is taken on board by the user, it is important to consider the user requirements from the psychological aspect, as this will further help interpret user behaviour.

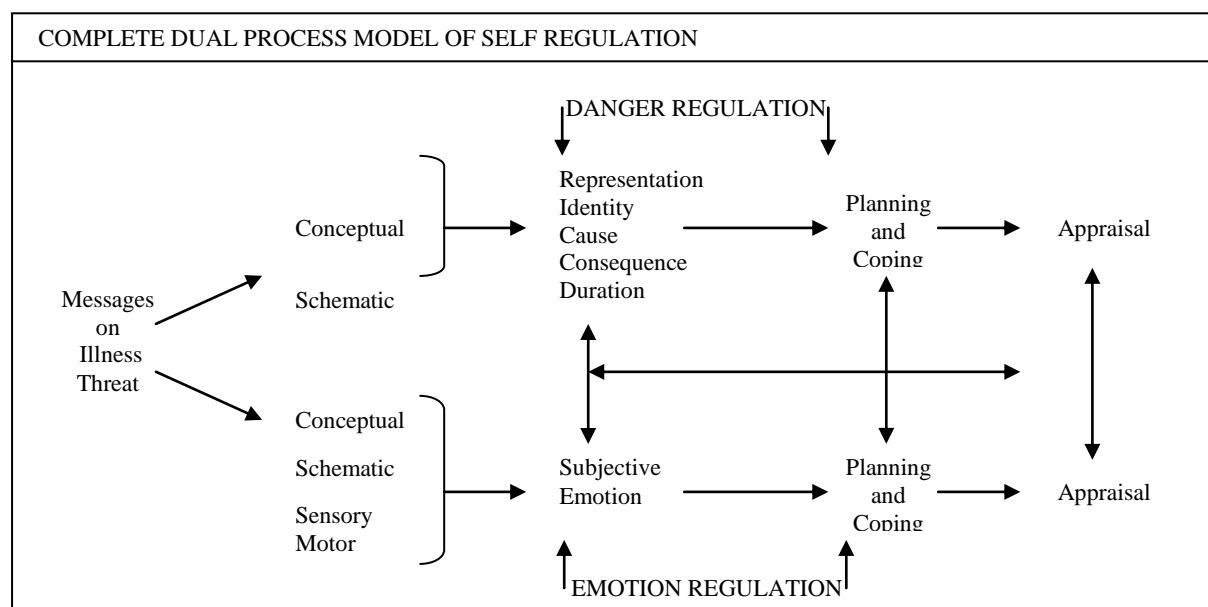


Figure 2.5: Complete Dual Process Model of Self-Regulation (Leventhal, Safer and Panagis, 1983)

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.

2.6.2 *Social Cognition Theories*

Social cognition theories aim to accurately predict behaviour due to the belief that behaviour has an implication for health. SCT's predict why individuals fail to commit to behaviour expected of them, and are governed by expectancies, incentives and social cognitions.

Several models have been developed using this perspective, including firstly the Theory of Reasoned Action (TRA) (Ajzen and Fishbein, 1980). The theory of reasoned action is a popular reference point of the motivational influence on behaviour (Madden, Ellen and Ajzen, 1992), supporting the idea that performing a particular behaviour leads to a particular outcome (Ajzen and Fishbein, 1980). It combines the underlying influence on an individual's belief with the subjective norm of performing that behaviour. This means that information or principal beliefs affect an individual's intention and consequentially their behaviour, as they expect a particular outcome. The relationship between intention and behaviour is affected by the stability of the intention, individual control and specificity of the task to be performed (Madden, Ellen and Ajzen, 1992) all relating to the attitude of the individual (Fishbein and Ajzen, 1975).

Ajzen (1988) took this further with the Theory of Planned Behaviour. This theory saw the effects of perceived behavioural control by the individual, to either motivate individual intentions, or directly link to having actual control on their behaviour (Madden, Ellen and Ajzen, 1992). It provides more resources and opportunities for performing a given behaviour, the more perceived opportunities individuals think they possess the greater their perceived behavioural control. This theory better determines target behaviour of those users that cannot exercise complete free will in the use of the system comparative to the earlier proposed theory of reasoned action (Madden, Ellen and Ajzen, 1992). In healthcare the necessity perceived by medical professionals to use a medical device, may outweigh some of the patients control over its use. It is important in these cases to be able to assess their response to the system in terms of attitude and behaviour to ensure successful deployment and use of the device. This would prove useful, when determining the role of user requirements in medical device development.

However the main criticisms of theories such as TRA were that although they are designed to predict behavioural intentions and actual behaviour, they were not a radically successful in either. Furthermore there seemed to be a significant gap between intention and behaviour that needed to be closed. Exploration into this idea created the need to put theory into

practice and steps were drawn to develop an intervention based on TRA (Sutton, 2002b, *cited in Ogden, 2007*). These steps define the preliminary work that needs to be done before the intervention, but not the intervention itself, which could be anything from persuasion, information giving to increasing skills and setting goals. These steps could be ideal in the initial stages of the MDL, to determine intention and behaviour of the users in regards to acceptance of the medical device.

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. 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 user motivation in using it. 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, relating to the input/outcome balance is sensitive to individual preference, as not everyone perceives an outcome to be equally beneficial (Huseman, Hatfield and Miles, 1987). It once again illustrates the fact that the system will need to appeal to various users and their motivations, to stimulate correct and regular use.

Many of these 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, Ngai and Chen, 2008). This is true for Leventhals' 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, 1975) shows that expectancy of a particular outcome alters ones intention and hence their behaviour, again also correct for the Theory of Planned Behaviour (Ajzen, 1985). 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, Stretcher and Becker, 1988). The incentive to change ones behaviour could be if their current behaviour poses a threat to their health or wellbeing and needs to be changed in order to reduce the threat.

2.6.3 Summary

In summary, the importance of education and knowledge dissemination, to promote remedial action by patients, has been recognised. The health belief and fear drive models show how important patient knowledge is to aid self-regulation, enabling patients' to balance out the fear factor, with a confident attitude, as well as allowing patients to handle the situation unaided, or through contacting the right sources at the right time. By fulfilling users' expectations user satisfaction is achievable. These expectations need to be reflected in the way the product is designed, as '*end user satisfaction*' is claimed to be critical (Au, Ngai and Cheng, 2008) in the successful implementation of an information system. Leventhal, Safer and Panagis (1983) have 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, expectations and control aspects. User satisfaction should be now imminent. Integrating these user needs into the design could enable them to be translated into attributes and design characteristics leading to user satisfaction of the system.

The health psychology perspective has somewhat humbled the research, by separating the methods suggested for medical device development from the users' intentions to use them. In doing so it has further raised awareness to cater for the sensitive stakeholders of the healthcare system i.e. the patients, on whom methods cannot be forced upon to 'extract' relevant information. Health behaviours and beliefs that individuals hold will reflect their intentions to behave in this case towards medical adherence and acceptance to a new medical device. This idea needs to be built into the process of MDD.

The Gap

The psychology perspectives has been concerned with showing awareness of users beliefs and behaviours and the impact these could have on the motivation or intention of using the device. There is a lack however of information on how to incorporate these theories to ensure the user's beliefs are accounted for or influenced in the process of development.

2.7 The Design Perspective

It is now only logical to give some thought to the *design perspective* – in the design of medical devices. Design being defined as:

‘The prolonged checking, pondering, and comprising on requirements which are often quite contradictory until there appears – as the end product of numerous associations of ideas, a network of ideas – the design.’ (Matousek cited in Shefelbine, 2002, p. 1)

2.7.1 Design Steps

The design process comprises four steps. The first being **Task Clarification**, here the problem is defined, needs identified and requirements established. Followed by the second step of **Concept Generation** where possible solutions are identified. Then the third step **Embodiment Design** takes place, where the selected solutions are elaborated upon and finally the **Detailed Design** step – in which the details are finalised (Shefelbine, 2002). These steps are reflective of those incorporated in the soft systems methodology as follows; the problem situation unstructured/expressed, conceptual model, real world vs. conceptual model comparison and feasible desirable changes respectively.

2.7.2 Verification and Validation

Design of medical devices also places a special consideration for verification and validation within the design process. Where verification ensures each step meets the requirements derived from the previous stage and validation ensures the product meets user needs. The requirements specification defines what is needed and is later used to measure solutions against – hence the need for them to be right and understood by all. Although requirements define what is to be achieved they do not specify how it is to be achieved. The three types of requirements are functional, business and regulatory.

2.7.3 Regulatory Requirements

Regulatory requirements are of particular importance in medical device development, as all devices must be approved by the relevant regulatory authority before they are released to market – national or international. All devices are classified dependant on the amount of risk they pose to the user and this determines the approval route. Regulatory requirements are categorized into standards; horizontal, semi-horizontal and product specific. Horizontal standards apply to all medical devices sold and used in a particular market area, for example,

the medical devices directive (93/42/EEC) applicable in Europe. All standards are not mandatory, although if they were all met it would help towards a more efficient approval process.

2.7.4 *Design Intuition*

The design perspective also needs to explore the intuition and creativity that leads to design, removed from the structured design process. Although restrictions apply to medical devices somewhat dictating innovation, there are design theories to be considered during the process of design that could further aid the success of a medical device.

First and foremost, in relation to healthcare, user behaviour can be influenced to accept medical devices by making them more pleasurable to use. 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 dependent on the task and even a dis-pleasurable task can be done by using a tool that is a pleasure 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.

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.

Extending upon the idea of ease of use or usability from a design perspective it is important to note the definition of usability, '*The extent to which a product can be used by specified users to achieve specified goals with effectiveness efficiency and satisfaction in a specified context of use*' from ISO 9241-11 (Jokela *et al.*, 2003, p.53) which is argued to be more of a concept, or guidance (Karat, 1997) than a simple definition. They argue that for a product to be usable the following factors need to be assessed before determining how usable the product is - learnability, effectiveness, attitude, flexibility, perception of usefulness, task match or functionality, task and user characteristics. In turn these factors need to be assessed by collecting information of how the users will carry out task using these products by observation and interviews, and then further assessed by task analysis, link analysis, timeline analysis and layout analysis. These techniques once took place at the end of a design cycle, however now can be incorporated within the design process at earlier stages to capture the user requirements and fulfil them.

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, Ngai and Cheng, 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).

2.7.5 Summary

It is understandable that designers will be one of the first to provide input into the design and conceptualisation of a medical device. It is their responsibility to appreciate the requirements of the various users of their end product, and incorporate this into design. 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, Kerkow and Landmann (2008) support 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.

The Gap

The Design perspective has described the steps of product development, but unspecific to medical devices and without user incorporation. The relevance of verification, validation and regulation are shown but without integration into the development process. This creates a gap as although requirements gathering is emphasised and users accounted for, a more specific process for the purpose of medical device manufacture is needed.

2.8 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 clear that there exists an overlap on user requirements research, which 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 Brockelsby, 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 logical to address each aspect as thoroughly as possible.

2.8.1 Similarities

Across the disciplines of IT, Ergonomics, Psychology and Design, there is a notable move towards user involvement. User involvement is considered to be advantageous when considered at the very early stages of product development. Within IT, more users can get involved due to decentralisation of IT Systems. The Soft Systems methodology from the IS perspective, addresses early stages of development explicitly, so it is ideally positioned to guide user involvement through this period of development. Ergonomics methods, design with the user in mind as these methods were developed for users. Its user centred design methods incorporate users at the heart of their design process and development into

participatory ergonomics means that users are seen as core designers who are empowered and influential in design, not just subjects. In health psychology the emphasis on understanding users and in particular their beliefs and motivations plays a big role. Beliefs and attitudes towards change are important, as the changing healthcare environment has provided the need to re-evaluate today's users of medical devices. The design discipline recognises that providing a positive experience can influence patient adherence. Hence, user input is incorporated to ensure aesthetic and usability features, enhance the pleasure of use according to the user's requirements. All have a preference towards early definition of user requirements, and can see the advantages of this.

These disciplines have interpretivist strengths in their methods, as well as the scope to learn through iteration. The soft systems methodology is an iterative methodology and provides ample opportunity to revise and redesign the device before going forward. Ergonomics methods are such that they can be applied where required, and can be used repeatedly. Some of the methods are iterative in themselves for example prototype development; clearly ensuring improvements are made as much as possible before going forward. The design of medical devices includes the step of verification, which keeps a check on whether the steps in previous stages have been met. This means one can go back and meet any steps that have been left out or not fully addressed.

Another similarity is the realisation that these methods or methodologies may not be utilised at their best in isolation. This was pointed out as a weakness of SSM, especially as it did not have any special tools or techniques to gather evidence for each of the stages it presents. Isolated use was also an issue when deploying the user centred design principles of Ergonomics. Such ergonomic methods need to be used in conjunction with a brief, to ensure the results are in line with the aim. Participatory research emphasises in fact the need to look at the system as a whole, its social and technical interactions, and its manager and worker cooperation. Health psychology also points out that a medical device cannot be seen in isolation from its user and the user's environment.

The idea of safety is seen as an important one. SSM's root definition step looks at the risk and safety aspects of development and ergonomics methods came about to design for safer work environments. Regulatory requirements in medical device development are incorporated by law and are based on combating the level of risk to user and hence address

safety issues. These disciplines show that safety of users is not compromised when involving them and safety is addressed in the methods they employ.

Ease of use of the product is another characteristic appreciated 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.

These theories strive for similar outcomes when involving users. 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.

2.8.2 *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 (Checkland, 2000); however IT methods can be insensitive to social/political issues (Lane and Oliva, 1998). Ergonomics has different methods available for different stages of product development lifecycle, with a view to iteratively involve users (Venturi and Troost, 2004). However these do stand at a cost-benefit trade off (Abrams, Maloney-Krichmar and Preece, 2004). The discipline of psychology focuses on user requirements through support of education and knowledge (Leventhal, Safer and Panagis, 1983). Psychology promotes that user effort relates to the users' expectations and requires motivation, possibly through incentives (Venkatesh *et al.*, 2003), this is something which the IT and ergonomics perspectives have not really explored. The Design discipline has a key difference in view of user requirements, which accrues to pleasure of use (Jordan *et al.*, 1996). 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; rather bring some advantages for being different.

2.8.3 *Advantages of Collaboration – Closing the Gaps in the Literature*

The advantage of establishing the similarities and differences between these disciplines mounts to the overwhelming need to collaborate between these disciplines in order to close

the gaps presented in the literature. Amalgamating corresponding ideas from across the disciplines investigated will help to fully understand the role of user requirements research from a single standpoint, as well as close the gaps highlighted throughout the literature search, when looking at each discipline and its theories in isolation. The differences bring with them individual strengths that have been integrated within their own specialities for far too long. Lending this expertise to be used with one another will strengthen the way user requirements research is perceived. 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 was seen as a gap, but can be complemented through the emotional response ideas present in both psychology and design. Similarly the gap present in the psychology literature on how to account for users' beliefs and behaviours within the development process can be addressed by incorporating these ideas to use within the SSM steps, alongside ergonomics methods.

In this way the differences between the subjects can be seen as strengths, when creating the bigger picture of the role of user requirements research in medical device development. A possible framework structure, illustrating how collaboration across the theories has reduced the gaps found in the literature is presented in chapter three, highlighting how these gaps found were addressed throughout.

2.9 Conclusion

This chapter has centred upon the idea of how important focus on user needs is to medical device development. The changes taking place in the healthcare industry dictate the involvement of many more users than before, but unless done correctly, the success of medical device development will continue to be limited.

Fundamental to this research was the knowledge of the user, and making any generalisation of what the user may want was unacceptable, as it fast became evident that there are a multitude of users in respect to medical devices. There are users in primary and secondary care, looking to use the device at any stage of the device lifecycle. This includes medical professionals, nurses and patients, all of whom have their own perceptions of what the device should be able to do depending on the purpose of the device and how they intend to use it. To be able to incorporate this diversity of ideas, it seems only natural to involve the user

throughout the development process. However it is important to predefine the level of user involvement and clarify how the research is being used, as it may be frustrating for the user, if after consultation the users' views are not seen to be having a direct action (Oliver *et al.*, 2008). Participation and empowerment are seen as the highest level of involvement (Poulton, 1997), through which the user feels fully involved, so incorporating these ideas also seem to be of added benefit to medical device development.

It is evident that the collaboration of knowledge across disciplines would benefit the successful understanding and involvement of users, in the healthcare system. The soft systems methodology will provide a foundation in the construction of a framework that is both logical and flexible for the problem situation. With the soft systems methodology basis in information systems and the cognitive and behavioural knowledge of psychology being applied using ergonomics and design methods, a wealth of knowledge will be incorporated in medical device development. Translating these ideas into the design of medical devices will ensure that the user requirements are caught from all angles and encompassed within the health information system, incorporate user requirements more thoroughly from the start, and hence make users more willing to use devices they have helped design. This collaboration will enable the true essence of the problem to be understood better, alongside the people.

Collaborating user ideas throughout the medical device development process should lead to medical adherence by the patients, positively affecting their health and their options. Medical adherence by practitioners will promote the use of the device, leading to fewer errors, better diagnosis, better treatment and better health for those in their care. Fewer reworks of medical devices will mean cost savings for the research and development side of healthcare as well as from increasing patient flow and increasing the efficiency of healthcare. Shah and Robinson (2007) see the benefits of access to user perspectives, lead user contributions and user and producer interactions being compromised due to the lack of resources, the lack of cooperation between users and producers, regulatory controls, and strategic issues. These negative factors also need to be overcome for the successful outcome of user participation. Finally, there is a need for the users to recognise the improvements and the potential these medical devices bring to the healthcare industry for it to truly progress.

The next chapter looks to produce a conceptual framework which illustrates the process of medical device development by merging the ideas present in the literature in a complimentary fashion.

3 CHAPTER THREE: *The Conceptual Framework*

3.1 Introduction

The literature made it evident that the medical device development process is not straightforward, nor can it be viewed in isolation from its users, functions or role in the healthcare system or society. The framework below (figure 3.1) was produced from the amalgamation of the theories and ideas which arose from the literature search. It used the Soft Systems Methodology as its starting point, and then added ergonomics design methods to each of the stages, which seemed fitting according to their descriptions researched. Further to this the idea of knowledge dissemination from psychology and a number of design related methods were added. The key to the framework is presented in table 3.1.

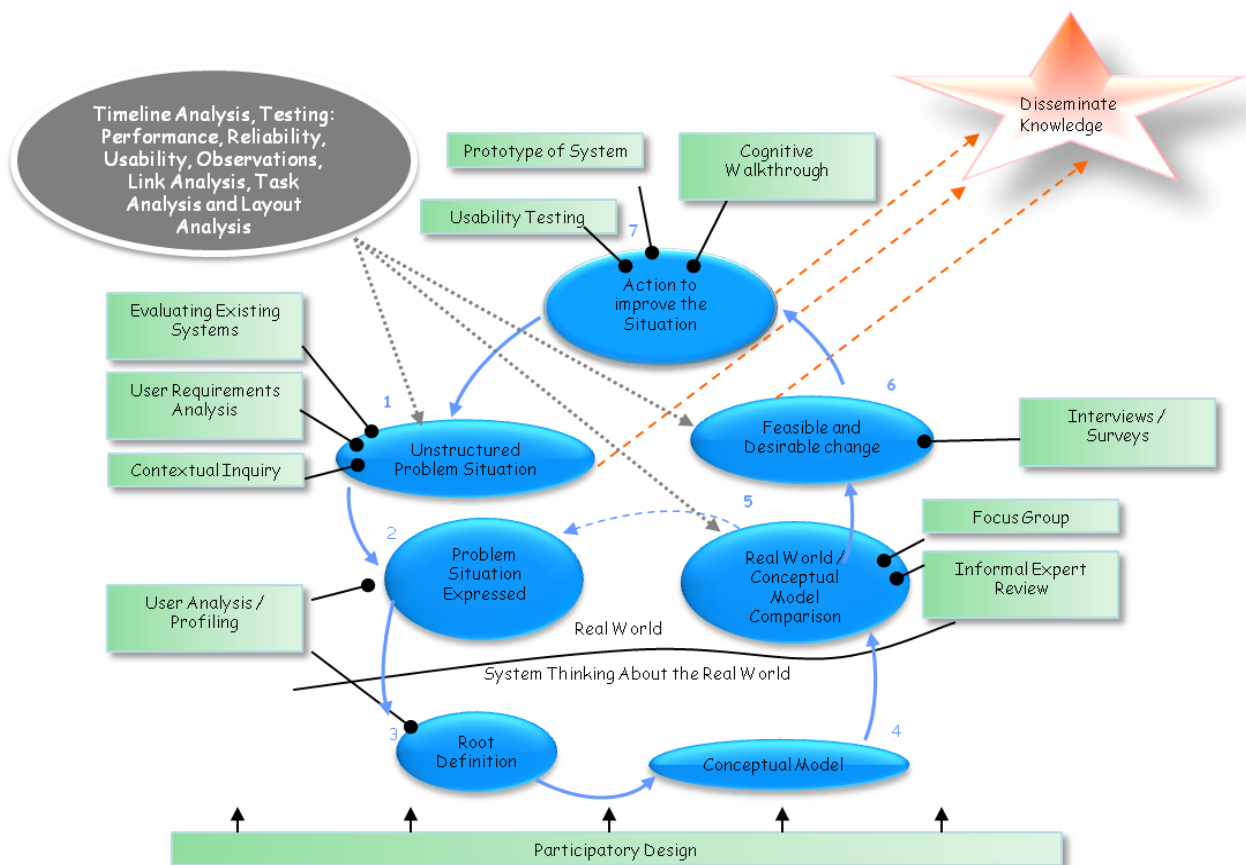


Figure 3.1: Preliminary User Involvement Framework in Medical Device Development

This chapter will focus on taking each segment of the framework, and work to refine the model and clarify what is involved in each step, for the users in question. This process should help to further enhance the framework to a high level model, ensuring any repetition and overlaps are adjusted accordingly.

3.2 Framework Breakdown

The key for the conceptual framework is presented in table 3.1. This details each of the symbols and what they represent in this framework.




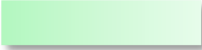







Symbols	Description
	Process Steps/Actions
	Process Flow Arrows
	Process Iteration
	UCD Methods
	Connecting UCD Methods to Processes
	Design Methods
	Connecting Design Methods to Process
	Psychology Methods
	Connecting Psychology Methods to Process
	Line to distinguish Real World from Systems Thinking
	Arrow showing incorporation throughout model

Table 3.1: Conceptual Framework Key

3.2.1 Stages 1 and 2

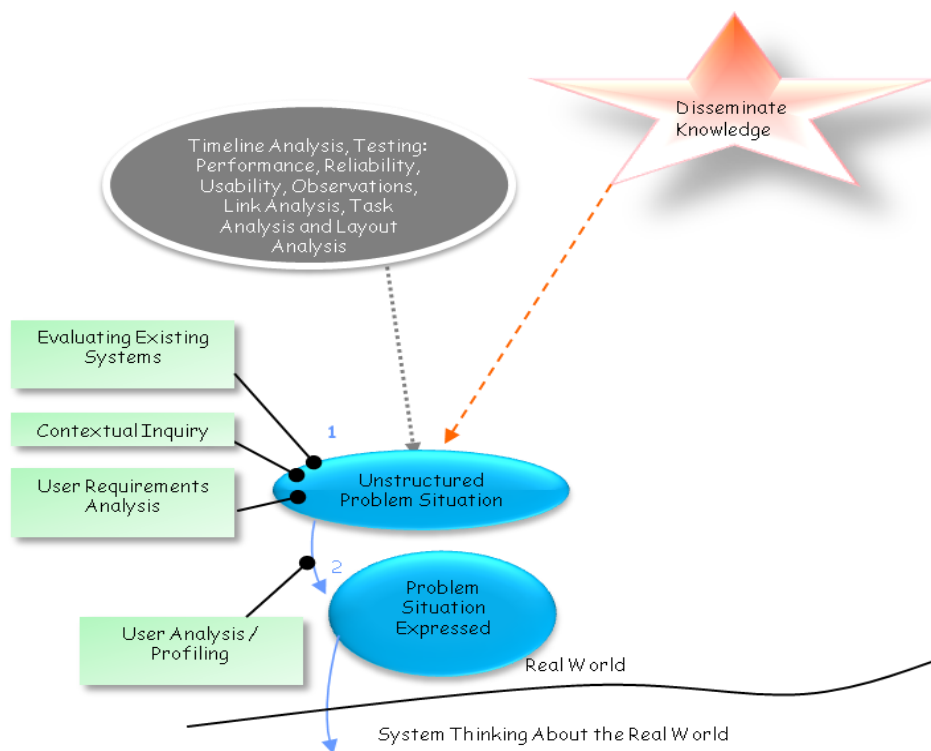


Figure 3.2: Stages 1 and 2

The first two stages shown in figure 3.2 are concerned with discovering the problem situation. The output of these stages will be a ‘rich picture’, as the formal annotation of the problem. The concerns here include both the choice of right methods put in place to capture the problem, as well as the problem being captured from the view of all those involved. It was notable from the literature that although SSM provides the stage as to what should take place at this point in development, there are no strict techniques in place of how the steps should commence.

A variety of methods from the disciplines of ergonomics and design, described in the literature, could be used in the execution of this step. The ergonomics methods suggested here are: contextual inquiry; user requirements analysis; evaluating of existing systems and user analysis and profiling. These can help to define more specifically the problem situation and capture the problems as expressed by the users. In terms of design related methods, which look to enhance design a number of methods can be used, including; timeline analysis, testing, observations and others. Incorporating these methods will address the gap in the IS literature. Where SSM lacks in tools and techniques to aid the completion of each step in the

process of development, the ergonomics and design methods will provide techniques appropriate to this stage, as well as the stages which follow. These can include methods which rely on user involvement or incorporate user feedback.

Investigating further into these methods to analyse the full extent of their ability to capture user requirements and understand the problem, a number of observations can be made. Firstly it is apparent that user requirements analysis can be moved to the next stage where stakeholder's views will be sought and further analysis can be made. This will allow these stages to concentrate fully on capturing the existing system and its users. The design related methods are not as necessary here, although techniques of observation can be combined with the contextual inquiry, to get a better viewpoint of the system and its users.

Even at this stage a need to disseminate knowledge to the users of what and why certain methods are being carried exists, something which is promoted by the psychology literature. Users need to feel sufficiently notified if not involved in any developments regarding the delivery of their healthcare. It may be suitable to enable access to the rich picture representation of the problem, to all users concerned. A refined version of the first stages of the model is represented in figure 3.3.

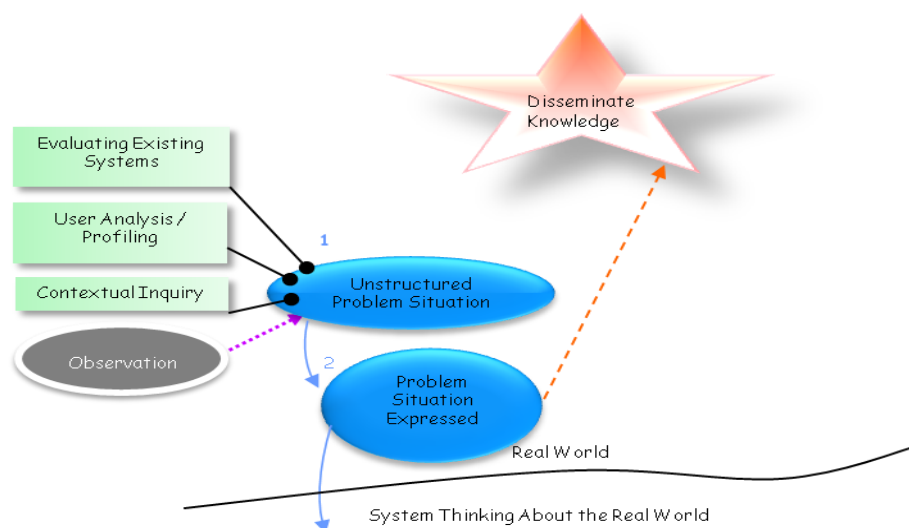


Figure 3.3: Stages 1 and 2 Refined

3.2.2 Stages 3 and 4

The next section of the model incorporates stages 3 and 4 of the SSM Model. These stages aim to visualise the relevant systems, analysing the potential problems and conflicts of

interest using the CATWOE checklist. Followed by conceptualisation of what the system defined during the root definition stage will do. The initial model described through the literature suggested the model as shown in figure 3.4. The participatory design box was added to represent that the whole model should include any participatory design methods where possible, and is not specific to stages 3 and 4.

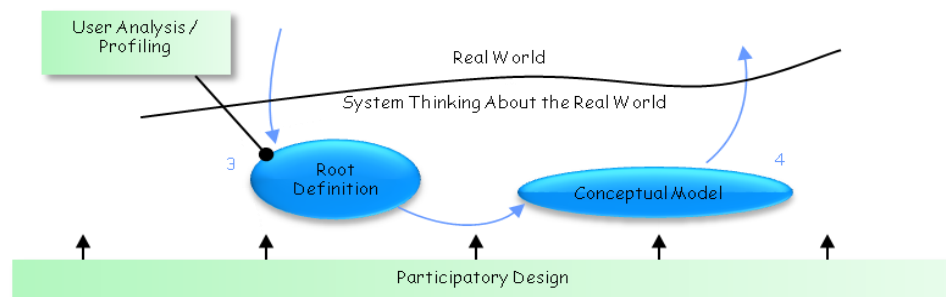


Figure 3.4: Stages 3 and 4

Further thorough examination of the model, illustrates the need for user requirements analysis to take place at this stage, instead of user analysis. This method will draw attention to the problems and conflicting viewpoints of the various stakeholders. It may also be useful to have focus groups at this stage, to find out attitude of the users concerning all system elements (figure 3.5). This is something which can take place as a participatory design method, in this way user centred design techniques and participatory ergonomics are combined with SSM. When drawing attention to the view points of various stakeholders, the behaviours and intentions of users can be measured as psychology theory suggests.

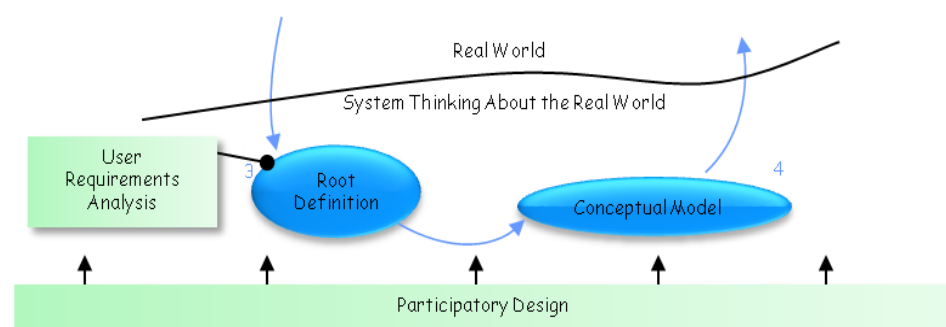


Figure 3.5: Stages 3 and 4 Refined

3.2.3 Stages 5 and 6

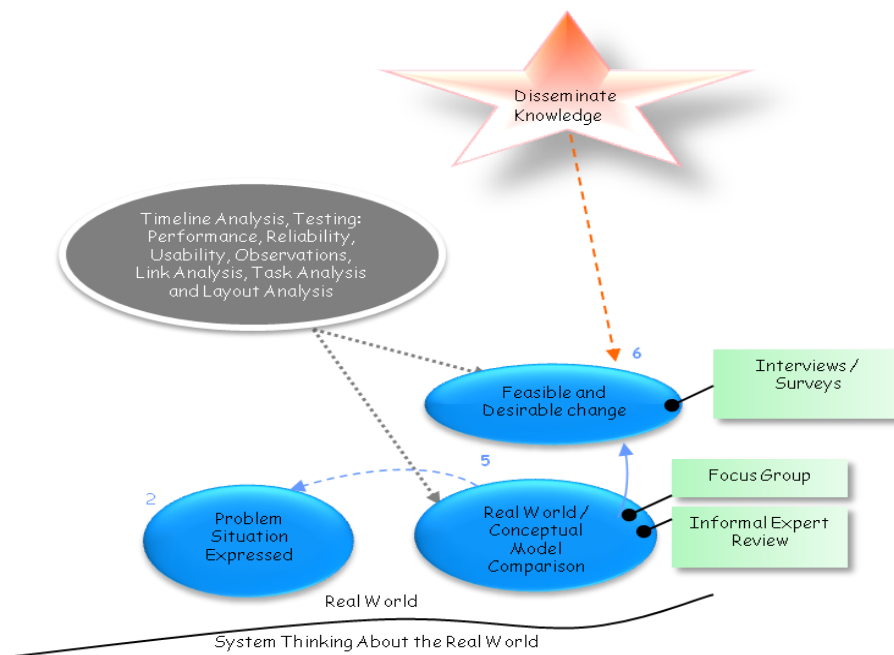


Figure 3.6: Stages 5 and 6

Stage 5 compares the conceptual model against the problem situation as expressed in stage 2, as well as against the views of the stakeholders before making recommendations. Following this, the desirable changes alongside the feasibility of these are assessed in stage 6. If there are any concerns, recommendations can be considered and any alterations made as this stage allows for iteration (figure 3.6). Iterative design is representative of design theories discussed, through which verification and validation of the device can take place. The UCD method of focus groups are needed in order to assess the attitude of the users and measure whether they feel their requirements are going to be fulfilled, in light of the problems expressed at the initial stages. Informal expert review would be invaluable at this stage in the process, as there is scope to address and take on board any constructive criticisms, and make changes as necessary, again incorporating ergonomics ideas. In terms of adding some design methods, link analysis and task analysis would be useful, to see how the system works as a whole as well as to see the efficiency of carrying out tasks within the system. This part of the model is expressed in figure 3.7.

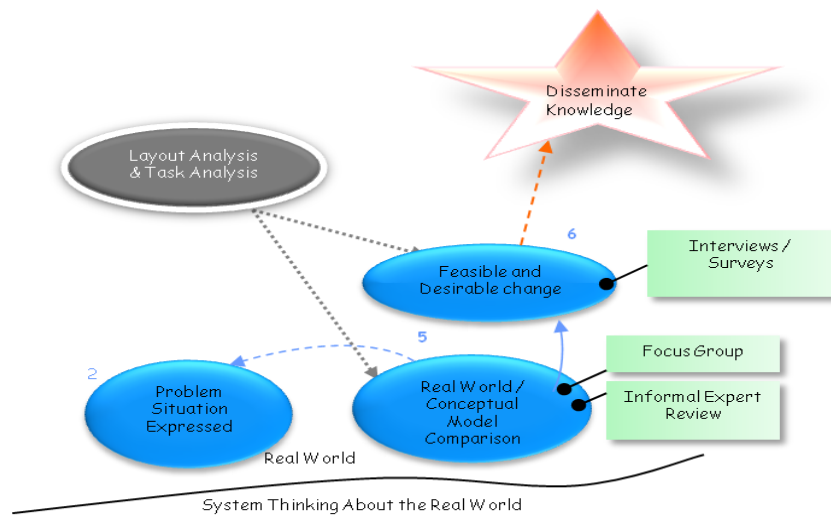


Figure 3.7: Stages 5 and 6 Refined

Again there is a need to express the concept to the user, and any proposed changes should be articulated so that the users are aware of any changes that may concern them. This is where psychology theories are used to include users, to disseminate information to ensure users are well informed, which could ultimately improve their buy-in to the product and acceptance of it.

3.2.4 Stage 7

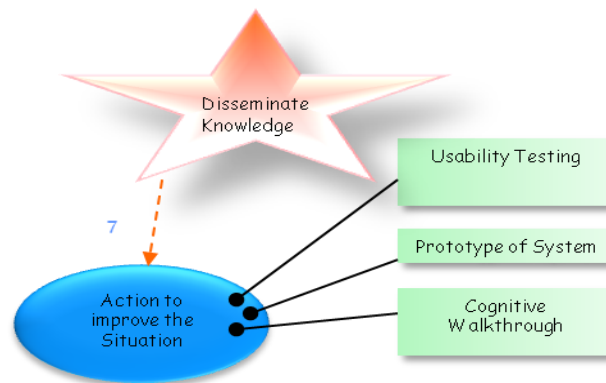


Figure 3.8: Stage 7

This final stage (figure 3.8) is where action to improve the situation can be taken. Dissemination of knowledge is vital at this stage. A prototype of the system can come about as an action, leading to further testing and cognitive walkthroughs.

However for the purpose of this research it is important to assess whether user requirements research played a significant role in product development rather than designing an end

product or even a prototype. Instead the scope of this research looks to see how effectively users can be involved in the early stages of MDD to improve user acceptance of devices after launch. Even without looking at the methods involved with producing and implementing the system, a fair number of activities involving the user have taken place in the early stages of development that this model addresses.

3.3 The Theoretical Framework

The final view of the framework has been constructed, after giving careful consideration to what each stage stands for and what the aim of each stage should be. This structure takes on board a number of elements from each discipline and is fused to form a single framework (figure 3.9).

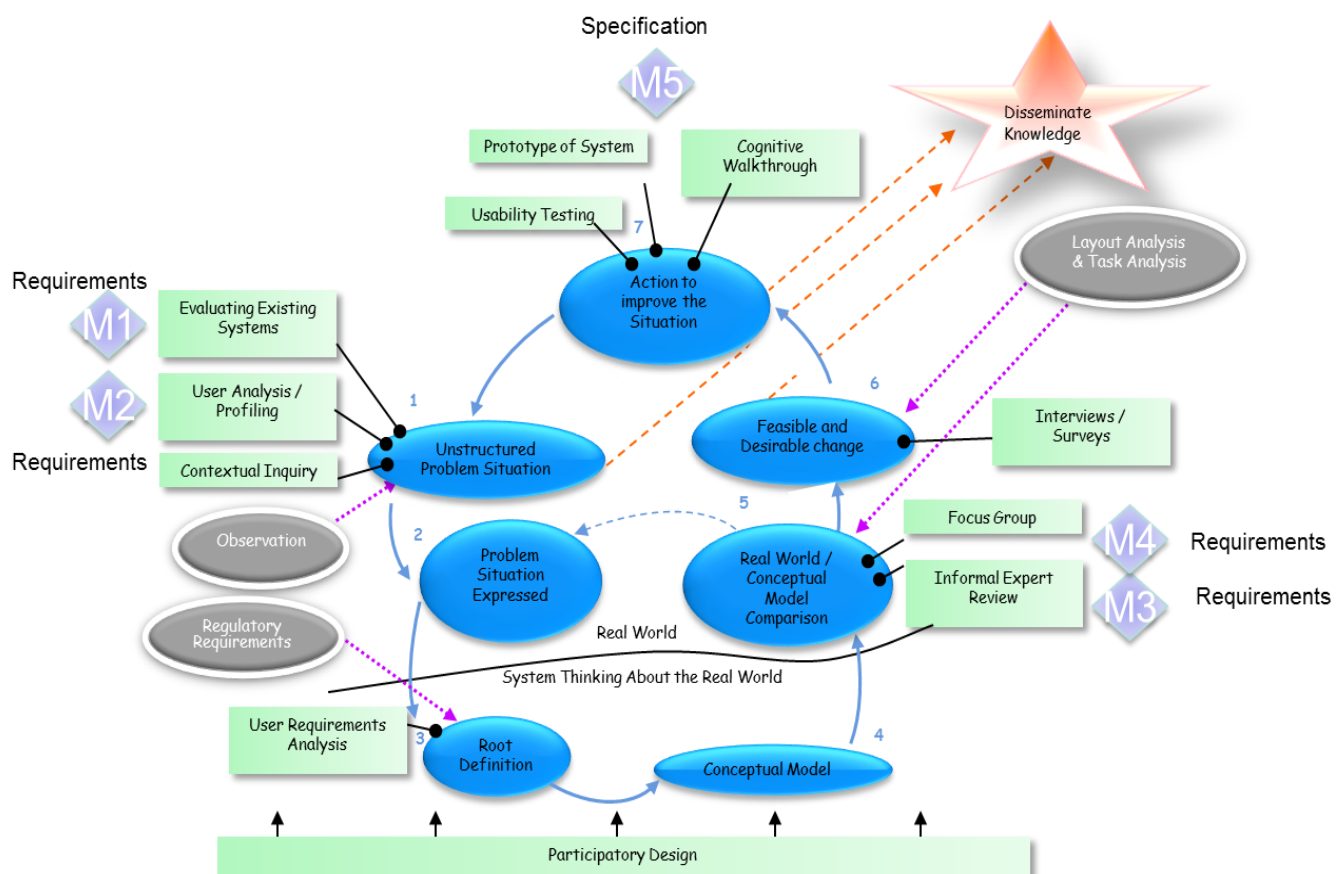


Figure 3.9: Theoretical User Involvement Framework in MDD

The framework is based on the soft systems methodology (SSM) from the IT discipline (Stages 1 – 7), 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; Rose, 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 conceptualize a possible solution, and then compare with the initial problem to analyze the feasibility and desirability of the changes. Action is recommended based on these judgments 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 (Abrams, Maloney-Krichmar and Preece, 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).

Participatory research also has its roots 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. It further has 5 steps (◇) relating to identify behaviour, these include; identifying target behaviour and target population (M1), identifying the most salient beliefs about the target behaviour (M2), conduct a study to determine which beliefs are the best predictors of behavioural intentions (M3), analyse the data to determine the beliefs between non intenders and intenders - these are further target beliefs (M4). Develop an intervention to change these target beliefs (M5). Applying these steps within the framework will ensure user's beliefs and intentions are taken into account during the development process, and there is a continual reminder of aiming for and ensuring user acceptance by the end of the process. This helps close the gap in the ergonomics literature

which although provides user involvement methods of how to involve the user, does not specifically work to create an understanding of the users willingness to be involved. The user's expectations of their perceived involvement and the extent and impact of that involvement may influence their acceptance, so needs to be considered during development. The steps M1 to M5 account for this, and step M5 does result in potentially providing information and training to influence the user's acceptance and compliance of the device.

Steps M1, M2, M3 and M4 have also been labelled as 'requirements' related steps, whereas step M5 is labelled 'specification.' This refers to the idea that some of the steps are more relevant to customers and others to designers. M1 and M2 would occur in line with the first stage of the process where the existing systems and target users are evaluated according to the requirements of the users. Steps M3 and M4 will help provide expert opinion and feedback, further extracting requirements of the users. The final stage, stage 7 would involve the designers more, as they would draw up the systems specification according to their findings on user requirements from the previous steps.

These methods overlap into design theory, and are used when considering; usability and user acceptance (Doerr, Kerkow and Landmann, 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. Design, supporting regulatory requirement in particular has influenced the framework. Elements of verification further support the need for iteration throughout this process, just as validation supports meeting of user needs. This appears in the framework as user involvement methods and steps taken throughout the process.

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 3.10). This aspect of the framework closes the gap significantly in the IS literature in relation to SSM, by providing methods to aid the execution of the methodology, and incorporate users giving the IS methodology a socio-technical advantage. This outer circle can be used to assess the extent to which users are conceptualized within the process of medical device development, as well as to monitor how thoroughly users have been engaged.

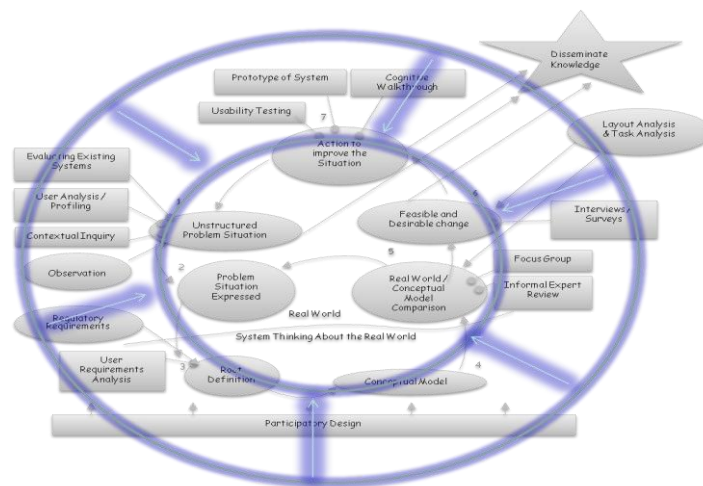


Figure 3.10: Inner and Outer Process of the Framework

This process can be further split (figure 3.11) 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.

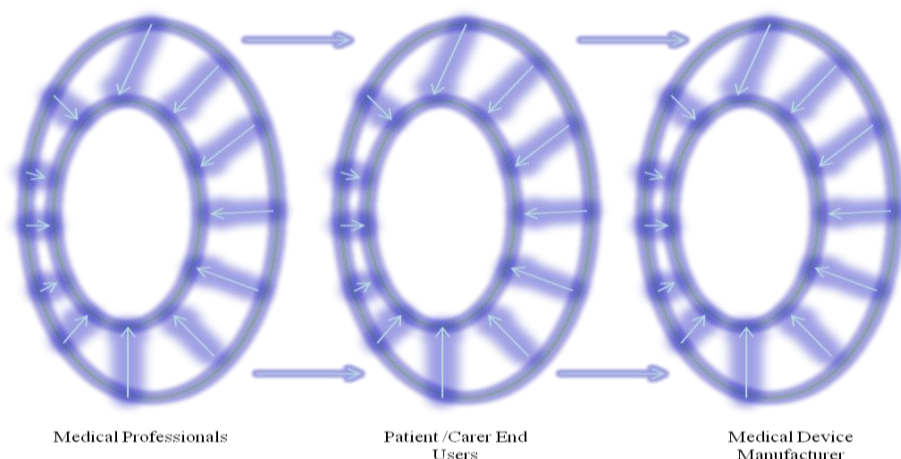


Figure 3.11: Split View of User Involvement in the Framework

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.

4 CHAPTER FOUR: *Research Methodology*

4.1 Introduction

This chapter will present the approach of the research, initially describing the research philosophy, within which the epistemological position of this research as well as the theoretical perspective is presented. Following this the chosen research methodology is discussed, subsequently producing the research framework for this study. The research framework is made up of the different phases of the research, including the exploratory, explanatory and interpretive phases. At the same time the framework builds in the phases of analysis, which inform the design outcomes throughout the research process. The data gathering instruments used in conjunction with the methods applied at each of these phases are described.

Following the description of the philosophical stance and the research framework, this chapter addresses issues relating to the credibility of this research. Issues regarding the objectivity, generalisability, reliability and ethicality of this research are discussed and in so doing justify the research pathway taken. The final part of this chapter looks at the proposed methods and tools that will be used to analyse the empirical research data.

4.1.1 *Research Proposition*

The research proposes that there is a role for the user within the development process of medical devices. The role of the user affects the success of medical devices and can be investigated firstly through recognising the different types of users concerned and then by understanding the extent of their involvement within the medical device development process, as well as their views and experiences of medical devices.

In order to address this question, identification of a holistic view of the process is needed alongside a theoretical standpoint of what this process should entail according to current industry practice in the area. Further to this, the ‘user’ needs to be understood, not only as a simple user with a concept of user involvement, but with the ability to incorporate the views and experiences of the end users, and how this affects or contributes to the development process.

4.2 Research Perspective

Certain decisions need to be made when delving into social research and according to Denscombe (2008) this includes confidently addressing issues of relevance, feasibility, adequate coverage, accuracy, objectivity and ethics. This chapter will look to cover these aspects and justify the research pathway constructed for this research. However before addressing these issues, the philosophical viewpoint of the research will be discussed, justifying the research approach taken.

4.2.1 Research Belief

The underlying research belief applied in this study is epistemology. This is more fitting than an ontological perspective which looks at the nature of existence and understanding what exists. Epistemology looks at what it means to know something, relying on philosophical background to decide on what kinds of knowledge are legitimate and adequate (Gray, 2009). Western philosophy has swung towards the *being* ontology whereby reality is thought to be made of clearly formed entities with identifiable properties. These entities are represented through symbols, words and concepts, which in turn leads to a representationalist epistemology, where signs and language can represent the external world. Representational epistemology moves on from a *being* ontology to a *becoming* orientation.

It is important to distinguish between the ontological or epistemological view at the start of the research, as this influences the research methodology that follows. As this research leans more towards the social sciences, and the social interaction of users with each other and the system, it follows an epistemological position. The reality that will present itself at the end of the research will be due to the interaction users have had with the system. The expression of user requirements that will be presented, based on the experiences of the user, will influence the extent of user involvement required in industry today for the process of MDD.

4.2.2 Research Paradigm

Three positions stem from epistemology, including; objectivist, positivist and constructivist. The epistemological stance taken for this research is constructivism, whereby truth and knowledge are constructed by individuals through their interaction with the world (Gray, 2009). Individuals *construct* their own meanings to the same phenomenon, rather than *discovering* a meaning or an underlying truth. This stance is most suitable for this research, in which users are being understood. Objectivism would not suffice here, as it believes in an

objective reality which exists whether or not individuals are aware of this truth or not. Positivism is closely linked to objectivism in that it believes the social world exists external to the researcher. It also adds that the natural and social worlds operate on a set of laws that can only be discovered through empirical inquiry. This research looks to learn from different users to benefit medical device development, and relies on the views and experiences that different user groups hold or indeed construct to increase present knowledge and benefit the successful development of medical devices.

4.2.3 Theoretical Perspective

The theoretical perspective most fitting for this research following constructivism is interpretivism. The underlying assumption for interpretivists is that knowledge is gained through social constructions (Klein and Myers, 2001). Interpretivism incorporates the view that social science research should reflect the distinctiveness of humans, and grasp the subjective meaning of social action (Bryman, 2008). Investigating users neatly lends itself to the social science notion of dealing with the actions of individuals, in line with this interpretivist perspective. Interpretivists rely on the judgements individuals make of a given situation, which for this case will be a healthcare related situation.

Interpretivism and postmodernism reject positivism and its emphasis on empirical inquiry and scientific laws being measured through observation alone. Yet postmodernism also falls short in its value to this research, as it rejects description of a 'reality' for a deeper meaning through representations of a social reality. In some respects this would be rejecting the view of the user, in order to make further interpretations as the researcher, as well as to match a theoretical interpretation. This was not the aim of the research, as the aim was to use the theory as a starting point to this research, to be built upon through the views incorporated on the users and their experiences.

Interpretivism has been categorised into different types of research by Klein and Myers (2001), and then further grouped into two distinct areas. Firstly, into the general foundations of interpretive research which includes the philosophical foundations, theories and methods, and secondly the application of interpretive research to information systems. This research will look to contribute to the latter, applying interpretive research to an IS phenomenon, using the former to understand the philosophical background of this research as well as social phenomenon. The research proposition of a role for users in medical device development, although looks within the healthcare domain, is being viewed as an information system and

hence being tackled from an IS perspective. Subsequently an interpretive structure can be used in the empirical investigations, to benefit this research. Methods such as interpretive case studies and field studies can be used to address the research proposition.

Following interpretivism, a number of approaches can be taken and in turn certain research methodologies. Table 4.1 adapted from Gray (2009), lists the potential approaches available for interpretivist research.

Interpretivist Approaches	Essential elements of this approach	Associated Research Methodologies
Symbolic Interactionism	Human interaction through meaning-making and interpretation. Meanings arise through social interaction Meaning is revised based on experience Change in perception of individual, changes meaning of objects and hence individual behaviour	Ethnography Participant - Observation Methods Grounded Theory
Phenomenology Research	People's experience of their social reality will help researcher to understand social reality Draws on subjective experience of subjective Eliminates bias through eliminating preconceptions See's value of interpretations of researcher and of subject	Interviews Small samples In-depth studies Longitudinal studies Qualitative methods
Realism	Takes scientific position, in which research such as culture, organisation exist independent of the researcher Systematic Analysis There are phenomenon that cannot be observed but do exist Some 'facts' are mere illusions Observable reality out there, but difficult to observe sometimes	
Hermeneutics	Social reality is socially constructed not an observable fact Social reality is difficult to understand through observation Interpretation is more important than explanation or description	

Naturalistic Inquiry	There are multiple constructed realities	Interviewing
	Inquiry is value bound to the researcher	Participant observation
	Inquiry is not generalizable, but specific to a case	Document and Content Analysis

Table 4.1: Interpretivist Research Methodologies (adapted from Gray, 2009)

The phenomenological approach seems most fitting for this research. It emphasises subjectivity, descriptions and interpretations, dealing with people's emotions, attitudes and beliefs (Denscombe, 2008) as well as people's experience of their social reality (Gray, 2009). It covers research styles that are removed from the scientific method of inquiry and do not rely on measurements or statistics (Denscombe, 2008). It looks particularly to understand how individuals make sense of the world around them (Bryman, 2008), using qualitative techniques.

Symbolic interactionism would have also been advantageous to this study, allowing exploration into an individual's interaction with the system, and how it can lead to changes in behaviour. Ethnography studies needed for such an investigation however could be difficult to accommodate in the time allocated for this research.

4.2.4 Research Methodology

Subsequently the research methodology which follows is predominantly phenomenological research. It emphasises inductive knowledge (Gray, 2009), able to pick up descriptions and experience of people in their natural settings. Research into the area of health has often taken a phenomenological approach as it allows for the individual healthcare users and their experience of life to be understood, removed from any preconceptions. There are many advantages to using phenomenology, including; the fact that it allows for complex accounts, gathering descriptions to reflect the complex social world (Denscombe, 2008). The research is humanistic, with a respect for people built in. This approach allows experiences to be explained in a way which is accessible and open to a wide audience and is suited to small scale research.

However at the same time there are disadvantages. There are issues that the small samples needed for such research means there are issues of generalisability with the research data (Gray 2009; Denscombe, 2008), and hence concerns are present whether this data is really representative. This issue can be addressed by following phenomenological research, but

also by taking advantage of hybrid research methods. This will allow incorporation of a number of methods to gather the qualitative data, through different sources of data and using various voices, i.e. both manufacturers and patients. Using multiple data sources gives the research a very liberal interpretive flavour, allowing positivist notions of triangulation to manifest within the research.

There is also the fact that methods following phenomenology focus more on collecting descriptions rather than analysis, giving focus to mundane features of life. Although this can be seen as a disadvantage of phenomenology, this actually helps this research to see how users incorporate medical devices within their daily lives due to old age or chronic diseases. In some instances this may well include looking at mundane or routine aspects of life, but at the same time helps to understand users' experiences, which is what this research is concerned with. In terms of analysis, although the phenomenological approaches do not provide any subsequent methods of analysis, there is the opportunity to select appropriate analysis methods after the data has been collected. This will be discussed in more detail later on in the chapter, as will issues of generalisability.

4.2.5 *Philosophical Stance of this Research*

Hence the following philosophical research perspective is taken to address this problem, adapted from Gray, 2009.

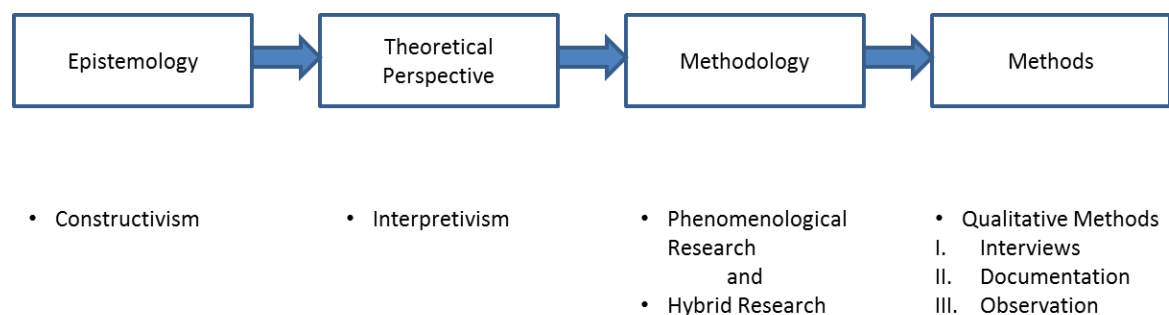


Figure 4.1: Philosophical Research Stance

4.3 Research Framework

The research will take the following structure:

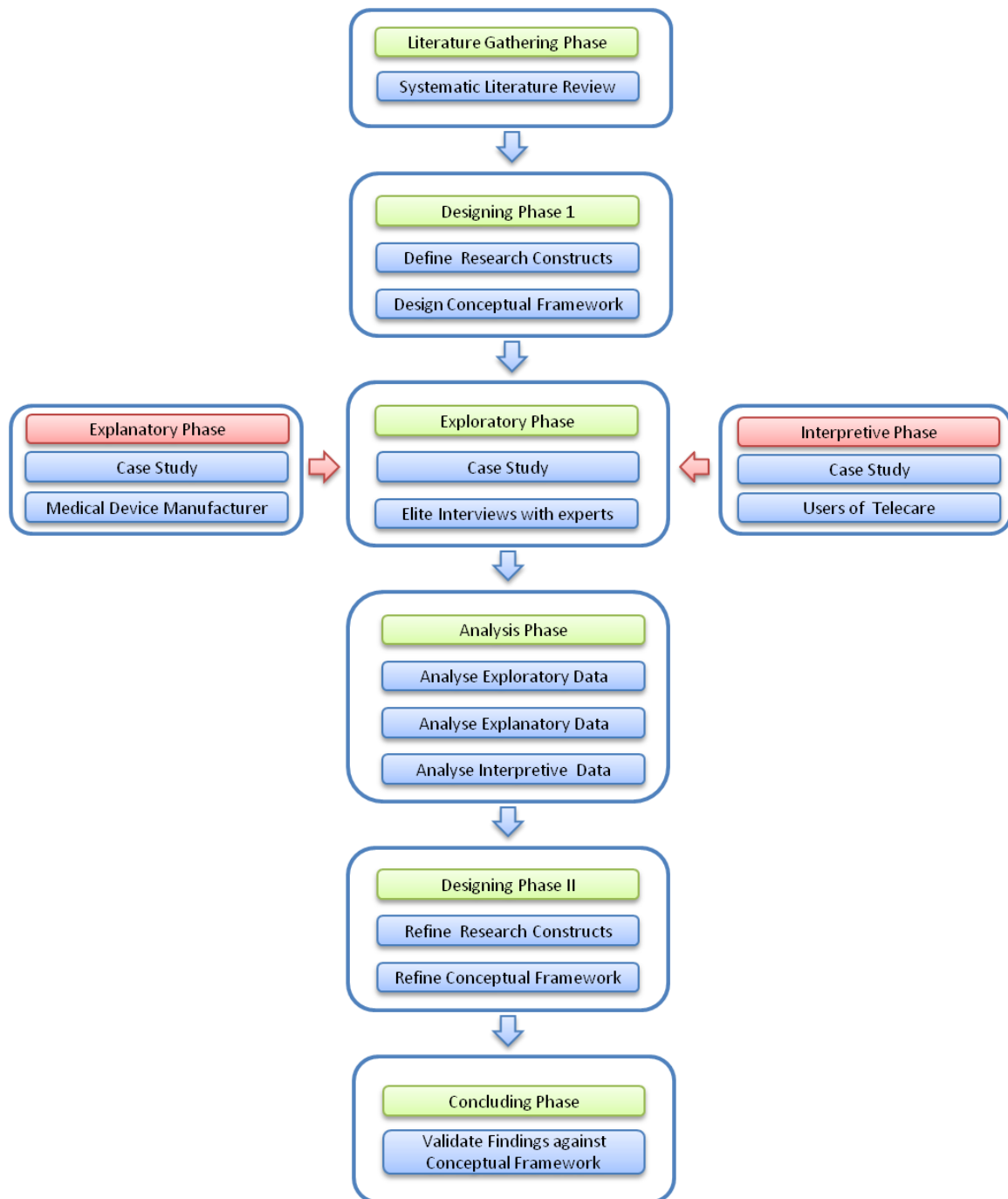


Figure 4.2: Research Framework

4.3.1 Literature Gathering Phase

Previous research in the area of medical device development needs to have been analysed in detail in this phase, capturing relevant information on medical device development and users. The broad content of the study is presented, providing linkage with other studies in this field.

4.3.2 Design Phase 1

This phase ensures that the constructs of the research are sufficiently drawn up, following the literary findings. Following this, the design of a conceptual framework which suggests a user involved process of medical device development is constructed. This is produced by looking at industry processes of medical design development as well as through incorporating user related methods across disciplines of information systems, ergonomics, health psychology and design.

4.3.3 Exploratory Phase

The exploratory phase will look to investigate and discover the process of medical device development from its practical standpoint, by exploring current practice and knowledge in the field. This involves interviewing experts in industry, through the elite interviewing method - the benefits of which will be described later in the chapter. This phase will not only validate the framework, but will further inform any design changes required to enhance the conceptual framework in light of these interviews.

4.3.4 Supplementary Data Collection

4.3.4.1 Explanatory Phase

The explanatory phase will use a particular industry example as a case study, looking to supplement the data collected in the exploratory phase, by considering industry processes in further detail. After gathering the holistic overview of the process from the previous phase, this phase will discover how the process is executed and why. This will enable further insight into how and when user engagement takes place to better understand the user's role in the development of medical devices.

4.3.4.2 Interpretive Phase

In conjunction with the explanatory case study, an interpretive case study will take place. This will explore peoples' experience of the system, and their perception of these experiences (Gray, 2009). This study will look to focus on a particular medical device and the users affected by this device. By looking at the rollout of a particular type of device, user perception of their involvement in relation to the development of the device can be understood. Their experience can provide a view to their level of acceptance of the device, and hence what can be done to make the device more acceptable to the end user.

4.3.5 Analysis Phase

The outcomes of the exploratory, explanatory and interpretive phases will provide further data in relation to the true role of the user in medical device development. This will feed into the analysis of the proposed idea of user involved medical device development.

4.3.6 Design Phase II:

This phase will refine the design of the conceptual user involvement framework of medical device development in light of the analyses of the empirical work. Industry practise should either back up the claims made in the literature, or indeed describe process constituents which occur in industry today undiscovered through the literature search.

4.3.7 Concluding Phase

The concluding phase will draw upon the different threads of the research and validate the findings against the conceptual framework.

4.4 Research Methods

The research framework described following interpretivism and a phenomenological research approach, makes use of qualitative research methods. Qualitative research includes the use of qualitative data from interviews, documents and participatory observations (Myers, 1997). A combination of these methods is used throughout the different phases of this study and will be described in this section as data gathering instruments. The method of interviews is used almost exclusively following a phenomological stance. This research will make use of this method by conducting different types of qualitative research interviews dependant on the user group in question, as well as in-depth case studies, to solicit the relevant information. Qualitative research is especially useful in this study as it helps to build understanding of a social phenomenon (Myers, 1997).

4.4.1 Data Gathering Instruments in the Exploratory Phase

4.4.1.1 Semi Structured Interviews

Semi structured interviews benefit from open ended questions which look for richness in the responses. This is necessary on all the research phases of this work. The research looks at acquiring knowledge from industry in the exploratory phase through elite interviewing. Confidentiality will play a great part to these businesses, and hence interviewing eliminates some of the restrictions that follow such a method. For example confidentiality issues means

that many ‘Elites’ have reservations of committing themselves to written responses on paper, but will be more open to discussing their views. Time limitations due to busy work environments means face to face interviews can assess the situation and ask the most appropriate questions within an allocated time.

4.4.1.2 Elite Interviewing

The first step towards validation of the framework is to be undertaken by the collection of primary data, using the qualitative research method of elite interviewing. ‘Elite’ individuals – those considered influential or well informed people within their organisations are to be interviewed, in this case senior management in medical device manufacturing companies within the research and development capacity. This specialised form of interviewing will provide a valuable source of information, as the interviewees are in a position in which they can provide an overall view of the process of MDD. ‘Elites are able to report on the organisations policies, past histories and future plans from a particular perspective, contributing insight and meaning to the interview process’ (Marshall and Rossman, 1999). By exploiting this method, the essential detail can be captured, leading to a better understanding of the gap between the theoretical and actual model of user involvement in MDD.

4.4.1.3 Interview Structure

Section 1: Semi Structured Interview Questions

The elite interviews will be semi structured as ‘elites respond well to a high proportion of intelligent, provocative and open ended questions that allow them the freedom to use their knowledge and imagination’ (Marshall and Rossman, 1999). The interviews are to be conducted as follows; starting by building an understanding of the current processes the companies have in place, followed by discussions around user involvement, stakeholders, medical device acceptance and adherence as well as regulatory expectations (Appendix 1). Any interesting comments are to be noted and followed up during the discussion.

Section 2: Graphic Elicitation Tool

The second part of the interview will use the theoretical framework as a graphic elicitation tool to focus further discussions around. The diagrammatical representation provides an overview of the topic, uniquely acting as a further stimulus to extract knowledge from the

interviewee. Researcher-generated diagrams as graphical elicitation tools are regarded of higher value rather than representations produced by the interviewee, as researcher-generated diagrams can illustrate the subject of study allowing interviewees to compare their own conceptions and experience against (Crilly, Blackwell and Clarkson, 2006). During the interview, the conceptual framework can be discussed, to further focus the discussion. This will also help gain expert opinion on parts of the process or methods or any business related ideas that should be emphasised.

4.4.2 Data Gathering Instruments in the Explanatory and Interpretive Phases

4.4.2.1 Semi Structured Interviews

Semi structured interviews will also be used for the explanatory and interpretive phases of empirical inquiry. These phases examine the user experience, in which clarifications or follow up questions may be needed for deeper answers. Hence the semi structured interview method is most appropriate as it gives enough room to probe for answers which is considered important when exploring a subjective meaning tied to phenomenological research (Gray, 2009). At the same time this method of interviewing ensures that a focus to the criteria of the research can be maintained. The interview schedules will be drawn up for these phases once the elite interviews have been conducted, as these interviews will be used to validate the findings from the exploratory phase.

This research process aims to refine the conceptual framework, by using available literature and current industry practice in the area to produce an ideal process for medical device development which involves users. The next point of validation is through the use of the framework in a practical scenario, to understand how and why the process takes place and the user experience of it. Only by applying user related techniques from the literature, and going through the process of development, will these techniques truly be assessed and measured against a real life medical device development process. The framework can test how the current process works through the methods it draws upon, and to which extent the users are conceptualised or appreciated during this process and in particular at which stages. The continuity of involvement can be determined, looking into how user participation and involvement is used to benefit the later stages of development.

4.4.2.2 Case Study

For an in depth analysis of new or next generation product development, the case study approach will be used. Case studies also follow from a phenomenological research stance and allow for a thorough examination of the relationships, processes and experiences to take place in a particular instance (Denscombe, 2008). This approach is appropriate for small scale research such as this. It helps eliminate the bias created from exclusively elite interviewing of the process of development by ensuring the voices of different users within the described process are also considered (Myers and Newman, 2007). By looking at one instance, insights into the complexities and wider implications can be gained, that would not have been understood from a high level view, 'the aim being to illuminate the general by looking at the particular' (Denscombe, 2008). The process of development is made up of its constituent parts; the explanatory case study in industry will allow understanding to develop on how these parts relate to each other and aid, contribute towards or learn from the involvement of users. The interpretive case study looking at telemonitoring participants will look at the end users of the product, and their experience of the device, and their role in its development if any.

The case studies will be made up of mixed methods including, qualitative interviews, semi structured in nature as described above, as well as observations and document analysis.

4.4.2.3 Observations

Qualitative observation is intended to be applied in this study and is considered a very direct approach of social research. It does not report on what people say they do or think, but draws on a first-hand eye witness account of the events (Denscombe, 2008). This data is reliant on fieldwork in natural settings (Mays and Pope, 1995) to facilitate data gathering in real life situations. Since the case study research will take place in the field, i.e. in business offices or patients' homes, the opportunity to take note of any observations which reflect on the research questions is present, and will be used as a complementary technique to readily gather insights (Mays and Pope, 1995), which are difficult to elicit through interviews alone. These observations may provide further opportunities to ask question where appropriate.

4.4.2.4 Document Analysis

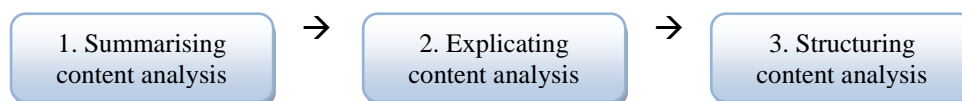
Document analysis systematically reviews or evaluates documents in order to develop understanding and knowledge (Bowen, 2009). Qualitative research requires multiple sources

of data to corroborate the findings as a means for triangulation (Bowen, 2009), discussed later in this chapter. In this research, document analysis will be used in combination with the other qualitative research methods used including; interviewing and observation, as a further source of evidence to aid triangulation.

4.5 Data Analysis

4.5.1 Method

Content analysis is an approach to qualitative data analysis which makes deductions from the textual data, by identifying categories and classes within it (Gray, 2009). In conventional content analysis, the coding categories are derived from the text data directly (Hseih and Shannon, 2005). Theoretical classes can be identified through the process of analysis, indicating the key patterns and associations in the data. After identifying the categories three steps follow to analyse the data:



Through these steps the material is paraphrased or summarised, clarified through adding context material e.g. dictionary terms and described according to assigned key features respectively. For the first step of paraphrasing a standard procedure of coding will be used. This will include the steps of; transcribing the data, coding i.e. identifying themes, familiarization, focused deeper reading, reviewing codes and generating theory (Gray, 2009). The final step of generating theory is not used in content analysis, which is its downfall as content analysis is not able to explore relationships between variables. However combining the coding methods with content analysis, can help to organise the text with detailed familiarization with it, as well as generate some links in the results.

The type of content analysis will vary when applied to the findings from the different phases of the research. This research has followed an interpretive stance throughout, in that it relies on the social interactions of the users with the system to determine and analyse findings according to the perceptions and experience of the users involved. The exploratory study has been set up as there is limited or insignificant literature in the area of current industry practice, hence conventional content analysis will be relied on to analyse the data gathered (Hseih and Shannon, 2005). The categories or themes identified are not preconceived; rather

they will derive from the research data. Use of open ended questions in the interviews aids this inductive technique. Each of the categories identified are then discussed according to the interview data as well as related back to theory and relevant literature in the discussion of the empirical findings. The conventional content analysis method is to be combined with directed content analysis in the second stage of the interview in which the use of a graphic elicitation tool is proposed.

Directed content analysis will be required in the explanatory research phase. Although the interview is scheduled to start with department managers presenting their role and the department's functions, relying on quite open ended question, the second part will ask questions relating to the themes drawn up out of the exploratory phase. Here directed content analysis can take place as further descriptions regarding the different identified themes will be gathered, and existing code developed for the exploratory phase can be used, before any new or further ideas are coded (Hsieh and Shannon, 2005).

For the interpretive phase, conventional content analysis will again be used as the aim is to describe the phenomenon of telemonitoring in the lives of its participants (Hsieh and Shannon, 2005). Themes relating to the experience of the patients will still be unknown at this stage, and the study looks to eliminate any bias when telemonitored participant's answer questions, in order to draw from the interviewees unique experience.

Although content analysis is unobtrusive, carried out without affecting the environment or person under study, the disadvantage is that the analysis is dependent on the researcher's interpretation (Marshall and Rossman, 1999). This can bias the results, however at the same time content analysis provides the opportunity for the careful checking and reviewing of the data under review as the data is analysed away from the source.

4.5.2 Tool

The qualitative data analysis will require the aid of computer-assisted qualitative design analysis software (CAQDAS). The transcribed interviews will be uploaded to QSR NVivo 8 software, which allows for the text to be coded, themed and retrieved efficiently (Bryman, 2008), subsequently drawing together relevant and similar facts and ideas from across the manufacturers views. This dictates a thematic analysis of the transcripts, identifying the similarities and differences between the different interview accounts, further making possible a direct comparison against the themes of the framework, its constituent parts and the

underlying theory grounded through the literature search – i.e. triangulation. In this way findings will be crosschecked, eliminating any bias in the qualitative research approach and enhancing the confidence in the findings (Bryman, 2008).

4.6 Factors Affecting Credibility of This Research

As suggested by Denscombe (2008) there are certain factors that affect the decisions made in social research including the objectivity and accuracy of research, adequate coverage i.e. sample sizes, issues of relevance and generalisability, feasibility and ethical considerations.

4.6.1 Objectivity - Credibility of Interviews

Interviewing can often create quite an artificial situation, requiring answers under time pressures, being intrusive to the social setting and potentially interfering with people's behaviour (Myers and Newman, 2007). To create fairness in conducting these interviews and eliminate interviewer bias, it is important to maintain a certain interview etiquette, which is consciously repeated for each interview. Myers and Newman's (2007) suggest seven guidelines for the qualitative research interview, which recognise the potential problems and pitfalls that may arise, ensuring preparation against such eventualities can be taken. Each of the seven guidelines (figure 4.3) will be addressed in order to give the interview programme a structure, which aims to maintain a degree of objectivity.

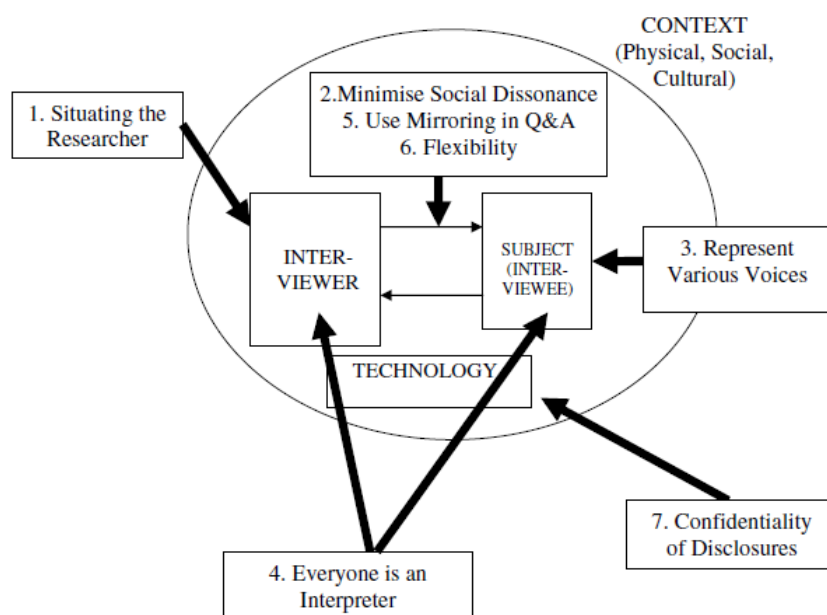


Figure 4.3: Guidelines for the Qualitative Research Interview

1. *Situating the researcher* – Ensuring introduction of myself at the start of the interview, my background and my research interest. Providing where appropriate a letter or information sheet detailing my credentials alongside the interview schedule.

2. *Minimise social dissonance* – Present myself appropriately to industry experts, and be aware of my patient interviewees to ensure they are comfortable with the questions asked.

3. *Represent various voices* – This research focus' on the multiple users of medical devices, and the data gathered will reflect this focus through interviewing manufacturers and patients, to ensure a variety of views are accounted for.

4. *Everyone is an interpreter* – recognition of the interpretive perspective of this research

5. *Mirroring* – All interesting points made by the interviewee will be noted and followed up straightaway or in further discussion during the interview. The initial questions will allow key terms and jargon to be expressed by the interviewee, which will be consciously used in the questions to follow where appropriate

6. *Flexibility* – All interviews will be semi structured, to give the interviewer maximum opportunity to elaborate and partly drive the discussion according to their views.

7. *Confidentiality of disclosures and ethical approval* – A consent form will be signed before the interview takes place, detailing preservation of confidentiality and anonymity when reporting the research. No attributions will be given to the views expressed by the interviewee and all persons and their views will be respected. Ethical approval will be sought from Brunel University Ethics committee as well as the relevant NHS Research Ethics Committee. Commitments made to respect confidentiality or report findings will be fulfilled.

As suggested by Myers and Newman (2007), using these guidelines as a checklist will enhance this powerful research tool and be of value in gathering data. Further to this it is important to ensure that the questions asked reflect the objectives of the research. Drawing the questions from the research constructs shaped from the literature search can ensure the focus is maintained.

4.6.2 Representativeness

Although it is preferable to conduct random sampling, this research makes use of non-random sampling techniques. This is mainly due to the particular medical device industry under review and the specific types of users being interviewed.

4.6.2.1 Sampling Strategies

For the elite interviewing in the exploratory research phase, criterion sampling strategy will be applied to select a sample for study. The main focus will be senior managers in the research and development side of medical device development.

In the explanatory phase the industry case study sample will be selected through an intensity sampling strategy. From the companies interviewed in the exploratory phase, one information rich case will be selected to review in depth. This will ensure that sufficient background on the company and their processes are known, and a judgement can be made on whether this company will suffice for an in-depth study. The study will include a review of the different departments involved in development to examine processes in greater detail as well as from the viewpoint of departmental managers, who will be more involved in the logistics of product development.

Criterion sampling will be used for the sample of telemonitoring patients in the interpretive phase. The criterion is to be a telemonitoring participant. The individual must be in receipt of a telemonitoring device. The participants of this sample will be specifically targeted and written to on account of them using telemonitoring equipment and having experience of it in their daily lives.

4.6.2.2 Sample Sizes

The size of the sample will aim for a minimum of eight with the industry and patient interviews. This is seen as a sufficient size, which ensures that different perspectives are captured until no new viewpoints are emerging from the data (Knight, 1999, *cited in* Gray, 2009). The sample size for the industry case study will depend on the number of departments across the business which are available, to be interviewed. One representative from each department will be interviewed.

4.6.3 *Interpretative Rigour*

Interpretative rigour relates to providing a full as possible demonstration of the evidence, which can be conducted through applying a technique of triangulation (Kitto, Chesters and Grbich 2008). Triangulation is used to ensure that the most comprehensive approach is taken to address the research problem (Morse, 1999) gathering information from multiple sources or by using multiple data gathering tools (Denzin, 2005). This improves reliability and validity of qualitative research (Golafshani, 2003) and increases confidence in the results (Thurmond, 2001). There are different types of triangulation, and this research will predominantly focus on methodological triangulation. Methodological triangulation will be used to strengthen the research, as a number of methods will be used to gather the data including; interviews, observation and documentation. Although triangulation is commonly related to a positivist research stance, in this research it is being applied solely for good research practise and not to prove a positivist research stance.

4.6.4 *Ethical Considerations*

It is important to get participant consent for the use of any data collected from or about them. Furthermore, it is important to ensure ethical use by using it for the purpose intended only, as there is concern for confidentiality, both by companies and individuals. The Data Protection Act 1984 deals with protecting privacy in relation to the processing of personal information (Bott *et al.*, 2001), relevant when conducting patient interviews. Making clear the extent of the patients' obligations, and their ability to withdraw from the trial any time is also important to ensure they do not feel any unnecessary invasion of privacy or at any disadvantage by participating or not in the study. Confidentiality also plays a big role for companies, as it relates to maintaining a competitive edge in terms of their products and processes. It is important to show understanding of this, and ensuring anonymity when disseminating results of the studies.

4.6.5 *Risk Analysis*

There is of course the risk that the proposed data collection sources may not be available or difficult to obtain when data collection commences. There are a number of possible alternatives for each of the research phases.

Although for the exploratory phase 'elites' would be the best source of information, if it became difficult to obtain willing participants, the search will be broadened firstly to the

whole of the UK and then to members of the organisation in less senior roles, possibly middle management or departmental management.

If a specific case study in industry proves difficult to organise for the explanatory phase, further explanations can be sought by arranging follow up interviews with the individuals already interviewed in the exploratory phase. These contacts could be further utilised to suggest others in the company that could provide a different view point on the organisational workings. This would help to get another viewpoint on the claims made in the original interview.

Including patients in the study could also prove difficult due to the extensive ethical review application process. To ensure this research does not omit the patient perspective, patient representative groups will be contacted through hospitals for interview as these groups will be able to speak on behalf of the patient and would have knowledge of the needs of this user group. However engaging with patients directly will provide real data of user experiences and any opportunities to interview patients will be pursued first.

5 CHAPTER FIVE: *Data Collection*

5.1 Introduction

This chapter explains how the research was conducted, against the planned research phases described in the previous chapter. Execution of the exploratory, explanatory and interpretive phases is described. Specifics of how the chain of evidence was constructed for each of the case studies are presented here, together with final details on the sample sizes, instrumentation, interview administration and analysis.

5.2 Exploratory Phase

The exploratory phase consisted of empirical research conducted in industry, with the intention of learning from industry, about their current practices. Qualitative interviews were held with ‘elites’ as proposed, across nine medical device manufacturing companies in the UK. The initial contact with companies was made through the industry links held within the EPSRC (Engineering and Physical Sciences Research Council) funded research group MATCH (Multidisciplinary Assessment for Healthcare Technology Centre), who sponsored this research, by applying criterion sampling. Contacts with research and development directors or equivalent were targeted first. Any contacts made were utilised in furthering access to people and companies through a process of snowball sampling.

The sample of interviewees were in each case managers holding senior roles, who were involved in research and development and / or had experience of overseeing a project from start to finish. After ethical approval was obtained (Appendix A1), criterion sampling was applied in order to ensure senior managers were recruited, and letters sent out were addressed specifically to managers who met this profile (Appendix A2), together with information sheets (Appendix A3) and consent forms (Appendix A4). These were considered the experts as they were able to provide factual knowledge about the process of development, and at the same time able to discuss their view of it, any benefits and concerns they had heading for the future. The interviews took place at each company’s respective locations for each case, lasting up to one hour in length. Audio recordings were made of all interviews and transcribed for subsequent analysis.

The interviews were semi-structured, conducted as per the design described in chapter four, section 4.4.1. Section one of the interview schedule, started by building an understanding of the current processes the companies had in place, followed by discussions around user

involvement, stakeholders, medical device acceptance and adherence as well as regulatory expectations (Appendix A5). Section two used the theoretical framework as a graphic elicitation tool to focus further discussion around (Appendix A6). Interesting comments were noted and followed up during the discussion.

5.2.1 Industry Cases Studied

Nine medical device manufacturers were interviewed, all of which work on a global platform, and are internationally recognised for their respective product portfolios. Table 5.1, lists the companies, summarising the interviewee's job titles and the types of devices each company makes. The user-ship of the devices, i.e. a list of all the users involved in the development of the devices is listed, alongside a list of the target user / customers of the devices.

Each company is denoted by a letter of the alphabet (A to I) for anonymity. Where there is more than one interviewee present, the letter is followed by subscript number, for example C₁, C₂.

Company	Job Role of Interviewee	Types of Device	User-ship	Target User / Customer
A	Technical Director	Safety critical medical electronics	Clinician, service user	Clinician
B	Senior Application Scientist	Laser Doppler system – burns imaging	Clinician, patient, nurses	Clinician
C _{1 and 2}	C ₁ CEO C ₂ R&D Manager	Diagnostic, treatment and preventative care solutions	Clinician, patient, opinion leaders, manufacturing team	Clinician and patient
D	R&D Manager	Wound therapeutics – wound dressings and electromechanical devices	Manufacturing groups, patients clinician, carer role, key opinion leaders – surgeon, dermatologist (consultant)	Clinician and patient
E	Territory Manager	Elective orthopaedic prosthesis – implants and trauma products	Design engineers, patient, clinician, surgeon	Clinician
F	R&D Director	Infusion care, airway management, temperature and pain and safety and vascular access	Consultant, nurse, therapist, physicist, anaesthetist, researcher, clinician, patient.	Clinical champion
G	Director of Applied Science, Point of Care and Diagnostics Medical Sales	Point of care devices, e.g. coagucheck and cardiac biomarkers	Clinician and patient	Clinician and patient
H	R&D Manager	Imaging systems, MR, CT scans, ultrasounds and X-rays, monitoring equipment, cardiac and home.	Clinicians, patients, radiologists, radiographers, physician, technician, marketing, applications and financial people.	Clinician
I	Trial Manager and User Assessor	Manufacture Electrodes for ECG monitoring, ambulatory monitoring, moving into home monitoring	Clinicians, nurses, patients	Clinician and patient

Table 5.1: Findings on Device Type and User Range for Company's A-I

5.3 Supplementary Data Collection Phases

Following the exploratory phase two further sets of data were collected, categorised here as explanatory and interpretive data collection phases. This supplementary data, took the form of case studies, their advantage being the ability to illuminate the general by looking at the particular (Denscombe, 2008). Case studies seemed most relevant here, as they would help determine the causal relationships rather than just descriptions of events (Gray, 2009). This approach looked to answer the how or why questions and will be used in conjunction with data collected in the exploratory phase, to ensure the validity of the expert opinion.

5.4 Explanatory Phase

The explanatory case study looks at industry in depth and is explanatory in that it seeks to understand why and how the processes take place, and how the business processes link across the organisation and within departments. The decision to look at one case in particular from the initial expert interviews conducted was taken in order to gather more detailed and valuable insights into medical device companies' processes and relationships. This served two purposes; firstly it expanded upon the holistic overview presented by the industry interviews, providing significant detail on how the various parts of the organisation worked together and affect one another. Secondly it made clear the feasibility of users fitting into the process of development from a functional perspective. The relationships with users and the social processes could also be understood better and help differentiate why certain outcomes might happen.

Company G (table 5.1) was selected as an information rich case, from those initially interviewed at the exploratory stage, by applying intensity sampling. This case was seen as information rich compared to the others as it targeted both clinicians and patients and had a vast product range to that effect. This meant that multiple users were included in the process and hence multiple-user involvement activities could be discussed. The exploratory elite interview conducted with this company determined that activities engaging both types of customers took place. Furthermore this sample offered access to multiple departments from which to collate data, which other companies approached were not prepared to do.

Descriptions provided on what the processes were in the exploratory phase, were further explained in the explanatory phase. The in-depth case study enabled the gathering of details of the activities of the various departments, to get a feel for why and how certain activities

take place and their relationships with the user related aspects. This included; how and when the user was involved, why some users are given priority and how this relates to the departmental and business objectives in this particular case.

5.4.1 Explanatory Case Study: Medical Device Manufacturer

The departments interviewed included the Technical Department (TD), Customer Services (CS), Marketing Department (MD), Supply Chain (SC) and Distribution Department (DD), with one manager interviewed from each department. Table 5.2 tabulates the details of the case study, showing that it is the process of development that is under analysis here, and details the inclusion and exclusion criteria.

EXPLANATORY CASE STUDY	
Unit of Analysis:	<p>The process of medical device development (MDD):</p> <ul style="list-style-type: none"> • The official process of MDD for company G • The perspective of management • The evidence of user involvement in the process of MDD
Inclusion Criteria:	<p>Departments which are involved in the process of medical device development, and communicate with end users</p> <p>UK offices</p> <p>Allow access to multiple departments</p> <p>Available within the allocated time.</p>
Exclusion Criteria:	Departments which deal with the organisational requirements of the business, e.g. human resources, but do not directly relate to the development process.
Key Participants:	Managers of departments
Number of Cases:	<p>Two:</p> <p>Case 1: Organisation</p> <p>Case 2: Department</p>
Number of Participants in each Case:	<p>Case 1: 1 Participant (Senior Manager)</p> <p>Case 2: 5 Participants (Department Mangers)</p>

Table 5.2: Case Study: Medical Device Manufacturer

Figure 5.1 represents how the explanatory case study was conducted (*adapted from Gray, 2009*). The case study was split into two areas – the organisation and the departments, i.e. it had multiple cases under study. Figure 5.1 labels these as *Case 1* and *Case 2*. Case 1, looked at the organisation as a whole, drawing on the expert interview conducted for Company G. Case 2 looked at the departments, conducting interviews with managers of the relevant departments. These two instances under study, were ascribed their participants i.e. the specific person or area to be investigated. The participants are explored in depth via research questions based on the hypothesis or research proposition (Johnston *et al.*, 1999). The chain of evidence following the selection criteria was built, starting with the conducting of the case study i.e. the qualitative interviews.

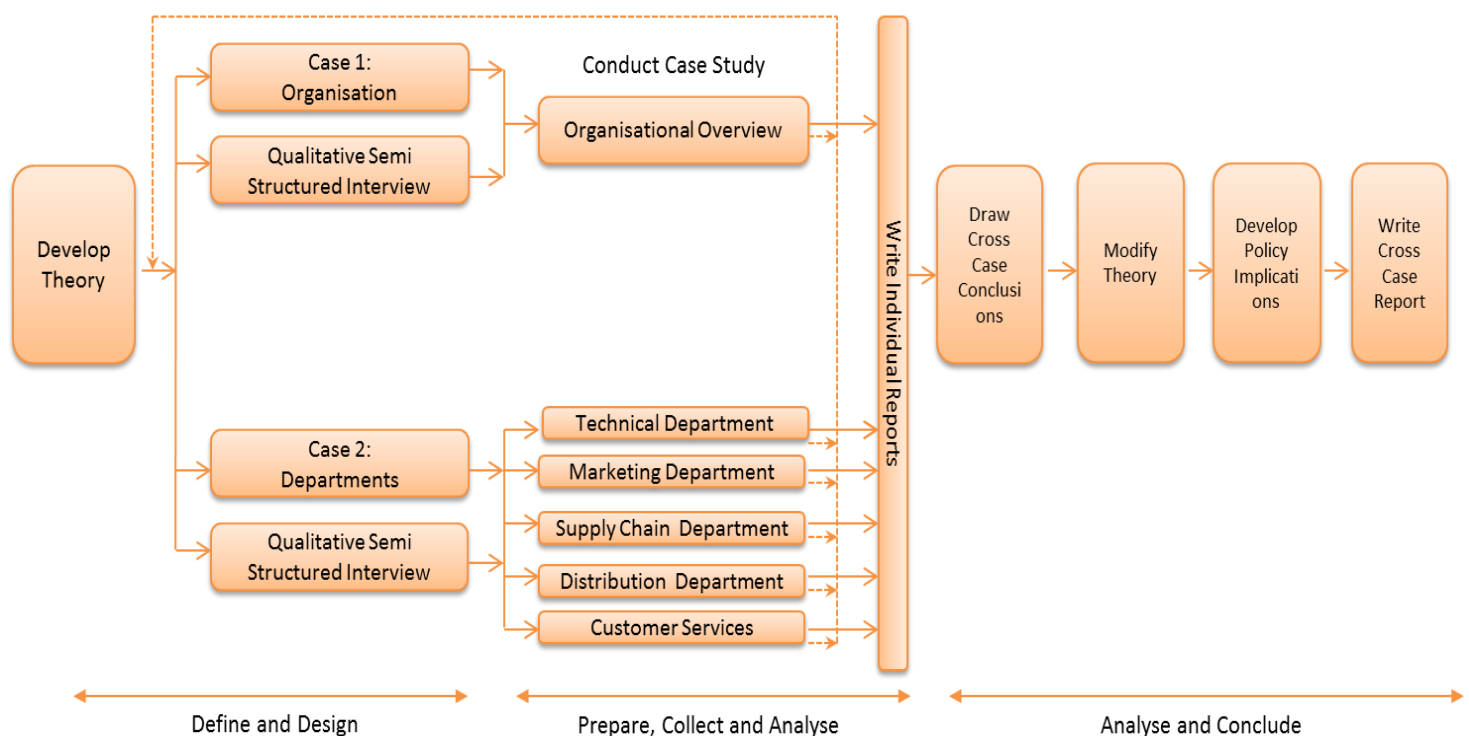


Figure 5.1: Method for Conducting In-Depth Case Study in Industry

The sample interviewed consisted of managers of departments. Due to global nature of this company, only some departments operated from the UK which restricted the sample available to study. The departments interviewed included the; technical, marketing, supply chain, distribution, and customer services departments. Each were involved in activities relating to the concept and feasibility stages of development, and had some role for the user which fed back into the iterative cycle of medical device development.

The interview schedule was drawn up as follows: The first part included a short presentation by the department manager on the function of their department and their daily activities, the second part of the interview consisted of follow up questions along the themes identified in the literature. Notes were taken and interesting points followed up by further questions. Observations were also made on the relationships between the different departments, how the offices were set up and the software used to input any user related feedback. Documents relating to the hierarchical structure of the organisation were also collected and reviewed. The interviews took place at the companies' UK offices, lasting up to one hour in length with each department.

The raw audio data produced was then transcribed and uploaded to QSR NVivo 8, which ensured the data could be organised appropriately. Each case was firstly uploaded under respective department headings with individual reports made for each. Then after careful scrutiny over the material, relevant ideas were selected and themed, building themed records of the data captured. From this the relevant conclusions could be made, theory modified and policy implications noted. The final analysis on this is given in chapter six.

5.5 Interpretive Phase

The interpretive phase was designed to further explore the end-user experience of using a medical device, and their perceptions of their role in the process of medical device development.

Interpreting the patient perspective meant the need to interview patients. Due to the difficulties in gaining such a group of participants for research, considering the time element of the ethical review process, this sample was selected when an opportunity presented itself. A link made with the director of assistive technology at Nottinghamshire City Council, presented access to telecare participants. The criteria for this study became telecare users (Table 5.3) instead of telemonitored patients. This sample was also a politically important case, as policy makers are still undecided about the value of implementing telecare initiatives, and such a study could influence their decision.

5.5.1 Interpretive Case Study: Telecare Device Users

The unit of analysis in the interpretive case study was the users of telecare. The evidence to inform this analysis came from a number of sources including interviews, observation and document analysis.

INTERPRETIVE CASE STUDY	
Unit of Analysis	<p>Users of Telecare:</p> <ul style="list-style-type: none"> • The perspective of telecare participants / patients • The perspective of carers • The perspective of service providers • Evidence of user involvement in the development of these devices
Inclusion Criteria	<p>Participants involved in the use of telecare devices within their home</p> <p>Devices acquired through the Nottingham Safe at Home programme</p>
Exclusion Criteria	Participants not using telecare devices within their home
Key Participants	Telecare Users; patients and carers, Programme Managers
Number of Cases	3 Cases
Number of Participants in each Case	<p>Case 1: 10 Participants (Telecare Participants)</p> <p>Case 2: 1 Participant (Assistive Technology Manager)</p> <p>Case 3: 4 Documents (Feedback Questionnaires)</p>

Table 5.3: Case Study: Telecare

Figure 5.2 represents how the interpretive case study was conducted. This case study was split into three areas – the telecare users, management and service user feedback. The interpretive case study once again had multiple cases under inquiry. Figure 5.2 labels these as *Case 1*, *Case 2* and *Case 3*.

Case 1, looked at telecare participants which predominantly involved interviewing the patients. Letters of invitation detailing the study information (Appendix B1) along with consent forms (Appendix B2) were sent out to potential participants. In some instances carers were present, having expressed their wish to accompany the telecare user during the interview. In such situations the carers were invited to take part in the conversation and offer their views. Direct observations also took place during the interview; these observations were overt in that if any observations were made during the interview relevant to the discussion, they were openly brought to the attention of the interviewee for their comments. Case 2 looked at the manager, running the assistive technology programme in

Nottinghamshire. His view on the aims of; the device, the service and its users was questioned. Case 3 involved the examination of documents, showing the analysis of feedback from users of the telecare service. This feedback came from patients and carers, dated February 2010 and November 2010.

Figure 5.2 diagrammatically represents how this was done.

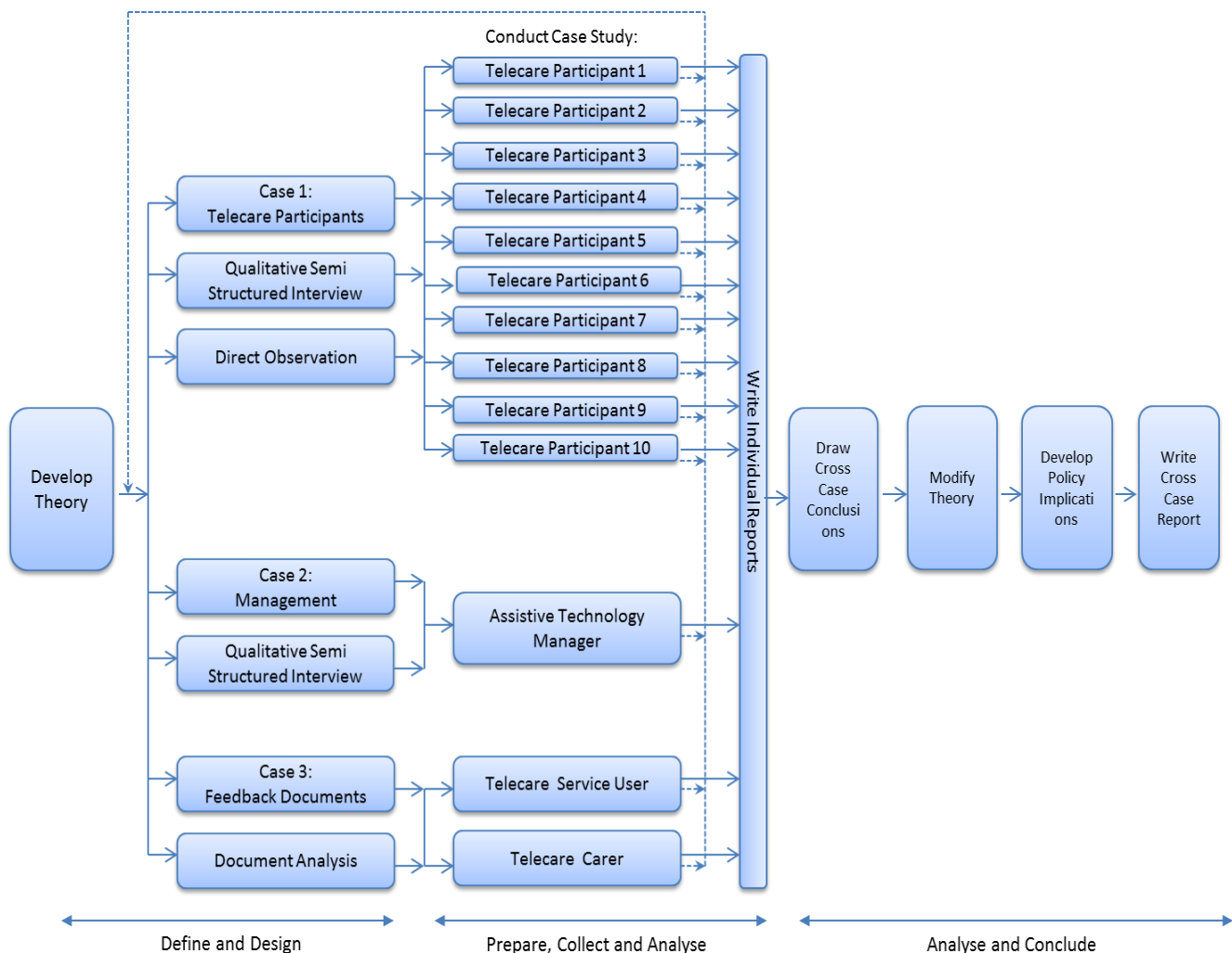


Figure 5.2: Method for Conducting the Telecare Case Study

As with the previous case study a similar course of action was taken; the interview schedule and protocol were drawn up and followed, producing raw audio data. This data was then transcribed and uploaded to QSR NVivo, which ensured the data could be organised appropriately. Each case was firstly uploaded separately, reporting on findings from individuals. Following this relevant ideas were selected and themed, building themed records of the data captured. In this case the themes did not incorporate all those relevant to manufacturers, as identified by the literature. For this case study a select number of themes

were taken, in a view to supplement the findings from the manufacturer perspective. The themes looked further at ideas of user acceptance and adherence, self-management through knowledge and patient contribution i.e. feedback and user experience. This case study can further add to the conclusions drawn regarding user involvement in medical device development. The final analysis on this is given in chapter six.

The patient interview schedule (Appendix B3), consisted of questions asked under the following headings: the equipment, determinants of acceptance, value of patient contribution, patient experience, self-management and adherence. These areas were representative of the findings from the exploratory phases of the research; both the literature search and ideas expressed in the qualitative industry interviews, relating to patient involvement.

Direct observation took place in the telecare participant's home, during the interviews (Appendix B5). It was structured observation as there was a clear idea of what needed to be observed. This included seeing whether the device was being used in the way the user said they were using it, mainly just by noticing the positioning of the alarm hub and the trigger devices. Further to this the presence of a Carer was noted, as well as any notable mobility issues of the telecare patient.

The interview scheduled with the assistive technology manager (Appendix B6), started by looking at the history of the telecare programme run by this particular council. How it came about, the problem it addressed, the target users and the data sources which influenced the decisions relating to the introduction of the telecare initiative were discussed. This was followed by questions relating to the progress of the telecare programme, how the user's needs are addressed, and user feedback is incorporated. The overall opinion on the success of the programme was also considered as well as future plans going forward.

Documents detailing feedback from users as well as from carers were collected (Appendix B4). This feedback looked at the user experience of the device and the service provided by the council. The data was collected in February 2010 and again in November 2010. The results of this feedback data are used in combination with the interview data to draw conclusions on this device.

The interviews with patients were conducted at the Patients homes, after giving them the option to be visited either at home or at the local council building. Due to the universities 'lone-worker' policy, a member of research staff from within the departments research group,

accompanied me on the visits. The interview with the assistive technology manager, managing the telecare programme took place in the local city council offices. Audio recordings were made of all interviews and transcribed for subsequent analysis. This is described in chapter six.

5.6 Reflection on Conducting the Research

The research was conducted following the exploratory, explanatory and interpretive phases to collect data. The data gathering instruments used for the exploratory study included the elite interviews, semi-structured in form combined with the use of a graphic elicitation tool. This worked well when capturing data from experts. The semi-structured questions ensured enough space for the experts to elaborate on the question, drawing on past experiences, current projects, and examples within their respective companies. Introducing the graphic elicitation tool in the latter part of the interview was advantageous as connections could be made on what had just been discussed, and any areas that had been overlooked were elaborated upon. If this had been introduced earlier it may have been detrimental to the research, potentially creating some bias in the answers by limiting the discussions around the theoretical perspective.

Thirty letters were sent out to different medical device manufacturers; followed up by an email after a one week interval. Yet it proved very difficult to obtain interviews in industry. The difficulties encountered in trying to get these interviews were mainly due to concerns around confidentiality. Further to this, busy schedules of people holding such senior positions meant many just couldn't afford the time. The search did start off looking at the local area, but was quickly extended out. Any issues or concerns expressed by those who did engage in some response via email were addressed, giving assurance of the anonymity of the process, as well as sending out information sheets ahead of time so that the interviewees were aware of what to expect. Two telephone interviews in which time or geographic distance was an issue were conducted.

When conducting the interviews it was very important to have some background knowledge on the products the company were making. Although this had briefly been looked into prior to making contact with companies for interviews, by visiting company websites, the details of this were extended upon at the start of the interview. Some of the global companies delved in very many different devices for healthcare, so knowledge of the interviewees' area of

expertise was needed. This would be advantageous to conducting the interview in that the questions could be adapted accordingly, i.e. in relation to a particular device or target user.

Conducting interviews in industry really presented a greater picture of how industry works. Quite often it seemed that the different companies were open to understanding and incorporating the perspective of different users, but constraints related to the nature of the business world became a barrier. In many cases businesses still managed to draw upon users views in a variety of different ways. Often this was through groups representing different user's e.g. patient advocacy groups.

The explanatory case study combined interviews and observation to obtain a greater understanding on the industry perspective. The interviews were semi-structured and were based on information provided by the departments on their activities. Questions were asked to either clarify or elaborate upon interesting points, which related to the aforementioned literary themes. At the same time any observations made on the tools being used by the departments which related to their communication with one another as well as their customers were noted. This in-depth industry case study which aimed to look at one particular case was agreed upon during the elite interview for that company. Initially this seemed a very straightforward step for the explanatory case study, however became difficult when the management changed. It took a lot of perseverance and persuasion to continue using this company for the case study. Several months passed before the study could go ahead due to the breakdown in communication. Once the case study commenced however, the company were very accommodating and willing to help.

The interpretive case study also made use of interviews and observations as well as document analysis to gather the user perspective. The interviews were semi-structured once again, and highlighted some of the areas identified through the literature relevant to patients. There were patients and carers present for some of the interviews, providing both perspectives to the interview questions. Observations were particularly important here, as it could be visibly seen and noted how the device was being used. In this case the device needed to be on the interviewees' person – which was not always the case. Documents analysis also added great benefit to this case study, as reports on service user (patient) and carer feedback were presented for February 2010 and November 2010. This analysis included responses from 222 service users and 185 carers in November 2010. The interviews enabled the opportunity for service users and carers to elaborate on the perspectives of these different users.

The preference to look at patients came about due to the shift towards self-management which became apparent through the literature search. Although industry had their own perceptions on patients as end users, it was important to get the view from the patient side. Patients proved to be very difficult to include in research due to the extensive NHS ethical approval procedure. Patients who had newly started using a medical device for their care were the initial target end user to include in the investigation, and the possibility to question telehealth patients arose. Nottinghamshire PCT was engaged in a trial, where telehealth devices were being given to chronic patients with CHF (chronic heart failure) or COPD (chronic obstructive pulmonary disease). However after pursuing this for a year, with still no acceptance from the NHS research ethics committee, different options were pursued. Discussions with those working for the Nottingham City Council involved with the telehealth project took place, and details were provided of a telecare project that was also taking place. After being informed that an extensive ethical approval would not be needed to interview telecare participants, a research protocol was drawn up and letters of invitation to potential patient interviewees were drafted to begin recruiting. Very quickly the care team sent out the letters together with an information sheet and consent form to potential candidates. The first ten replies were contacted, and interviews arranged.

It was very important in the telecare study to understand the situation of the telecare participants. The first interview conducted was with a lady who was suffering from Multiple sclerosis (MS). After ringing on the doorbell several times, the author rang the contact telephone number. The carer who lived across the road answered, and came to unlock the front door. Upon going in, the author found that lady was in quite advanced stages of MS and was unable to physically move. This did have an impact on the questions, as asking questions like ‘has the device changed your life?’ seemed a little out of context, as clearly the disease was having the greater impact on lifestyle, with the device being just an aid. Further to this, although the telecare devices are there to provide assistance in case of an emergency, in this case the participant was using the device to reach the assistance of her carer – who was also her mother, on a daily basis, sometimes several times in the day. This was because she could no longer use a phone, and was living alone. Other issues came forward when arranging interviews. As many of these participants were elderly, they were very concerned about their security, and wanted details from how many interviewers would be attending to which vehicle should they be expecting on their premises.

To ensure objectivity Myers 7 guidelines for the qualitative interview were followed. Before every interview the author was careful to introduce themselves and the research, providing information sheets and obtaining consent forms before the interviews commenced. The author presented them-self appropriately, and at the same time ensured awareness of the interviewee. For the elite' interviews, basic research on the company was conducted prior to the interview, obtaining some knowledge on the companies' products via their websites, as well ensuring understanding of interviewees job role. For the telecare participants, basic information on the patient was obtained which included details of the telecare participant's condition if any, and demographic information. Various voices were considered as in industry top level managements and departmental management were questioned. In terms of end users, carers as well as patients were addressed where available. At the same time all those under interview were asked about different users involved in the process of development, or in their care and the significance of this involvement to them. The author was sure to further the discussions around interesting points, and the flexibility of the semi-structured interview accommodated this.

The sample sizes were important when conducting elite interviews and telecare participant interviews. The sample sizes were nine and ten respectively, in line with the proposed minimum of eight interviewees. Reliability of the data was made possible, through triangulation of data methods used. The interviews were supported by observations made, and again through analysis of documents obtained. This made the data collected more reliable. Ethical approval was obtained before conducting any of the interviews. Interviewing in industry was approved by the Brunel University Research Ethics Committee (Appendix A1). Interviewing telecare participants was conducted in conjunction with Nottinghamshire City Councils 'Safe-at-home' initiative; separate approval was not needed as they have a programme of seeking feedback regularly to improve their service.

6 CHAPTER SIX: *Empirical Data Analysis and Discussion*

6.1 Introduction

This chapter includes the analysis of all the empirical work conducted, and is broken up by research phase; exploratory, explanatory and interpretive. The themes of analysis are first outlined to present the structure of the themed analyses that follows. The themes are drawn out of the findings through coding the interview text. These themes are followed by coding schemas, which set out the references made to interviews, documentation and observations for each of the phases. This is followed by the themed analysis, which is the analyses of the interview findings presented under themed headings as deduced through the content analysis, making up the main bulk of this chapter. Rather than summarising each phase separately a final conclusion is reached at the end of the chapter which draws on all the threads of the empirical research, bringing the findings across the different phases together. After the conclusion a section of design action is presented, explaining the design implications to the conceptual framework in light of the empirical findings.

6.2 Overview of the Exploratory Phase

Themes identified through conducting content analysis relating to medical device development and user involvement were captured. These themes include;

1. Stages of development
2. Identifying the user
3. User involvement
4. User acceptance
5. Feedback and iterative design methods
6. Knowledge dissemination
7. Regulatory requirements
8. Business requirements

This chapter begins with an analysis of the industry interviews, under the eight themes listed. The thematic analysis identified a number of key ideas that are characteristic of the manufacturer's perspective. The results provided a holistic interpretation of the process of development and the factors that influence or contribute to this process. Tabular summaries of the findings are presented and then related back into the design of the conceptual framework later in this chapter.

6.3 Themed Analyses

This section captures the findings from the interviews and links them to the conceptual framework. The use of multiple types of data from the interviews and from available literature triangulates the results, aiding their reliability.

The coding system used for this analysis is as follows: Each company or case is denoted by a letter A through to I, each letter representing one of the nine companies interviewed. Where there is more than one interviewee present the letter will be followed by a subscript number 1 to 2, for example C₁. This will be the case for all quotes from the interviews.

6.3.1 *Stages of Development*

The main stages of medical device manufacture are formally noted as the stages of ‘concept, feasibility, design and a confirmatory launch phase’ (Company C₁) or similar (table 6.1: formal named stages). Significant activity takes place during and prior to the concept and feasibility stages, which although admittedly is not formally prescribed by these companies (Companies B, C, E and F), is deemed crucial by them when setting the specification. The design steps have been defined in the literature wherein the process for the design of medical devices comprises four steps; task clarification, concept generation, embodiment design and detailed design (Shefelbine *et al.*, 2002). These steps are also reflective of those incorporated in the soft systems methodology (Checkland, 2000) as follows; the problem situation unstructured/expressed, conceptual model, real world vs. conceptual model comparison and feasible desirable changes respectively.

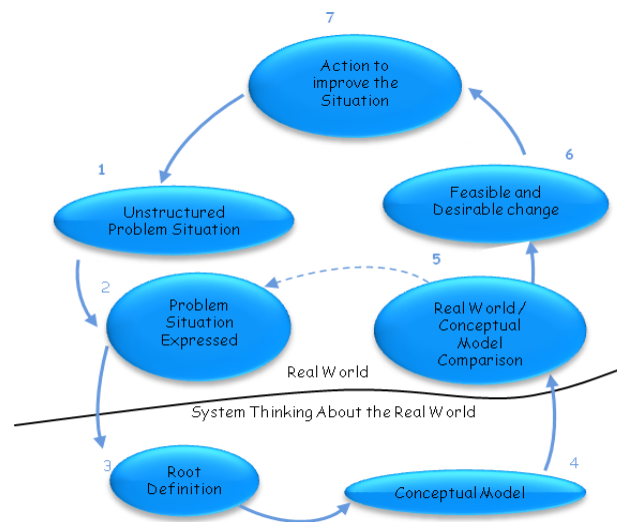


Figure 6.1: Inner Structure of the Conceptual Framework

The fundamental early stages of the process of development across these companies was the same in parts to the inner structure of the framework proposed (figure 6.1), despite the varying terminologies used.

To start with, the concept is based on a variety of potential factors, including; modifications of existing products - ‘a lot of our products are evolutionary rather than revolutionary, so the development is usually increasing the performance of existing systems (Company H). A new idea - ‘a design engineer comes out with something that they think, oh fantastic... we are finding that more and more the design team will come up with an idea’ (Company E). A new technology (Company I), it has been validated in the literature that Information Technology is the most significant tool that can improve the quality and productivity of healthcare (Whitten *et al.*, 2008; Bates 2002; Issenberg *et al.*, 1999) and using IT can open new ways to reach citizens and enhance citizen participation in the healthcare process (Lapao, Santos and Silva, 2007). It is also agreed that technology could make possible management of patients in the community as well as provide a step towards empowering patients towards self-management (Jacobs and Lichterstein, 2003). The concept can also be based on a solution to a problem (Company F), or academic research - ‘it often springs out of the equipment we build for research (Company B), but these are considered to be a small percentage of devices, with academic circles having limited funding to develop the device beyond a prototype (Kaplan *et al.*, 2004). Long term patient data from clinicians, can also be used for concept development, ‘clinicians are operating day in day out, they’ll look at

their long term data from patients that they've operated on and can see patterns in success or failure' (Company E). Kaplan *et al.* (2004) validates this by suggesting that for new devices typically a physician or an engineer inventor conceives of a device solution, instigates the patent process and starts a preliminary prototype.

Identifying the problem can be seen as a step prior to the concept stage, and sometimes this already involves use of ergonomic methods (table 6.1: preliminary steps) to identify users, failings or imperfections in an existing system or portraying new concepts. Table 6.1 looks at the stages of development and differentiates between stages within the development process as 'preliminary steps.' The preliminary steps are often not agreed by the companies (Companies B and D), and in such cases the expertise and experience of the project team are called upon, which may be limited. The methods described and categorised under 'preliminary steps' in table 6.1, can neatly fit into the first two stages of the theoretical framework (figure 6.2) which looks to un-structure and express the problem through identifying the existing system, its problems, its users and the environment. According to Panescu (2009), identifying the market potential and clinical need is also a necessary part of securing the right funding.

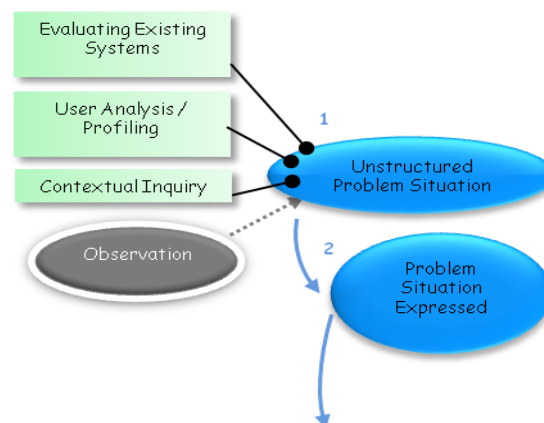


Figure 6.2: Ergonomics Methods Used In the Conceptual Framework

These 'preliminary steps', are all involved with understanding and conveying the problem through identifying the existing system, its problems, its users and the environment. Company D explicitly mentioned that they 'would 'evaluate existing systems' as an offline exercise.' This involves detailed data collection which is needed to provide evidence for the development cycle to begin, as 'in medical device companies it is all about evidence' (Company E). This can be in the form of market data, user data or design related data. 'From

the research and development point of view, we take those user inputs and kind of start off with a very open mind about how we might approach coming up with a solution' (Company D). Interviews, questionnaires and surveys were common methods used to access data prior to product development. The companies interviewed all specified this to be useful in collating feedback from users, as quite often the products were evolutionary and were an improvement on existing devices.

6.3.2 *Identifying the User*

In relation to user profiling, all the companies interviewed try and distinguish their users from the beginning. This is necessary as users can be as varied as the devices themselves (Daraghmi, Cullen and Goh, 2008). Company A start the process of MDD with a detailed risk analysis in which all the types of users are identified. Company B start with feedback from their users on existing products. For company C 'the first step is really about understanding the user' (C₁) so that they can justify the need for the product. They have a specific process within the company that they have to follow, to develop user needs. General internal assessments on user needs are promptly validated by actually involving customers, users and all the stakeholders from the process. Similarly for company D, 'the input for research and development is very much; user needs and market assessment. We have specific processes within the company that we have to follow to develop user needs.' Company F also take the view that 'the first step is really about understanding the user, to understanding what is the need and being able to validate that need they justify outside input.' Nebe, Grotzbach and Hartwig (2006) suggest that knowledge about the types of customers creates a considerable advantage for the company as well as for the customer, so the company needs to understand the users and the market equally.

As every project undertaken will vary from the one before, the early assessment of user needs is a significant undertaking as it will contribute to the design specification at the end of the requirements gathering phase. MDD is seen as 'very much a customer or consumer led process' (Company C₁). The 'more user input you can get at any level is better because its user feedback as well' (Company D). Manufacturers recognise that the 'only value of building in the user inputs is to support the process by taking it forward and paying attention to their views' (Company D). It has been suggested that user involvement is derived from a consumerist agenda which is being enforced on health research and service provisions (Wright *et al.*, 2007). Following from this the user is seen as someone who should be an

active citizen in participatory research (Park, 1999).

It is a sound presumption that all the manufacturers interviewed are aware of their users and the need to understand them and their needs from the start. However, due to no real defined process of user involvement, it is up to the expertise and opinions of those in the business how they incorporate users, which may not be enough for the guaranteed success of medical devices.

6.3.3 User Involvement

6.3.3.1 Type of User Involvement Methods

Manufacturers did use many ergonomic methods throughout their development process. These methods varied across the companies interviewed as listed in table 6.1 (ergonomics methods specified). These methods took place at different points in the early stages of development, reflective of the proposed framework (figure 6.3), and involved different users including; patients, clinicians and design engineers. ‘We do a general assessment from our own point of view to develop the user needs internally what we think is coming up, but then we go through a validation step of actually involving our customers, users and all the stakeholders from the process’ (Company D). Abras, Maloney-Krichmar and Preece (2004) agree with this idea that embedding user involvement techniques from the start assures the product will be suitable for its intended purpose.

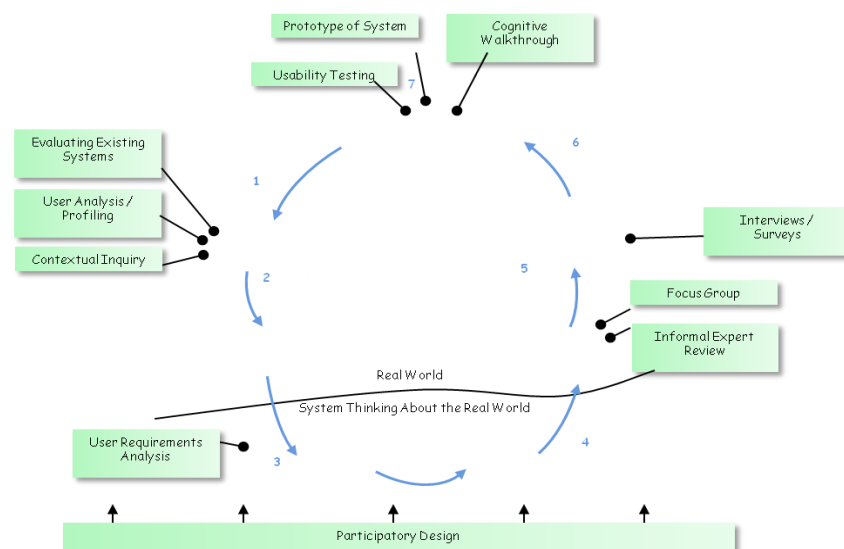


Figure 6.3: Ergonomics Methods Used In the Conceptual Framework

Some companies involve users when generating ideas, ‘we’ve done what we call ‘rapid customer feedback’ where we have actually got a focus group of people together and shown them four or five different ideas, discussion round what they would prefer and try and build that up into a prototype moving forward’ (Company D). The rationale behind this was to have a quick decision on which option to go with, or the best bits to narrow down to.

It was evident that various ergonomic methods were being used but in places quite inconsistently, ‘we have done contextual inquiry (CI), but on a very limited number of products,’ (Company D) The issues can be around the fact CI is quite an intrusive technique and it can be inappropriate to ask questions while tasks are being performed in a busy healthcare environment. Observations on the other hand ‘we emphasise, although very informally’ (Company D). Sometimes these techniques were not known to the whole team and required further training as with Company F and G. Further to this, some initial marketing activities are being outsourced to external companies (Company A, I) but there is the danger with this that manufacturers may be missing the opportunity to meet with their users and hence miss some crucial details. Across the companies interviewed there was a greater push for conducting observations and shadowing, ‘we use it (observation) to learn about indications that we are not operating in yet’ (Company D). This is validated through the literature as observation is seen as a core approach for an ergonomist (Stanton *et al.*, 2005), as it feeds data into other methods for requirements gathering. ‘Observations or ethnography is what we have started doing more recently but it is not deliberately part of our process at the moment’ (Company D) expressing their concern that during the early phase it was difficult as a business to engage in such methods as ‘the nature of them (ethnography studies) is that they are quite expensive, and the nature of this is that it is quite early stage so these two things are quite difficult to bring together some times.’ This is not a surprise as the practical constraint of conducting ethnography includes the time factor, which could potentially take years (Martin *et al.*, 2006).

Expert review panels and focus groups were evident across the companies, consisting of various members including key opinion leaders, representatives of advocacy groups as well as design engineers. ‘We actually get a focus group of people together and show them four or five different ideas, discussion round what they would prefer’ (Company D). These groups create a forum for all the required users or experts to be able to discuss their requirements together, ‘we would have a group of complimentary expertise around the table and then you

would have them discuss and prioritise requirements,' (Company C₂) reflective of a multidisciplinary approach. 'We certainly use our clinical advisory panels' (Company F). The best use of such a focus group would be at this stage where a conceptual solution can be discussed against the problem, allowing any concerns or interest to be expressed at this point.

Task and layout analysis from design theories are also used. These structured methods help to compose a rich picture of the user and how they behave to assist in design, according to Hackos and Redish (1998). In a medical scenario, these can be extended to take the form of clinical trials to judge the successful use of the product. Feedback on patients clinical trials might be used 'for later input into design of the next generation product' (Company G). Patient's preference trials can also provide feedback and be used 'for marketing purposes to say for example, that our product is preferred to another competitor product on the market' (Company G).

6.3.3.2 Benefits and Limitations

A point was raised that 'it is a completely arrogant attitude, but incredibly easy to think - *I know what the user wants*' (Company C₂). The benefit of user involvement as seen by Company C is that it enables them to address the usability and the softer sides of the product development. 'Involving users betters the amount of prompt feedback during development' (Company C₁) and also 'acts as a vocal advocate for the technique' (Company B). It means that companies can 'understand the extremes and be able to cope with extremes' (Company F), and 'improve the longevity of the device' (Company E). Company D propose that 'if everyone is performing the same on some functional performance of products, then how do you differentiate between different products... by using the consumer model of usability as the differentiator.' Negating such involvement would disadvantage the company as 'firstly it doesn't involve everyone and second it's not going to work if it's in the regulatory requirements that you need to do that, but the experts haven't endorsed it' (Company F). Wright *et al* (2007) express that involving various users in research provides a different perspective from that of clinicians and academics, based on the unique experience of the one living with the illness and reflects on the interests of the general public.

Evidently despite the enthusiasm for user involvement, there are certain reservations expressed by industry about excessive user involvement. 'If user involvement is formalised or becomes part of regulation it would... well help isn't the right word – it would force

people to do it' (Company D). Further to this companies should be aware of and cautious when dealing with patient expectations. 'If you tell a patient that you can develop it and customise it, it's something that they would immediately assume would be better for them, but it's not always the case' (Company E). The more information a patient is exposed to, it can cause them more worry over procedures, then actually provide benefit. In terms of competition there is a worry that 'the same clinicians will be targeted by our competitors – these people talk to one another so there is a risk of leakage and leakage of intellectual property even if we put the appropriate legal systems in place to protect that, it doesn't actually stop anyone from doing it – it's something we have to be mindful of in our position' (Company D). Furthermore, it's not necessarily seen as a competitive advantage 'if we are involving users and our competitors are too, it's not necessarily a competitive advantage, seen as a limit on the value that relationship building with clients would bring' (Company D). From the experts there were a wealth of concern relating to the impact on their business and competitive advantage, but in terms of detrimental to research there was not too strong a case. Wright *et al.* (2007) in their study looking at the criticisms facing public involvement, looked at concerns of the cost of involvement, where it was found that objectivity and representativeness among other criticisms, were seen as aspects that relate to the practice of research, and hence can be rectified by paying special attention to study design and informing the users on the objectives of the study.

6.3.4 *User Acceptance*

User acceptance should be seen as quite a separate concept from user involvement, as user involvement does not automatically guarantee that the user will accept the device, contributing to its success. The merits of a system can only be effective if the system is used so it is necessary to understand why people decide to use a particular information system (Mathieson, 1991), in this case a medical device. A variety of devices can be on offer for the same condition by different companies, so it is very important to discover what determines the approval of a particular design by the user.

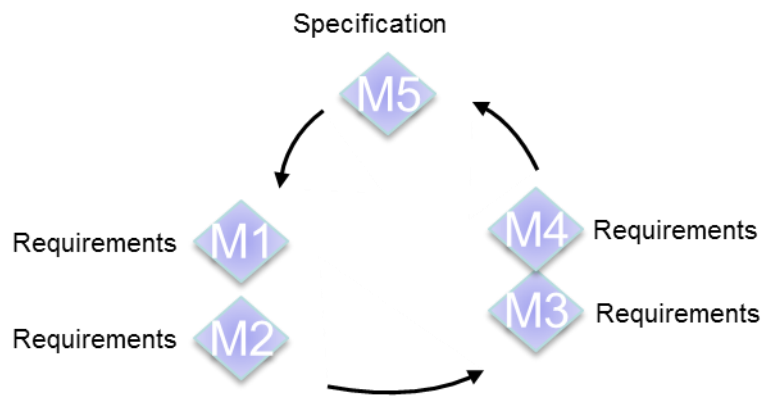


Figure 6.4: Steps Representing Behavioural Intentions

Steps M1 to M5 (figure 6.4) represent a scheme to identify behavioural intentions of the users, adapted from the theory of reasoned action - TRA (Sutton, 2002b, *cited in Ogden, 2007*). These steps help predict behaviour and its implications on health, with methods included to be carried out before the intervention, but not the intervention itself - this could be anything from persuasion, information giving to increasing skills and setting goals.

The first two steps; M1 and M2, align with the first stages of the framework in which the existing systems are evaluated. These pinpoint the need for the target behaviour and population to be identified, and the expected beliefs and behaviours of that population. In relation to determining behaviour of end users, Company D was of the opinion that ‘It is inevitable if you involve someone at the beginning you are going to get increased buy in to that product, like an advocacy to it as an outcome’. Hence some caution should be taken when influencing user behaviour, depending on the role of the user group in question, ‘in a clinical trial setting we are very deliberate not to influence how people feel about things, where as in an advocacy group we are very deliberate to influence how people feel about things’ (Company D).

Step M3 - conduct a study to determine which beliefs are the best predictors of behavioural intentions, can be useful when predicting the success of the device and to identify user’s response towards it. ‘We always aim to make our products as intuitive and simple as we can. We do a lot of work in the early design phase to ensure this, so the expectation is that when a customer comes to use the product, whether it is in trial or routine, compliance should be good’ (Company C). If there seems to be a problem in user acceptance of the device, this can be identified early on and the relevant changes made.

Step M4 allows analysis of the data to determine the beliefs between non intenders and intenders into further target beliefs followed by step M5 to develop an intervention to change these target beliefs. ‘Our compliance and adherence monitoring is done at a much larger scale as kind of market surveillance and I think that is appropriate for our product range.’ (Company D) In terms of influencing user acceptance to the product, company D took the view that ‘if you speak to the same person you spoke to on the outset they are always going to support you, as they are more bought into the process’ (Company D). At the same time company F admitted that for them ‘user compliance is difficult to measure and applies to very few of our products... it’s more use and effectiveness and the feedback on it which is measured.’ This was mainly because ‘our products go out and they don’t, always, stay in this controlled medical distribution network and vary in clinical practices around the world’ (Company F).

From the industry perspective, there does not seem to be any concrete evidence to suggest that user behaviour is influenced, other than presumably when selecting advocacy group members or marketing the finished product. There is no indication of company’s systematically influencing behaviour through the process. There may well be no need, but needs to be addressed further from the end user view to decide whether this part of the conceptual process holds any real value.

6.3.5 Feedback and Iterative Design Methods

Companies encouraged the opportunity to analyse data as it was collected, for example to develop the requirements specification. Company I involved their users to collate the information ‘we had an initial focus group on what the requirements may be’ (Company I). The requirements specification set some parameters that needed to be considered during innovation. A number of ideas can be generated taking these requirements into account and through further participatory design a single solution can be reached.

Participatory design methods e.g. personas were evident across all companies, ‘the early parts of the process would be where you prototype so it’s where you justify, build and get the feedback and then refine’ (Company C₁). This is reflective of the literary position taken on such methods as it has been argued that it is the participatory design approaches which seek to involve users more deeply (Jansson, Mortberg and Mirijamdotter, 2008; Crawford *et al.*, 2002; Kensing and Blomberg, 1998). Often the prototypes are based on existing equipment with modifications in software, followed by ‘a process of on-going improvement and

development' (Company B). At Company I, 'the prototype was given to the users without too much guidance or lead from the investigator, it was really an observation of what the clinicians first impressions were of the device and how they thought it could be used in the environment that they worked in.'

At the early stages the prototypes / mock-ups are designed to evaluate the product internally, as with company E, 'for a quicker representation, we take patients' CTs directly, from that do a rapid prototype, which very much tends to be a wax model, a shell, of what they're trying to achieve and at this point there's nothing to do with the patient; it's purely an idea on paper. They'll set their mock up models of it and then do testing protocols.' Devices are also tested internally against their technical specification. Products that are reliant on software upgrades, reduce some risk, as software problems are easier to correct, and newer software versions can be released as and when needed, for example with company C, 'we would try to have a very simple device and the technical stuff is all built into the software' (Company C₂).

When asking companies about the amount of iteration that took place, there was no standard answer - 'on some of the components, we went around one, maybe two, iterations. Yes, we're pretty close, let's just tighten it up. Others, we went through seven, eight, nine, ten, eleven, twelve iterations, refining the process. So, there's not a standard answer, I'm afraid' (Company F). There was clearly vast amounts of iteration to the extent that cut off points in design had to be decided 'there is a point at which the design is fixed, and that's it. You can't move on until it goes to the second generation. It's always a tough one from a development point of view because it costs a lot for fixing it now' (Company C₁). So depending on time and budget allocation, extra improvements may get left to the next generation versions. The reason behind this is stated as 'in clinical diagnostics, you would not wait until you have something that did everything you could think of because you would never get it out there. The research is always moving on, there is always more you can do' (Company C₂). The type of iteration that takes place varies, but according to the literature usually falls under user centred design methods in which end users influence how a design takes shape (Abrams, Maloney-Krichmar and Preece, 2004), covering methods that iteratively involve users at every stage of the development process (Venturi and Troost, 2004).

Following a conceptual model of a potential solution, stage 5 solicits user and expert views external to the company, and allows for a direct comparison to be made against the initial problem (figure 6.5) to evaluate the extent to which it has been solved. This is reflective of

the iterative design process as encouraged by information systems methodologies ensuring a more refined design outcome. If the solution is not effectively addressing the problem, stages 3 and 4 can be revisited and redesigned before moving forward.

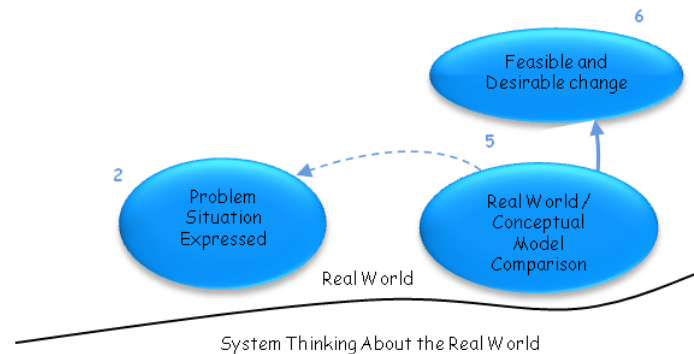


Figure 6.5: Iteration

The companies interviewed were well aware of the potential value of gaining feedback: ‘the feedback from clinicians, definitely dictated how things were going to go... the feedback was implemented into the design of the device, in terms of even the frequency that the data was going to be measured in, really tailored to suit the clinicians and the environment that they worked in as much as we could (Company I). There was also value of feedback from different user groups and patients and clinicians were involved as required, depending on the type of product being designed. Company G stated ‘if it’s a product for point of care that’s going to be used by patients, there would be different stages throughout the process where we got direct patient feedback.’ From one company’s perspective ‘sometimes it is necessary to get something out to the wider market and really get a more comprehensive & confident feedback so that you get the specifications for the second generation right’ (Company C). This is supported by company B ‘there are various things that feedback from *practical* usage.’

The relative use of any input provided by users was considered to be left at the discretion of management, and not always used. However, the manufacturers clearly recognised that the ‘only value of building in the user inputs is to support the process by taking it forward and paying attention to their views’ (Company D). Those interviewed also claimed that they did realise the value of any input, ‘any input we do get we would for sure use it, if not for the immediate product then incorporated for second generation product at least’ (Company D). Similarly with Company I ‘sometimes you may not be in a position to take on board feedback, and it would just be noted for future products.’ At the same time the interviewee commented that ‘it depends on the stage of development, for example the early version of our

device, was given to our clinicians for assessment, and the feedback that they gave was implemented into the design of the device straight away... really being tailored to their needs' (Company I). So although user input is at the discretion of the management, it does not mean it will not be used, rather factors affecting the business situation also need to be considered.

6.3.6 *Knowledge Dissemination*

Although there were many claims of involving users from the start, companies were also somewhat precarious when disseminating information in order to remain competitive 'we try not to involve people when it is too low level, because we are trying to protect ideas very much at this point' (Company D) was one comment. 'In some cases when we are doing research the company name isn't disclosed, working through research agencies and intermediaries' (Company C₁) the reason given for this was so as 'not to raise expectations, if the project doesn't go forward.' Company I agree saying 'the marketing aspect does raise expectations in some situations, causing problems if users are disappointed with the reality.' At the same time if there are 'competitors working in this space, the project can be quite sensitive and there may be limited feedback' (Company C₁). Company A 'don't provide knowledge about the product to the end users until near the end – competitive edge needs to be accounted for.' So although feedback is sought from users at the beginning it is fairly one way i.e. companies look to receive information more than they expect to give. This is due to firstly being mindful of the competition 'once we have registered our IP, our intellectual property will be in the public domain and we are a lot freer to disclose information to patients or clinicians,' (Company D) and secondly the business objectives 'information will most likely be given to patients once the in vitro testing has been done and once they've had the ethical approval to go onto a full blown clinical evaluation with patients' (Company E). This shows that in fact not a lot of information is given to the end users during development, and is seen as especially risky in the early stages. This is understandable as companies want to maintain and protect their competitive edge. This is not in line with the literary position taken, and the part of the conceptual framework that relates to figure 6.6. An important aspect that arose from the literature was to disseminate knowledge i.e. making information on new products available to its users and stakeholders, as well as liaising with them for their feedback. Health psychology models described in the literature, for example the health belief and fear drive models (Leventhal, Safer and Panagis, 1983) show how important patient knowledge is to aid self-regulation and motivation to act on any health related concern.

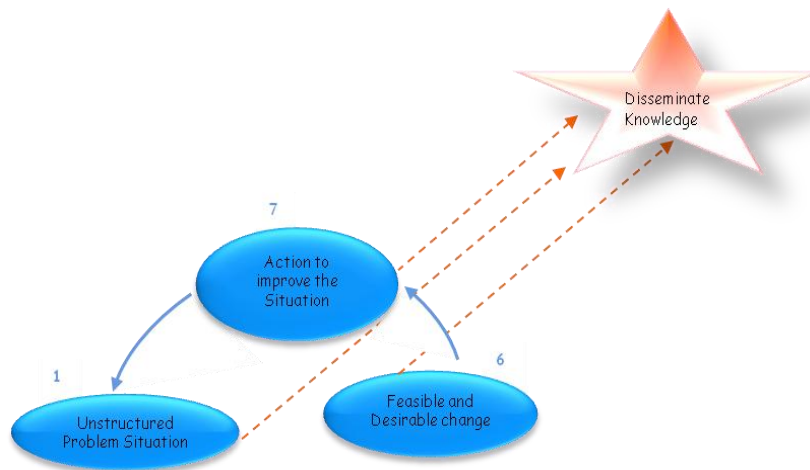


Figure 6.6: Knowledge Dissemination

6.3.7 Regulatory Requirements

The position regulatory requirements take in the design process is dependent on a company's personal preference to a degree. Regulatory requirements are mentioned in this research due to some of the quality and usability standards that could potentially impact the level of user involvement by a company. Further to this the level of 'burden' of regulation felt by some companies, means they make compromises when it comes to user involvement as are trying to manage and deliver on the obligatory requirements of device development first. Some agree that regulation should take place 'from the outset' (Company G), and for others 'standards are not obligatory... but you need to have a (documented) reason why you don't comply' (Company F). For some companies 'the only regulations that occur from the start are copyright, and making sure that your design is not impinging on anybody else's design' (Company E) and emphasising knowledge 'on 'state of the art' up to date developments in your field' (Company A). For others, regulatory obligations start at the feasibility stage, 'typically regulatory obligations don't really kick in until our feasibility phase and get more and more 'burdensome' shall we say as we move through the process,' (Company D) when the design outcomes need to be specified and reported to the relevant authority. It can therefore be argued that it is not necessary in the concept phase. Company D express 'in our concept phase we have deliberately taken out the steps that relate to the regulatory requirements, to give us a bit more of a freer space to innovate in.' Similarly for company C 'usually after specification is designed we need to think about the regulatory compliance fitting in, so a lot of it will be fixed quite early on in the development phase, so its documented right through' (C₁). It is wise to start taking onboard regulatory requirements

early on to ensure safe advances in healthcare, as there are concerns that the FDA (Food and Drugs Administration) device approval is becoming expensive in terms of time as well as cost (Lee *et al.*, 2006).

In the design of medical devices, regulation is of particular importance, as all devices need to be approved by the relevant authority, before they are released to market (Ward *et al.*, 2002). Companies do use regulatory requirements as a guide - ‘I think the regulatory framework would guide the process, (used as) more of a checklist’ (Company C₁). With time pressures in the competitive market, it is important to get the necessary obligations carried out, and extra elements can come after – in perhaps a second generation version. The conceptual framework produced from the literature was reflective of this idea. Here the regulatory checks were incorporated at stage 3 - the root definition stage (figure 6.7). This gives enough room for brainstorming and innovation of initial ideas, before they are organised into potential solutions with consideration for any regulations that may apply.

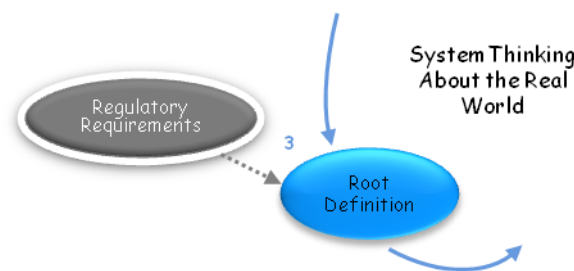


Figure 6.7: Regulatory Requirements Incorporation

There were suggestions that user involvement was to become part of regulatory requirements, so all companies would have to incorporate this in their process ‘even if companies don’t want to they are going to have to as regulation are pushing that way’ (Company D). It has been found through Nebe’s study, looking into the practice of a healthcare software company, that the lack of a defined way of documenting user and usability requirements, cause inconsistencies and difficulties to apply product changes in the future (Nebe, Grotzbach and Hartwig, 2006). The way the larger company’s operate with evolutionary product design, it would be advantageous for them to regulate even the usability aspects.

6.3.8 Business Requirements

The differences between manufacturers in terms of the types of methods they adopt, the type of user they include, and the numbers of activities companies engage in are largely dependent on two things. Firstly depending on what makes business sense to the company, and secondly

on whom the advocates of the products are. Although business requirements can be seen to be removed from the focus on user encapsulation in medical device development, for a medical device company the business requirements and hence business strategy does impact the level of user involvement that takes place and hence requires some discussion and insight.

The interviews made clear that launching a new or modified product to market brings with it certain pressures for manufacturers of medical devices. New medical product introduction is dependent on many factors for its success; 'success is not just dependent on design, it's about supply, it's about cost, it's about can the sales team sell it, can we get the price for it but it's also about user needs. So it's a whole series of business, clinical, design issues that come together' (Company F). For manufacturers 'medical device development is ultimately a business, rather than just a design' (Company F) hence any decisions made relating to user involvement reflect this reality.

The market size of the opportunity does play a big role for some companies when deciding to invest. 'This probably seems quite unfair from an ethical perspective, but if you've got a disease that affects a very small number of people in the world, unless you could make a massive improvement, from a business perspective you would not get the sign off for the investment into it' (Company G). This depends on the aims of the company; a lot of the large manufacturers want to increase their influence and control of the market. However a smaller company that specialises in such niche opportunities may well be willing to invest in such a technology. What does not make business sense for one company may still be worthwhile for another.

'Differentiating a competitive position plays a big part in reducing market risk' (Company C₁). With this come pressures to work within tighter deadlines to get a product to launch. For example 'if the product team says it is going to take 'x' amount of time to launch a product, the board of directors will ask for x-20%' (Company D). This sometimes means cutting out features which are 'nice-to-haves' to ensure that there is time to fit in regulatory requirements. Being aware of 'state of the art' developments in your field (Company A) and making sure you are not impinging on anyone else's design (Company E) is part of being a medical device manufacturer. Ensuring that design are kept confidential and getting the right copyrights and patents in place (Company D) is of high importance in the medical device industry, especially as 'development cycle's can last from anything between eighteen months to three years' (Company D) – meaning a lot of time and money has been invested in the product before it is

launched. This makes many projects quite sensitive and companies can be apprehensive about disclosing their names during trials, nervous of competitors working in that space as well as of raising patient expectations.

Informal expert reviews consider the advocates of the product who are quite often the leading clinical surgeons or specialists in their field. Clinicians were specified as advocates for all of the companies and hence it is in their interest to work closely with the manufacturers as the product could be tailored to their needs. Companies B and G specified patient advocates too and their activities reflected this – informal observations for feedback, preference and clinical studies, look and feel studies were emphasised. The involvement of clinicians and or patients is seen as almost a business requirement.

The companies interviewed all had extensive contacts with clinicians (Companies A and B), through comprehensive advising boards - to reach out to the professional field (Company C), internal recruitment of clinicians as well as external contacts (Company D) and through contacts with key accounts and key hospitals (Company F). Device development does require an active involvement from clinicians from the very beginning (Kaplan *et al.*, 2004). The appropriate clinicians are identified depending on the type of product that is being developed. Clinicians involved in the study, are involved throughout the development (Company F) and would become advocates of the product (Companies C, D and E) or clinical champions (Company F) used as a reference point for the design, as well as to promote the product when launched. This is validated through the literature where clinicians are seen to often take leadership roles or act as integral members of the design team, having intimate knowledge on the device (Kaplan *et al.*, 2004). Clinicians also have access to long term patient data, enabling identification of trends between patients and devices – an advantage to manufacturers gathering requirements. The clinicians' involvement however does produce conflicts of interest, which needs to be addressed to ensure 'patient safety, data integrity and public trust in the process.' (Kaplan *et al.*, 2004).

Patients are seen as a channel to understand user needs through meeting, shadowing and gathering their inputs (Company D). It is believed by some manufacturers that patients do hold an equal voice to clinicians (Companies C and D), and that patients influence the clinicians decisions (Companies A, B, C, D, E and G). In these cases companies do have comprehensive advising patient boards, however this is limited to the nature of the product in question. There is a limit to the value of talking to clinicians alone, and power relationships

means clinicians can dominate a discussion where different user groups are involved. The growth of patient advocacy groups has increased the demand for patients to be involved in research as a fundamental right (Wright *et al.*, 2007). This was supported by industry ‘There is a role for patient advocacy groups to act not only as a counter to clinicians but also medical device companies – it’s not something you want to cut back on’ (Company C₂). Unfortunately whereas clinicians can become advocates of a product due to their position and influence, ‘the overall effectiveness of speaking to a limited number of patients is seen as relatively inadequate’ (Company D).

Table 6.2 outlines the case for and against patient and clinician involvement, and proves that companies recognise the value of input from both. The difference present, where one user takes precedence, is often down to the type of device being designed. In places where there are conflicts between user groups some companies are working to systematically eliminate bias by the aid of computer software or by facilitating extensive discussions with representatives of the different user groups until a decision is reached. Compromises are reached after the necessary elements have been accounted for.

6.4 Summary of Findings

The following tables provide a summary of the findings across the nine companies interviewed.

Table 6.1: Shows the stages of medical device development, as practiced by each company. This also lists the different ergonomic methods that were mentioned, as well as a description of how users were involved that do not fit a specified method.

Table 6.2: Describes points made for and against the involvement of patients and clinicians. A variety of methods to deal with trade-offs is also listed.

Company	Stages			User Involvement
	Formal Named Stages	Preliminary Steps	Ergonomic Methods Specified	Actual Role of User
A	Risk Analysis → Feasibility → Verification → Validation	None mentioned	Surveys, observation / ethnography – contracted out, product walkthrough with client, ergonomics of design check, clinical trials, mechanical mock-up	
B	User Data Collection → Concept → Design	Academic Research and Field research – Feedback from clinicians not documented	Risk Analysis, prototyping, informal observation, competence training,	<ul style="list-style-type: none"> • Informal discussions with clinicians in the field
C_{1 and 2}	User Data Collection → Concept → Detailed Product Specification → Launch →		Questionnaires, risk analysis, red flags, in home demonstrations, qualitative focus groups, prototyping, rapid prototyping, expert review workshops, one-to-one patient discussions,	<ul style="list-style-type: none"> • Passive involvement – providing samples. • Patient advocacy groups – direct contact for immediate feedback.
D	Concept → Feasibility → Development → Confirmatory/Launch Phase	Shadowing/observing patients and clinicians in their natural setting, evaluate existing systems,	Brainstorming, ethnography, observation, prototyping, rapid customer feedback – focus groups, healthy volunteer studies, pre-launch clinical trials, user profiling (marketing function), contextual inquiry,	<ul style="list-style-type: none"> • Validation step to actually involve users in developing user needs • Users involved at clinical trial stage • Involve stakeholders to size opportunity through market assessment • Building relationships with users in the community through informal visits, and links with professionals and facilities in the area.
E	Concept → Design → Testing		Mock-ups, CAD, CAM drawings,	<ul style="list-style-type: none"> • Medical engineers work alongside clinicians when drawing
F	Detailed Data Collection Phase → Concept → Design	Identify / express problem	Pictorial scenarios	<ul style="list-style-type: none"> • Survey's conducted at international meetings • Clinical advisory panel consulted • For specialist products users in key hospitals and key accounts are approached
G	Internal divisional Q Standards – internal quality reporting, action plan of all steps. Scientifically and technically assessed.	Feedback from clinicians, patients and technical customers incorporated into development steps design.	Marketing studies, preference trials, clinical trials, 'look and feel study'	<ul style="list-style-type: none"> • Patient input taken throughout process • Post launch patient studies to feed into next version of product.
H	Evolutionary product design – increasing performance of an existing system.	Prioritise important features due to limited funding. (rank and vote on by physicians according to importance)	Market research (building by integrating components present in market).	<ul style="list-style-type: none"> • Advisory boards of physicians – to find out their need • Patient feedback through hospitals testing first models of product. • Academic advisory board of experts in the field
I	Design → contractually manufacture → build → test		Observation, focus groups, field testing, prototyping, training	<ul style="list-style-type: none"> • Clinical Feedback • Device evaluated in hospital / ward involving clinicians and nursing staff • Clinical trials / technical trials / volunteer studies

Table 6.1: Stages Of Development And User Involvement For Company's A-I

Company	Patient Involvement		Clinician Involvement		Dealing with Trade-off
	For	Against	For	Against	
A	N/A – No feedback from patients		Feedback from Clinicians		Not mentioned
B	N/A – No feedback from patients		Feedback from Clinicians and Nurses		<ul style="list-style-type: none"> ‘Improvement for one user will always benefit another user’
C₁ and 2	<ul style="list-style-type: none"> Equal voice of patient and clinician Comprehensive advising patient board 	<ul style="list-style-type: none"> Patients cannot imagine a solution or have insight 	<ul style="list-style-type: none"> Equal voice of patient and clinician 	<ul style="list-style-type: none"> Power relationships mean clinicians may dominate 	<ul style="list-style-type: none"> Workshops – complimentary expertise of different user groups
D	<ul style="list-style-type: none"> Have valid inputs to contribute early Informal ethnography in patients natural setting provides less constrained answers Patient influences clinicians decision Patients aware of their problem 	<ul style="list-style-type: none"> Limited number of patients is inadequate to make a generalised outcome Patients don't know how to address problem 	<ul style="list-style-type: none"> Have valid inputs to contribute early Hold buy decision Aid technical validation of existing systems 	<ul style="list-style-type: none"> Limit to the value of talking to clinicians only No advantage competitively Power relationships mean clinicians may dominate Less emotive 	<ul style="list-style-type: none"> COPC – Customer Oriented Product Concepting Tool
E	<ul style="list-style-type: none"> Nature of product means limited patient input required – involved in clinical studies to test wear rates. Custom made implants – e.g. high flex for western countries (sit on floor to eat) 	<ul style="list-style-type: none"> Telling patients too much can be detrimental – cause unnecessary worry Use of internet information incorrectly 	<ul style="list-style-type: none"> Renowned clinicians involved Clinician becomes advocate of product Provide access to long term patient data on device usage 	<ul style="list-style-type: none"> None mentioned 	<ul style="list-style-type: none"> Not mentioned
F	N/A – Very few patient focussed products	<ul style="list-style-type: none"> Use of internet information incorrectly – not peer reviewed 	<ul style="list-style-type: none"> Clinical Champion – acts as reference point for design 	<ul style="list-style-type: none"> None mentioned 	<ul style="list-style-type: none"> Design is a compromise: cost vs. features compromise Compare the extremes to ensure can cope with the range (of users).
G	<ul style="list-style-type: none"> Input from patients across various stages of development Patients willing to take responsibility for their care growing in number Patient access to information will push for greater healthcare 	<ul style="list-style-type: none"> Non-compliance <ul style="list-style-type: none"> Incorrect instrument use Non compliance with therapy 	<ul style="list-style-type: none"> All user involvement takes place through healthcare professionals. 	<ul style="list-style-type: none"> None mentioned 	<ul style="list-style-type: none"> Best product vs. Least cost Accuracy and precision for clinician vs. convenience and discreetness for patient
H	<ul style="list-style-type: none"> Patient feedback through hospitals testing first models of product. 	<ul style="list-style-type: none"> No risk, as just getting opinions 	<ul style="list-style-type: none"> All the ideas come from clinical people They are the end user hence their input is very important 	<ul style="list-style-type: none"> No risk, as just getting opinions 	<ul style="list-style-type: none"> Prioritise important features due to limited funding. (rank by importance) Vote to reach consensus
I	<ul style="list-style-type: none"> Involve patients in the environment where device is intended to be used Important to get feedback from people that will be using the device Easier if clinicians also aim to cater for patient needs 	<ul style="list-style-type: none"> Involving later in the development is going to be more expensive – so needs to be early Sometimes not in a position to take the feedback on board for that version of the device. 	<ul style="list-style-type: none"> Clinical feedback has been invaluable They will be driving the device forward and using it on patients 	<ul style="list-style-type: none"> Some clinical nurses more willing to embrace a new device than others – need to make sure everyone is on board for success. 	<ul style="list-style-type: none"> ‘Our clinicians have been very patients focused so not a lot of conflict as yet’ ‘If conflicts do arise, we sit down, discuss and try and resolve those issues’

Table 6.2: Clinician Vs. Patient View For Company's A-I

6.5 Overview of Explanatory Phase

The themes identified through the exploratory research phase were used to analyse the data collected through the in-depth industry case study. The difference was that this time they were department focused, and some internal communication as well as external communication with users became of importance, as it gave some insight into how the data or feedback collected from users was used and by whom.

6.6 Themed Analysis

The coding system used for this analysis is as follows. Each department is denoted by a letter as follows and will be the case for all quotes from the interviews.

- a. Marketing – M
- b. Customer Services – CS
- c. Technical Support – TS
- d. Distribution – DD
- e. Supply Chain – SC

6.6.1 Stages of Development

To understand the stages of development, each of the departments were assessed in the role they had to play to support the early stages of development, namely the concept and feasibility phases of the medical device lifecycle. It was evident that some of these departments did have a greater role to play later in development, i.e. after the product is launched. However, owing to the current practice of evolutionary product development, these departments had much to offer to facilitate the succession of next generation products that followed the initial product launched.

Each of the following diagrams show the activities that take place within each department, alongside the internal and external communication that takes place, between departments and as well as with customers. Any user related data gathering methods, like the UK survey that takes place for this company, have also been indicated. Each department does have different ways to gather feedback and to communicate Company G's message effectively, the following pages diagrammatically represent this information for each of the departments interviewed within this company (figures 6.8 to 6.12). This information was collected through the case study research method chosen and described in chapter 5, explicitly from this company, and represents their processes alone.

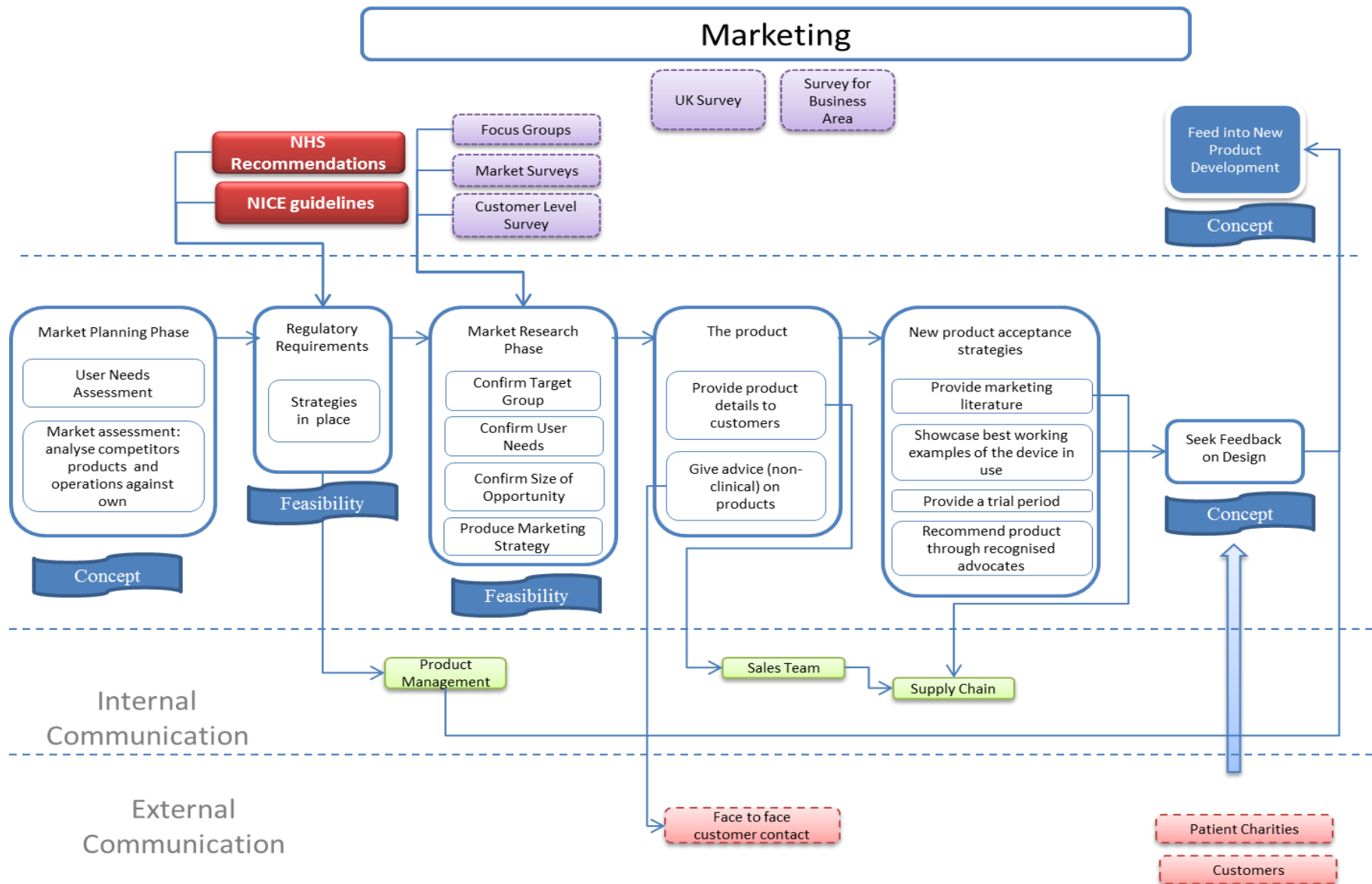
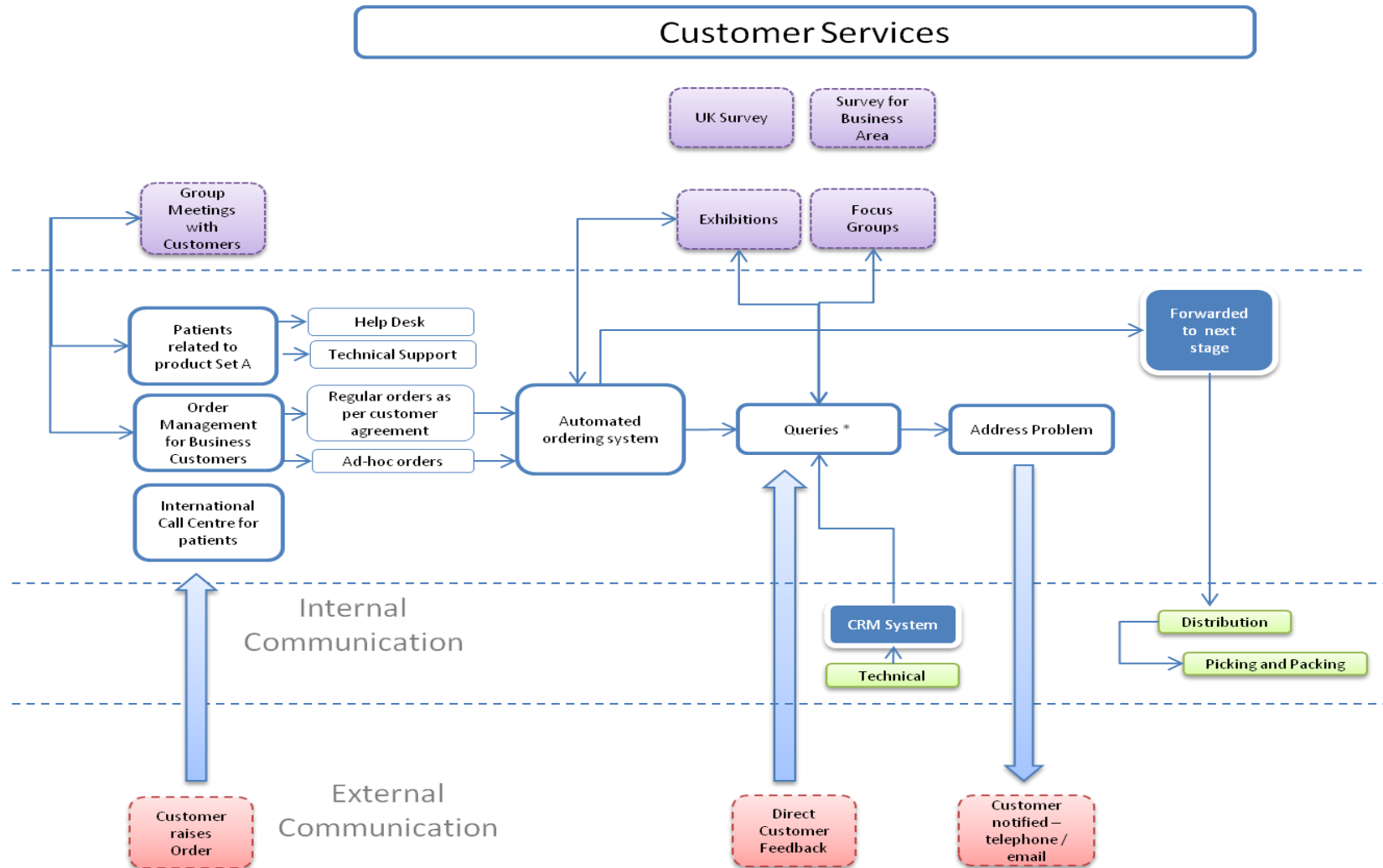


Figure 6.8: Marketing Department (M)



* Dealing with 90 work instructions on various processes, dealing with a diversity of patients and products

Figure 6.9: Customer Services (C.S)

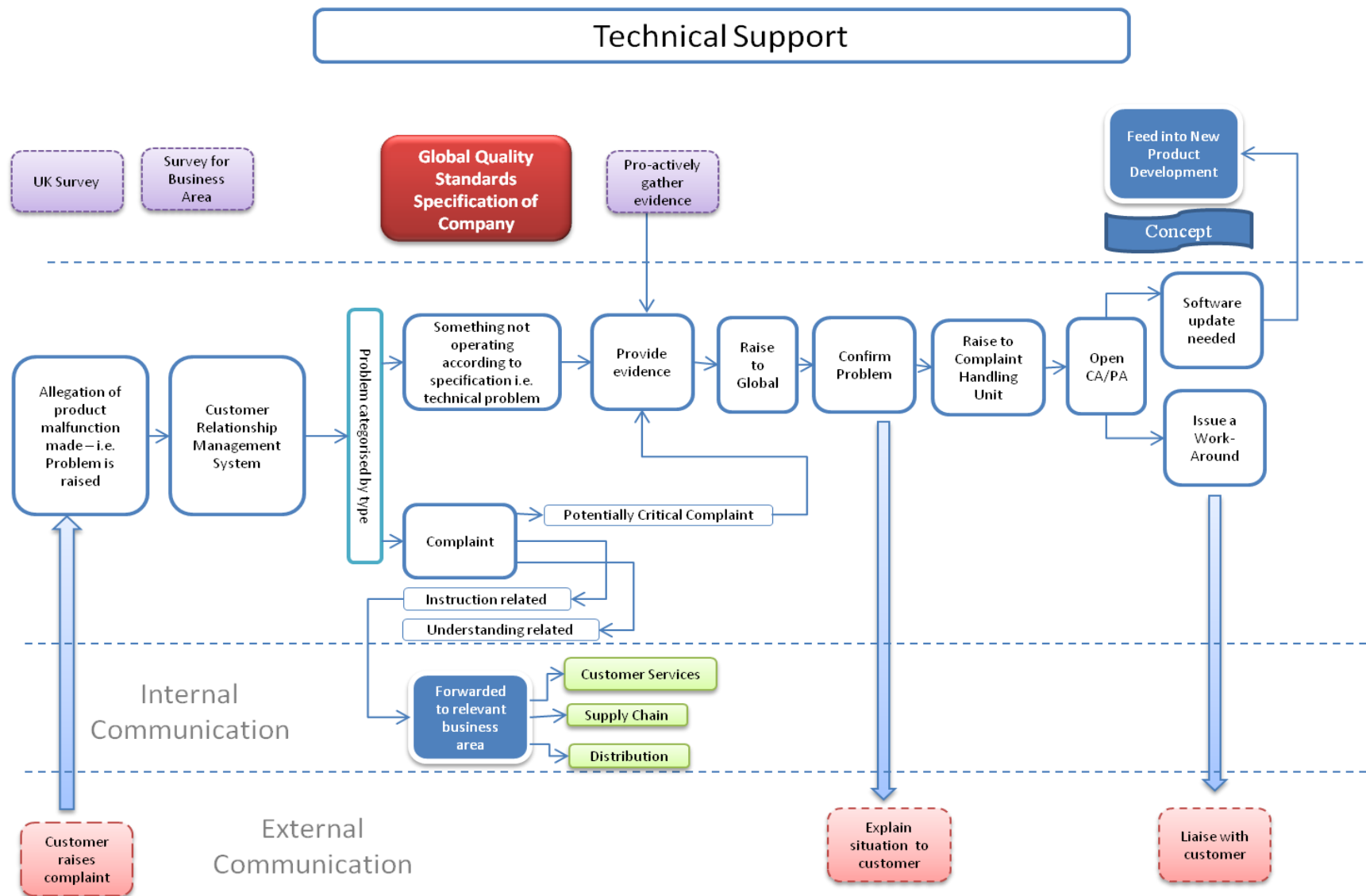


Figure 6.10: Technical Support (T.S)

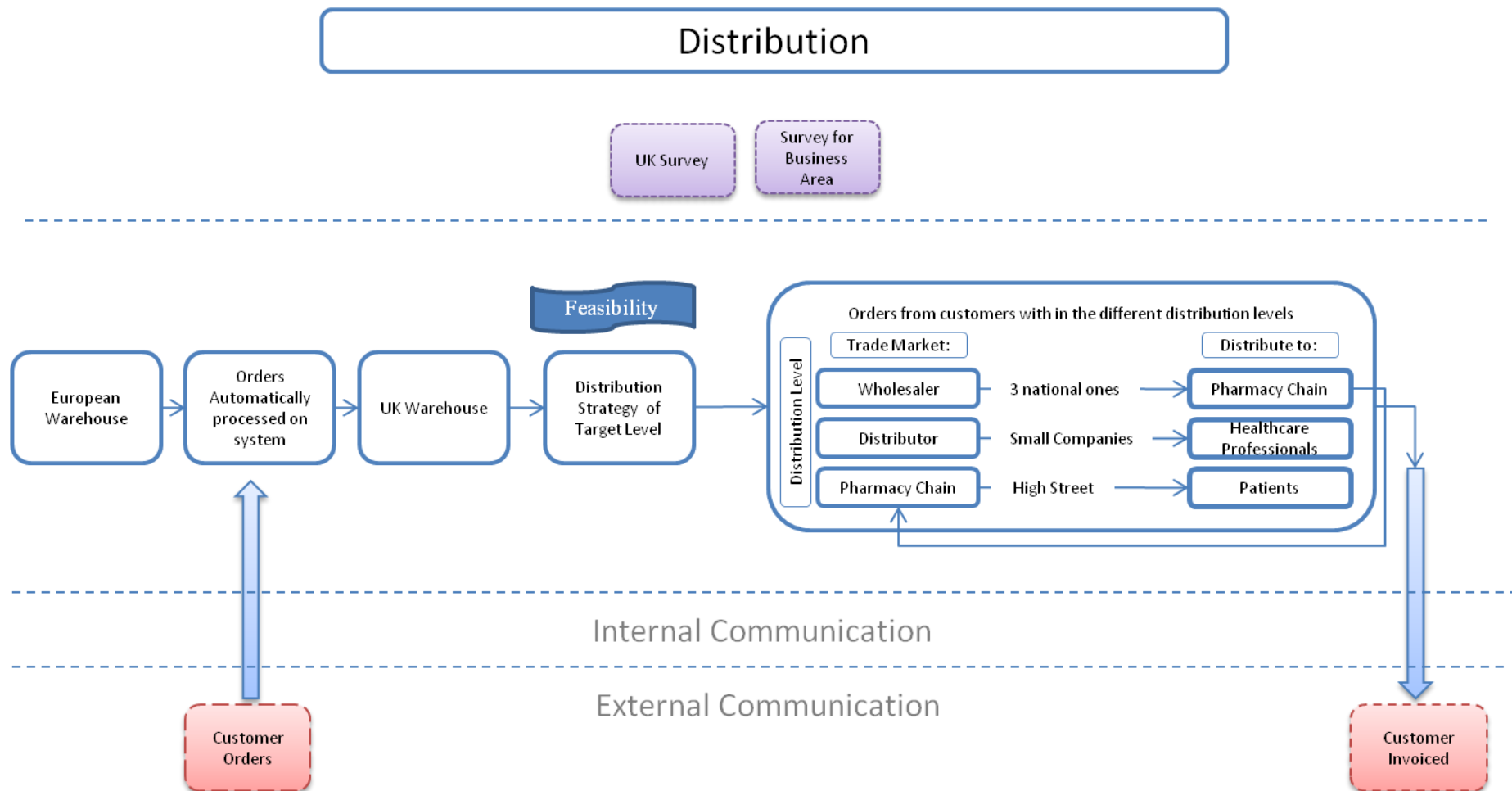


Figure 6.11: Distribution (DD)

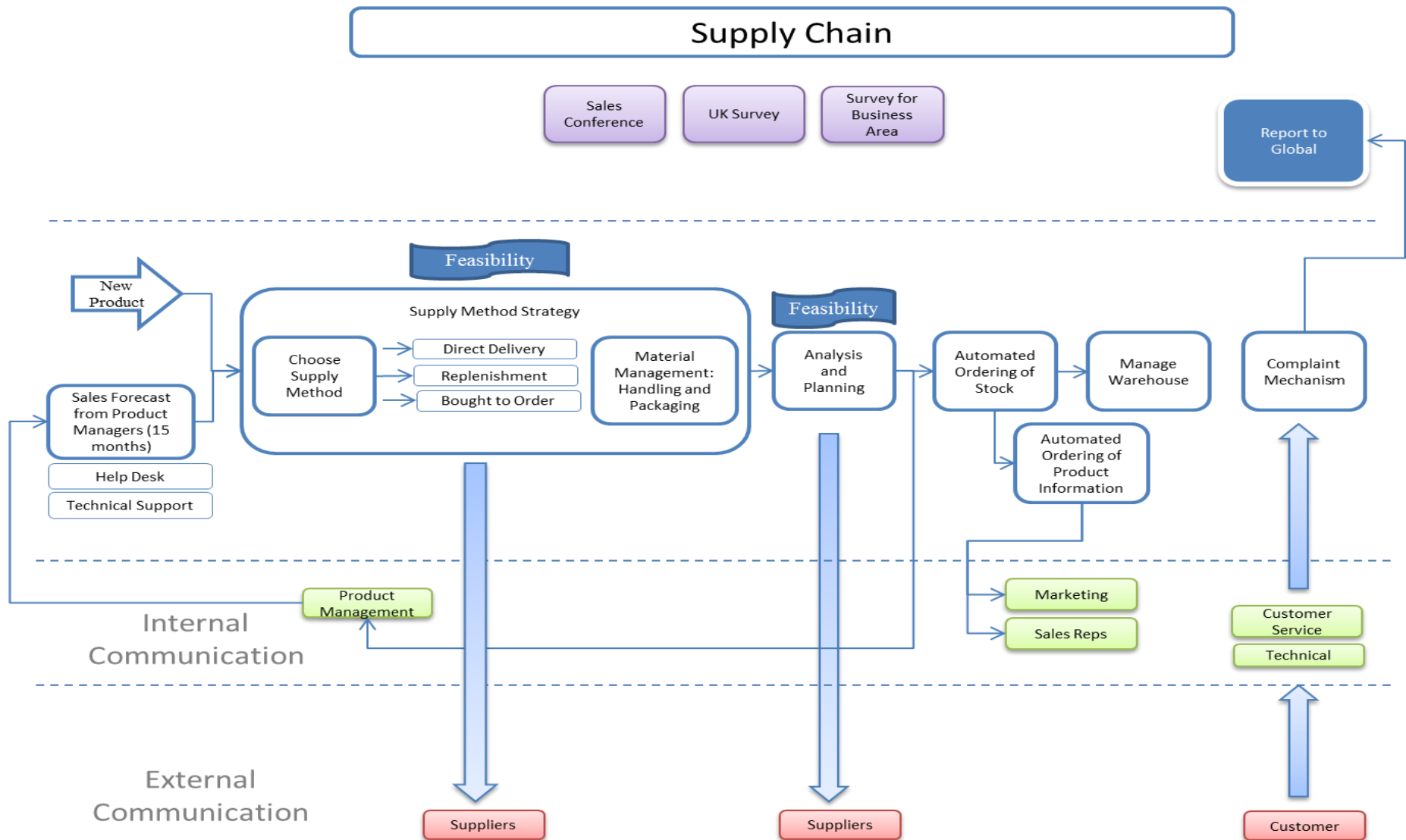


Figure 6.12: Supply Chain (S.C)

To start with each department is involved in activities which benefit the concept stage of development. The marketing department has a clear role to play, as it provides the initial market and user data that feeds into conceptualising an idea for new or next generation product development. As the company is a global player in the medical device industry 'the initial look at the market would have been done by the global team, because they wouldn't just be looking at the UK. They'd be looking at, at least Europe, if not broader than that' (M). In figure 6.8, the market planning phase is seen as one of the key activities, flagged up as supporting the concept stage. 'Through the marketing planning phase we would analyse. We know our own products, so we analyse against that of the competitor and how that company operates. Look at our strengths and their relative strengths and weaknesses and think right, here's how we can differentiate' (M). This stage is important as it not only assesses the competition but also assesses the market and user needs 'A particular example is where it has been recognised that there's a gap in one of our products. It's not fulfilling the market needs of today thereby we know there's a demand. So we did some market research on that just before Christmas' (M).

Following on from that is the feasibility phase in which the early work done in the planning phase is expanded upon 'so that now we've kind of confirmed the type of target group we're looking at and the size of that potential' (M). Going forward 'more and more details on customers are gathered, as we need to know exactly how they would support and implement the new product' (M).

Customer services (figure 6.9) shares the view that 'I think it's more about concepts of how does the market want to move' (C.S). This can be to the point where 'the concept is driven by the customer themselves - even a hospital, they may have a test that currently you can't run on a piece of diagnostic equipment, and you have to do it manually in a lab, for example. You know, they will tell us that and we'll try as an organisation to develop a product to plug that gap' (C.S). Strictly speaking the customer services department does not directly feed into the concept and feasibility stages of development nevertheless have much to offer in terms of feedback which can aid the design of new or next generation products, this will be discussed later in this chapter.

Technical support (figure 6.10) are in a similar position, where although the direct influence into the early stages of development are not clear, they also play a big part in collating and collecting evidence related to the technical specifications of products, usability of the

products as well as customer relations of the business. Again this will be discussed further under the feedback criteria of this chapter.

There is a role for the distribution (figure 6.11) and supply chain (figure 6.12) departments in the early stages of development. These departments engage in activities relevant to the feasibility stage of development. As described by the distribution manager 'it's linking through at the very early stage of the development, it's not just is it the right product but is it what the market really needs at this level' (D). This refers to the different distribution levels the company may target their products at including; wholesalers, distributors and pharmacy chains. The effect this can have on the product design may include for example the size, as pharmacies would not tend to stock bulky items, this would not be such a concern when selling through other distributors to healthcare professionals or hospitals. The logistics of how products need to be managed are just as important as the product itself, even down to the packaging. 'So as well as research and getting the right product, if you get the right product and you can package it badly, you do really restrict your uptake of. So that's really important to think about' (D).

Similarly the supply chain strategize early on, 'initially when new products are set up or new instrument lines are brought in, a decision has to be made as to which supply method we're going to use and that's done in conjunction with the business area – whichever one fits best with their customers and the types of product that they're shipping' (SC). As well as planning the supply method that will be used, the handling of the product also needs to be managed, for example 'some of our products are stored at room temperature; some are kept in the fridge; some are kept in the freezer and have to be shipped on dry ice as well' (SC). All these things are considered before the decision is made on the best way for a particular range of products. The planning and organisation in the background ensures that 'when an order comes in, the system immediately knows how to deal with that order, where to send it to and everything else' (SC).

In summary, the different departments all have a role to support the early stages of medical device development, 'We (technical services) are dealing with existing products that aren't working to the technical specification and Marketing deal with the development of the products going forward' (T.S). Quite often this is because product development is progressive, and builds upon the company's current portfolio of products to continually update and improve the product and product range.

6.6.2 Identifying the User

Identification of the user is done by the marketing team, when they make an assessment of user needs, through market and user survey data. At the feasibility stages of marketing, the target group is confirmed, alongside the user requirements, and the size of the opportunity. 'Because we are selling the product to a worldwide market, it's got to appeal to enough customers to justify the development cost of that' (T.S).

As well as end users, the different departments liaise with different users and user groups throughout the development process. This includes; government authorities i.e. NICE (National Institute for Health and Clinical Excellence), key opinion leaders which includes hospitals, universities and GP consortia. Business customers, patients, patient charities, patient advocacy groups and clinical advocacy groups – which are sponsored by Company G.

6.6.3 User Involvement

User involvement is present at various stages of the development lifecycle for Company G, and across all departments.

It is the marketing department that engages in user involved studies to inform the design of new development. 'Well we would do market research to get feedback, we would be doing market surveys, market research surveys, focus groups, it would be the feedback from them that we're trying to see why this product as opposed to another one' (M). Further to this the global team also engage with UK users, when possible. With reference to operation manuals, usually managed by the technical support side of the business, were reviewed using the interview method by the global team. 'The Global department look after all the operating manuals. They asked to come over and do interviews with certain customers that have recently got Roche equipment. They wanted their opinion and they did a kind of market survey with a questionnaire as well. They sometimes do that kind of thing' (T.S). Foster Jr. and Franz support this view, saying users become involved here, as they are trying to help the analyst identify system requirements (Foster Jr. and Franz, 1999). It is clear that Company G realise the importance of such engagement, and although this was done after the product is launched, is a sign of the continual improvement, not only in the design of the devices, but the conveying of instructions and information to customers. It must be stressed again that this company like many other medical device manufacturers engage in evolutionary product design, so any user involvement and feedback sought regarding products in the market, really

do feed back into the design and user requirements of products to come. The literature suggests that traditionally marketing by device companies was done by representatives, who visited individual physicians with information of new products, which has now been extended to other marketing activities (Brennan *et al.*, 2006).

The users involved, who are looked upon for feedback, include an array of people within the healthcare system. This includes healthcare professionals, clinicians as well as representatives of different patient advocacy groups and patient charities. Company G tries and incorporates the views of all concerned strategically. 'We have had events where we've had healthcare professionals, patient representation from this type of group and some patients present. And the whole event is set up and projected out at the meeting so that we can get feedback and the patient advocacies / patient charities can give a good intermediary role. So they will actually understand what we're trying to do as a company and try and say to their members, well, look this is what we see happening and this is how we feel it can develop their particular need' (M). It was voiced by Fudge, Wolfe and McKevitt (2008), that it is the professional that decides the area of service improvement; the service user could participate in. This was seen as down to the variations professionals and service users had in their understanding of involvement (Fudge, Wolfe and McKevitt, 2008). Often service users are kept away from providing input where clinicians have a big role, or from the technical side of the process (Fudge, Wolfe and McKevitt, 2008). This shows that all users are not asked for feedback for every stage, rather the company can pick and choose, quite diplomatically where it wants input from which user.

Despite the size of the company, the scales of such techniques vary considerably. In relation to focus groups 'we would do maybe six focus groups where you've got a particular project in mind and that would perhaps go on for a couple of months.' There is also the development time to consider, so 'you wouldn't do those too frequently because to all intensive purposes you can't change that quickly anyway. So you know, it may be on an annual basis.' Certain projects may require greater attention in terms of focus groups depending on how they are doing in the market. 'So in times of successful outputs and sales going well you kind of stick with it. If the market is changing like it's doing at the moment, or if there's new products coming out from your competitors then you'd probably re-evaluate it and just make sure you've still got the solid position that you need.' (M) Activities such as providing peer

support, or satisfaction surveys are also considered as involvement (Fudge, Wolfe and McKevitt, 2008).

In terms of specific ergonomic methods it was conveyed that ‘we do ethnographies and observational studies, but it wouldn’t necessarily be that detailed’ (M). This again was reflective of Company G’s target to appeal to a global market. ‘I think if you talk about a local area it gets so local it’s quite different and quite unique. I think we’re limited on just how much countries are doing that and I think we probably end up a few rungs higher than that’ (M). Conducting observation studies in a specific location or hospital setting is not regarded as the most valuable practice for Company G, as ‘it has got to be something that adds value to the system and adds value not just in one country, that’s the other thing. I think what surprises me is – like you were saying a blood test is a blood test wherever you do it – every country works slightly differently. So, something that might really appeal to customers in the UK may not appeal to somebody from another country’ (T.S). A meta-analysis conducted on observational studies in 2010 concluded that the risk of bias is very important to consider when conducting observational studies (Stroup *et al.*, 2000).

So when finding out what the customers really want ‘you try and be smart as much as you can otherwise you dilute all your resources.’ (M) The target users are pinpointed through amalgamating various factors related to that group, for example ‘we need to speak with 45 girls plus, we know that it’s going to be more of an incident within the appropriate rural settings rather than an urban setting because of the proximity to a hospital for example. We know that perhaps the competence in using that machinery requires people to be in a social class of A and B. So they might need to have the income, need to have the education’ (M). Through these predefined assumptions the company can narrow down their efforts and resources, without becoming too specific to a certain geographic area.

‘In terms of surveys – there was a global survey done last year’ (C.S) in which every country could ask up to two questions each, unfortunately the use of this was seen as little. ‘To be honest with you from a local perspective, what we call a local affiliate which is this country as opposed to our sort of global organisation, that’s not a lot of use to us because we got to ask two questions in that survey and then you couldn’t ask anything near enough detail to get meaningful responses to do something with’ (C.S). It appears that having a global survey is a fairly new method adopted by the company however. ‘I personally think local surveys were useful. Years ago we used to do such surveys and we’d get output that was about this thick

(*gestures a 2inch gap between fore finger and thumb*) to go through - it even had individual anecdotal comments from customers. So, I could use that information. But over the last few years because of, you know, the extortion of cost of those, the company has decided not to do those' (C.S). This is validated through the literature, as being up to the company to decide whether the extra expenditure in the global survey met their own requirements (Crow *et al.*, 2002). The financial cost element has affected even this global player, reducing a user involvement method which had been seen as useful in place of a survey which apparently yields inconsequential results.

However in place of such a large scale survey there has been introduced surveys which operate by business area. 'I know by business area they do that, and at a much more sort of local area because they have these groups and they have these meetings with customers and they get feedback through those. And they will obviously feedback to me if there's any issues there that need to be addressed' (C.S). These too have their downfalls in that 'again sometimes you didn't get enough information because there was a limit to the number of questions you can ask' (C.S). At the same time everyone who has some influence and impact for the customer on a particular range of products, wants to be able to ask questions to be able to improve their own areas.

Again these were not really seen as helping reduce the financial pressure, 'they were very expensive surveys, and sometimes again you couldn't drill down to the number of questions that you needed to really find out where it's going wrong' (C.S). An example of the difficulty in deciphering the meaning behind comments was sometimes due to the way the question was interpreted. 'I'll give you an example here, one of the questions used to be something along the lines of 'how would you rate your deliveries on a scale of xyz? – Whatever the scale was'. Now, deliveries can mean a number of things. Some people see that as the point from which they place the order. Some people believe that to be the service that the carrier gives. Some people think that should include from the point where it's dropped off at hospital to their department. So, you know, they'll give you a score but you don't know which aspect, if it's wrong, or even if it's right, they're actually measuring you against' (C.S). This became a problem because 'you can't then ask another question saying do you mean this or do you mean that. So, sometimes again that wasn't really actionable information' (C.S). The respondents expectations, experience and desires play a role here (Crow *et al.*, 2002), so paying attention to the details of the question in relation to the user is

of particular importance. Significant issues are identified 'If I couldn't really identify where things were going wrong, then we probably would do another survey or something of that nature. But generally our customers are pretty satisfied these days' (C.S). The surveys are used in conjunction with other areas of the business to get some real meaningful data out of.

The other user involvement method described was that of clinical trials, 'trials for us are critical because it helps us prove the validity of our products' (M). Clinical trials boast a dual role for Company G, 'obviously it's not just about getting a product to market, it's about actually then having backup data to sell your product. So, if you can prove that it's reduced the need for drugs in 30% of cases because of your product - this diagnostic test or you save the NHS half a million, that is part of your pre-sale stuff. So, it's not just about improving products, it's also about acting as the sales tool as well for an organisation' (M). From these trials the company look to learn about patient groups, 'after the clinical study we try to understand what's coming out of the patient groups that respond in different ways. How can we then go back and understand what drew the positive group and what were the problems from maybe the negative group?' (M) Clinical trials are randomised and eliminate the selection bias present in techniques of observational studies (Hannan, 2008).

These clinical trials are done in a pure setting as possible and are once again globally set up after which 'they will use external companies in the UK who are experienced in running clinical trials to find potential patients' (C.S). The UK team at Company G then essentially deals with the responses, 'if there is technical support needed or they want to place orders for things' (C.S). They also collect any data that the global team require. Again however these clinical trials are becoming less common in the UK, 'they're few and far between now, really done at a much more global level and it's all sorted before it even goes into the business to business customers hands' (C.S).

6.6.4 User Acceptance

From the previous interviews in industry it was difficult to assess the way in which user acceptance of a device was measured or encouraged, and how this related to the success or failure of the device. From looking at the different departmental functions in depth it became clearer when and how this was supported. They have several measures in place which endorse the product and steps to measure any problems and the likelihood of customer dissatisfaction before the product is launched. This is very important as an analyst of the

system / device is likely to perceive acceptance of the device more highly than the user (Foster Jr. and Franz, 1999).

The marketing department are involved in many activities, with the aid of their sales team to ensure buy in to new products. For example using a reference approach ‘we might realise that in one hospital in the country they are getting the full benefit out of a particular product, whereas another hospital needs convincing or there’s something that isn’t quite working for them. So, it might be, we would see if some people at that unconvinced unit might want to visit the other hospital to see for themselves how it’s operating, thereby seeking a reference approach’ (M). There were also other techniques such as providing a ‘trial for a period of time’ (M) or through recommendation using for example ‘a voice recognised in the field of cardiology, to provide a strong enough opinion to actually convince them’ (M). These techniques were introduced after the product was launched, as concluded through the expert industry interviews from the previous chapter. Involving users more in the development of the device can lead to expression of acceptance by the users (Foster Jr. and Franz, 1999).

Measuring the success rate of a product was confidently described as ‘hard to quantify, unless you do it the way we do it’ (T.S). This assertion was further explained ‘we look at the complaints on a particular product against the number that have been sold, where you look against; the product that was complained about, how many cases there have been in total and how many are serious’ (T.S). In this company the difficulty to quantify would be expected as not only are there a number of device systems, there are a number of different products that can be used in conjunction with these devices, as well as various analysing techniques that follow. A fault can appear at any point and needs to be traced back. However the confidence in success was given the figure, ‘from 2,000 devices in the market, we could have one complaint typically’ (T.S).

‘The worst case scenario would be when there is a problem and it has to get written to the regulatory authority’ (T.S). However when there are serious errors in products there are a number of strategies to ensure the product is removed and replaced effectively. One example is that of the INR meter. There was an error in dating test strips correctly, which meant the meter would not take the reading. In this case the test strips were replaced with those correctly dated ones; ‘So that’s been withdrawn from the market and we’ve provided replacements with a different lot number,’ (T.S) there was nothing wrong with the actual reagent or the test strip itself. In another instance the reagent was reacting against a certain

ingredient in patient medication, giving erroneous glucose readings. ‘There is an exchange going on at the moment where we are removing one set of strips and providing them with something better, so that’s a normal product exchange with a recall.’ (T.S) In this case the strips were recalled and exchanged with an improved version of the strip that did not cause such adverse reactions. Another example is of a handheld product ‘where we have a problem in that the touch-screen cracks quite easily, because the customer is under contract we wouldn’t quibble about it, we would just give them a new one, and the old one goes comes back for refurbishment’ (T.S).

Clearly user acceptance is pushed by the company, predominantly as a response to customer comments and complaints, but also during the sales process. By looking at the number of complaints, the relative success of the product and in turn the company can be measured, followed by steps taken to aid the continuous progress of the company.

6.6.5 Feedback and Iterative Design Methods

This section will look into alternative methods, used which aid the collection of feedback and allow for iteration in the development of a device, other than the qualitative and quantitative research methods, like interviews and surveys used by the company. Feedback which is actively sought through some face to face interaction was described by the company at various stages of the process ‘Not long ago, to our Health and Advisory group I said what I would need to understand is how the market will change in the next 18 months with these two or three factors coming on board. I want you to tell me whether you think you like it or not. I want you to give me the feedback otherwise I can’t do anything about it’ (M). Clearly there is the potential for the company to be quite direct in their approach, possibly due to long withstanding relationships they have with their advisory groups. ‘Sometimes they are very positive because you’ve actually asked the question so part of them thinks, oh well, thank you, we appreciate it, and not everybody says that’ (M). On the other hand it was revealed that ‘usually we have to tread carefully and package the message in the right way if you really want the feedback. I said, yes, I want the good stuff as well as the not so good stuff so do tell me if we’re doing something well. But if there’re issues coming out then I need to know’ (M).

The main argument coming across relating to seeking feedback was the need for the company to show willingness to take feedback on board. This can be demonstrated through the way the company actually use that information. ‘So we would then respect and recognise the

feedback and actually feedback when we're able to change things. We do that for patients and for healthcare professionals. Obviously, if you do nothing about it then you kind of fall short of their expectations' (M). Clearly gaining feedback and using it effectively is the responsibility of the company, and at the same time helps to nurture any relationships the company has with interested stakeholders. 'I think if something's wrong, I think because you're going to continue to do business with that customer it is important that they know that you care enough about what they say, to take your feedback on board. So, I think you need to acknowledge that. And where possible, obviously if something is developed I think it is good to feedback to a customer' (C.S).

There were also a number of trials conducted for each product, before bringing the product to market. Multi-centre Evaluations (MCE) was one, which was conducted in order to get the CE marking on a product. 'Any type of product can't be used unless it has that CE marking' (T.S). The CE mark is the manufacturer's declaration that the product meets EU health, safety and environmental requirements. The product is 'put in different countries in different types of laboratories or different environments, typically in five sites' (T.S) they run the new system in parallel to the old one 'so, if they've got an old system that they're running their patient sample from, when they've done them the first time and recorded the result, they would take the same samples and run on the trial system and that's how they test to see whether the software works the way it should, whether mechanically its sound and that kind of thing' (T.S). After evaluating the product in this way, the CE mark is given, and by doing this more data is generated to validate the product. 'At that point you can actually use the results that come out of it to actually report to clinicians or dealing with patients' (T.S). The CE official mark can also be issued by a Notified Body (NB), an independent commercial organisation on which the European Union is heavily reliant to implement regulatory control over medical devices (Kaplan *et al.*, 2004).

Further to this First Customer Monitoring (FCM) then takes place. 'When a new product is brought to market, several countries within the Company G world will be chosen to be part of this FCM and the customers are monitored really carefully to see how easy they find the system to run, the likability of it, improvements, things that they don't like and that is collected at the beginning and that will feed back into improving the product going forward' (T.S). Again this helps to further validate the product and the results can be used when selling the product to other customers 'some of that data will then be available to other

customers. So, if they want to see, how the new system compares to the older system, we'd have that kind of data generated from those trials' (T.S). This type of post market surveillance functions are the responsibility of the member states (Kaplan *et al.*, 2004).

The MCE and FCM are both further trials taking place before launching the product. Both ensure that feedback is gained and any further improvements needed, can be made. This shows that there is a great deal proceeding product launch in way of trials and product validation. This supports the iterative stance medical device companies are taking, as found in the exploratory part of this research, as well as literature relating to participatory design methods and user centred design.

Some of this feedback will be relevant for new product development, but some will be focused on improving on existing innovations. To recognise changes and iterations taken on a product, devices and customer interactions are logged. 'Each instrument has a unique serial number and as we install it we put it on the system so we have a complete record. So you've got traceability, as some of the large systems may be in for ten years, and every interaction with the company or customer is recorded' (T.S). In such case all complaints and improvements are continuously logged and tracked.

All sorts of feedback is gathered from all of the departments, not necessarily within special clinical trial settings or methods in place for gathering feedback, but from a variety of different sources too; 'In lots of ways we get that direct from patients and customers, our business customers. We get it through third parties, so it might be our own reps and we collect that feedback, depending on what it is, what type of complaint it is, we take that information, we put it into a system where we record that' (C.S). This will be any comments, complaints or requests that come through from the customer that use Company G's products. Again this information is most valuable when developing the next generation version of a product. 'Product development lifecycles are very long, so it can take years for that to happen,' (C.S) so it becomes even more important to gather all the feedback possible to direct new development. Organisations launching product modifications are entering more mature markets and can expect more rigorous patient expectations (Rochford and Rudelius, 1997).

'The feedback in terms of the safety side or the technical side would all come back through technical support. It all goes into a clarifying system because that's the official Company G library of all technical support issues.' (M) Technical support see themselves as almost the

intermediaries between 'the customer and Global Customer Support, it will be in effect the global team that will go on to fix the problem. It is the role of the technical services team to provide evidence, and collect all the information relating to the problem raised, 'it is a very proactive thing, the minute somebody says, I think that's a problem; we're duty-bound to sort that out' (T.S). The information that comes through in the form of a complaint 'may get forwarded on to another department if they're involved, or we may deal with it within customer services' (C.S), so the relevant departments are involved in sorting out related issues. 'Feedback from customers gets collected – and that's not just from the UK, but from everywhere – and the product development team will incorporate that. It can't just be something quirky, it's got to be something that adds value to the system and adds value not just in one country. In a worldwide market, it's got to appeal to enough customers to justify the development cost of that' (T.S). Sometimes however a complaint is raised but in actual fact 'it is because customers have problems because they haven't really followed the operating instructions, there doing something which isn't quite right.' (T.S)

On other occasions it is not that a product is not working to specification but that the customer just does not like it 'there is a distinction between customer dissatisfaction or is it broken? We can deal with things that are broken, that's easy, but when it's just that they don't like something it's more complicated' (T.S). To deal with dissatisfaction, the information will get fed back to the marketing department who take it where necessary further 'they have a whole series of meetings with product management in Germany to feed that into the lifecycle of the product.' (T.S)

Subsequently complaints may be in the form of comments or requests due to dissatisfaction. 'Often customers' requests can be things that we perceive as, you know, not viable for us to do or they're to do with product development. So, in those situations really all you can do is say, we think that's a great idea, you know, then we'll look into that and certainly keep it in mind when we're developing the next generation of X, Y or Z' (C.S). This kind of feedback or ideas are clearly useful when developing the product forward, and as customer services has quite a customer facing role in that it places orders for this company, there is usually great scope for collecting such feedback.

6.6.6 *Knowledge Dissemination*

This section will look at the exchange of information between the company and its customers. How the company communicates with its customers, healthcare professionals and patients.

For new products there are deadlines in place of when communication should start regarding informing potential customers. 'We're going through the planning phase at the moment for a new product now so we know exactly what we want to do. And really when it comes to the part in the year whereby we've got nine months to get it to market, we're then going to start engaging with our key customers and let them know that it's coming to the market. So we would start a communication with them certainly well ahead of it coming to the market' (M). This is different for existing products; the communication takes place depending on any changes that take place and the type of change. 'Assuming we have any change, we'll notify them and that will either be in writing or verbally or both depending on whether there's an issue in which case it will go out very quickly. If it's an update or it changes a degree then we would just communicate that to the representatives and customers that purchase it' (M). If the company make a product improvement a special communication is made to inform the customers, 'If there is a new version of the software, customers are given a new version of the operating manual, for new reagents new instructions, and for small changes it might be introduced as an addendum... I mean we issued a new system 18 months ago and we are already on version three next month, so part of rolling out the system we would go and install that but we would also give them instructions and training on it' (T.S).

Another way of informing patients is through intermediaries 'it's always very difficult sometimes to get a group of patients together because you don't know anything about their clinical background, but we would work with patient charities as they are probably the intermediary routes to patients' (M). There was also the acknowledgment that there was a limit to what could be done as notably the manufacturer is not in a position to give clinical advice. However they can give advice on the product 'we can talk about new product's coming out, what they think about it? How would that improve any management maybe they currently entertain? So we would seek their feedback in terms of any design features or training features' (M). In such cases providing information is just as much about gaining feedback on it, as it is informing and selling to customers.

6.6.7 Regulatory Requirements

Adhering to regulatory guidelines is a key part of development for medical device companies, and as regulations differ across the different countries Company G operates in, need to be rigorously managed. Company G produce their own quality guidelines that incorporate all regulatory requirements, to which each country must comply. The guidelines aim to provide a quality standard for the finished product, as well as all aspects of the development process. ‘So, we document all our processes and we audit against those and we monitor against those as well to make sure people are doing what they should be doing and recording, for example’ (C.S). These guidelines are seen as a positive foundation when developing products ‘If you think about the model for the future or if you’re looking at how products are developed. How they are commercialised and then how they are adopted, would depend upon the rigor sometimes of the guidelines presented’ (M). Regulatory legislation is based on correlating the degree of device regulation with the degree of risk posed by the device (Maisel, 2004). This is further seen as a constructive challenge and motivation to work towards ‘If all the effort has gone in and yet there’s no real recommendation from the Health Service, no guidelines coming out, people tend to sit on their hands a bit’ (M).

Regulation is also of importance when there is a problem or complaint against a product ‘so, if we’ve got a quality issue with a product we would record that and report that and clarify both globally and locally’ (C.S). In the worst case scenario, where there is evidence of a serious malfunction of the system, the regulatory authorities need to be informed. ‘Any critical or potentially critical complaints are managed by the global team, they would take the responsibility for informing the local regulatory safety authority; in the UK this would be the NHRA’ (T.S). Maisel agrees that it is very important that a device is not rushed to market, at the expense of ensuring the safety of the person that needs to use the device (Maisel, 2004).

6.6.8 Business Requirements

As with any business venture medical device companies strive to competitively differentiate themselves, the difference is medical device companies need to differentiate themselves as a business as well as on the medical arena. Company G specify their business areas predominantly being the sales and marketing side. Each department hence has their own agendas to differentiate themselves, as evidently the quality of execution of the stages of development relate ultimately to the success of a device (Rochford and Rudelius, 1997).

With customer services, there is a keen interest in eliminating the use of automated phone services. With an automated phone service you are asked to; dial one for this and two for that. 'Customers hate it' (C.S). So, the view was taken by Company G that whilst customers can't always get hold of the individual that can help them at that moment, they get through to someone at reception. 'The calls all come through and customers will always speak to a human the first time, even if it isn't the specialist. That's something that the other companies don't do' (C.S).

A business needs to deal with user dissatisfaction, which includes customers as well as staff. As previously mentioned dissatisfaction of a customer is seen as a different type of feedback, than when it has been reported that something is broken. There are further systems in place to deal with such issues 'sometimes you get things where a customer doesn't like something, like somebody may not have spoken to them the best way or delayed their appointment. That's more about the behaviour of Roche rather than a product from Roche and we have something called an NRC system, a Non-Regulatory Complaint. It's like a whole different system' (T.S). This system is also managed within the customer relationship management software, within the same computer but there's an online form, so anybody can fill it in, including any internal dissatisfactions between departments. Such a programme ensures that's the customer interactions and business relationships are managed in an appropriate manner, and given as much importance as the product itself. This is very important in managing inter-departmental relationships as perceptions on the importance each department believe they have, in relation to other departments can vary considerably (Rochford and Rudelius, 1997), which can be detrimental to the running of the company.

In the future medical devices are 'I suppose mimicking what you can have in the consumer market and trying to emulate that in diagnostic applications' (C.S). This is in the attempt to make devices smaller and smaller 'because generally it's known that people want convenience, small and discreet, particularly if it's a medical device' (C.S). For manufacturers of medical devices, the political climate of the country also has an effect on the progress of medical advancements, especially regarding financial investment. 'The financials in this world are very much geared around the here and now and they struggle to pay for the here and now. And that's very short sighted obviously of Governments to a certain degree, because prevention saves a lot of money down the line. Medical

advancements need long term investments, you know, putting cost in now that will actually pay benefit in 20, 30 years' time, you know. That's the sad part really' (C.S).

The need to work on the service that comes with the products to truly progress in this field, is also evident through this companies aims. They provide a system called MLS, which is Manage Laboratory Services, introduced a year ago. It's a new service offering that other competitors just can't do. Everybody that's done it before has pretty much gone off the market, they're not doing it' (C.S). This system ensures that Company G can offer a hospital laboratory one point of contact for all of their ordering, irrespective of whether it's Roche products or another supplier's products. So, you know, it's about being able to be certain that you can deliver things and then deliver them consistently' (C.S).

6.7 Overview of Interpretive Phase

This study, looking at patients was conducted as a supplementary exercise, to further back up the claims made by experts in industry, regarding user involvement in the development of medical devices. This study was designed to take into consideration medical devices recently incorporated in the lives of patients, in order to understand, how they came about having the device, their involvement in the design and installation process if any, and the perceived value of their feedback.

6.7.1 Background to the Device

Electronic assistive technology also known as telecare is the device or range of devices being used by the cohort of patients interviewed in this study. Telecare refers to remotely delivered care and support, which could include response to emergencies, treatment and medical device or continual monitoring (Tang and Venables, 2000). In this study telecare devices are being used to alert for emergencies. It is seen as one possible solution to dealing with the increasing elderly population and the increasing prevalence of chronic disease. As the healthcare system is struggling to cope, new ways to manage these patients is being pursued. Telecare equipment is used to assist people in managing their everyday tasks, providing home safety and personal security for older, vulnerable people with long term health risks, so that they may live independently for longer, within their own homes, which is becoming an increasingly important location for care and cure (Tang and Venables, 2000). Telecare is currently being rolled out and managed by local councils around the country, to manage care

in the home. Nottinghamshire County Council supports a 'Safe At Home' Telecare Service. This combines technology and support to provide help in an emergency.

Various sensors and detectors are installed in the home, providing the individual recipients as well as their family and carer's with added security and confidence while at home. Elderly and frail people, who are prone to falling, can get the reassurance and confidence to maintain an active lifestyle through telecare (Doughty, Lewis and McIntosh, 2000). Telecare can alert an emergency situation, leading to early and timelier intervention. It empowers the user, providing the opportunity to introduce self-management skills, improving the quality of life by enabling independent living for longer for telecare users. At the same time telecare reduces healthcare use, potentially reducing healthcare expenditure (Tang and Venables, 2000). This is especially significant in the case of telecare where the cost/benefit impact on healthcare systems concerning safety and security monitoring has the weakest evidence base. Telecare combines technology and service practice towards a new approach to health and social care delivery and despite the limited evidence base around this innovation, the merits of these interventions are still acknowledged. There is however a risk that telecare requires strict compliance to medical regimes, suggesting the need to be mindful of patient empowerment for telecare to truly succeed.

The telecare participants were questioned on how well this aim was met, and about their experience and perception of their involvement in the design and development of this medical device. The study explored user perspectives on telecare technologies and assessed the nature of patient involvement in the installation and use of the health technology, determining the patient's perspective of their own health, correlating against actual outcome i.e. their health status. This study is a supplementary step, intending to capture further the importance of research into the requirements of users, aiming to better comprehend the role users play in the development of medical devices, how important it is to understand their experience and whether this is in line with the experts view of how and when to involve the end user; patient or carer.

6.8 Themed Analysis

The interviews were categorised into themes which were produced in relation to the empirical findings of the exploratory phase. These were themes associated with patients as users. Ideas discussed in the interviews included; ease of use of the equipment, ease of learning, feelings

on health status, any concerns on the technology, aspects of self-management and knowledge about how to deal with an emergency and how patients have needed to adapt their lives.

This chapter will consolidate the findings that relate directly to user involvement in medical device development, and support the arguments presented by industry experts in part in the exploratory and explanatory parts of this research.

The coding system used for this analysis is as follows: Each telecare participant is labelled P1–P10. If any carer was present and is quoted, they are labelled C1–C10, corresponding to the patient in question. The Assistive Technology Manager will be referenced as ATM. This will be the case for all quotes from the interviews. If any reference is made to documentation, this will be referenced as D1 – D4 (Table 6.3), representing the summary feedback questions (Appendix B4).

Document	Type	Date	Sample Size
D1	Summary of service user feedback questionnaire	February 2010	163
D2	Summary of carer feedback questionnaire	February 2010	138
D3	Summary of service user feedback questionnaire	November 2010	222
D4	Summary of carer feedback questionnaire	November 2010	185

Table 6.3: Interpretive Case Study Documentation

Any observations will be labelled as O, followed by a number (1 – 4) after reference to the patient in question, for example P1.O1 - patient 1, observation 1. For a full list of observations please see appendices (Appendix B5). For operational purposes the terms telecare user, telecare patient, telecare participant and service user will be used interchangeably. The carers referred to in these interviews are the family members that look after the telecare users, who are their partners, parents or children.

6.8.1 *The Telecare Equipment*

The telecare programme got a real kick start when the government issued a preventative technology grant, which Nottingham City Council invested into the Telecare programme as opposed to other possible programmes. Acceptance that managing the care of the ageing population is the responsibility of the national health services has helped shift the focus of care from hospitals to the home (Celler, Lovell and Chan, 1999). The equipment itself was

acquired through a variety of ways, and has a variety of forms. The care-alarm is the hub of the system which raises an alert to the call centre via a telephone land line. Technology such as this can make it possible to assess an emergency situation for appropriate care from a distance (Dienemann and Castle, 2003). This can come with a personal trigger – in the form of a necklace or wristwatch, as well as a variety of sensors detecting, smoke, fire, carbon monoxide, movement and falls, which are dispersed in the home or worn by the older person, connected to a call centre (Hanson *et al.*, 2007). Table 6.4 shows the types of devices each participant had, whom it was recommended by and why, as well as the length of time they have had it and the number emergency situations.

Participant No.	Type of device	Recommended by	Reason for recommendation	Length of time with device	No of emergency situations
1	PULL CORD, SA, CO.M	Occupational Therapist	Multiple sclerosis patient, living alone	4 years	Not clear
2	NECKLACE ALARM, SA, CO.M	City Council	Wheelchair user, living alone	7 months	None
3	WRISTWATCH & NECKLACE ALARM, SA, CO.M	City Council	Senile dementia patient	9 months	Two
4	NECKLACE ALARM, SA, CO.M	GP	Sciatica Patient, Falls	10 months	Four
5	WRISTWATCH ALARM, SA, CO.M	Advertised at Day centre	Advanced Alzheimer's Patient	12 months	Two
6	WRISTWATCH ALARM	Read about	Safety of elderly gentlemen, living alone	8 months	None
7	NECKLACE ALARM, SA, CO.M	Daughter	Safety of elderly gentlemen, living alone with restless leg syndrome	6 months	None
8	NECKLACE ALARM	Friend	Lymphoma Cancer Patient	10 months	None
9	WRISTWATCH ALARM	COPD Nurse	Emphysema, Heart Attack Patient	12 months	None
10	NECKLACE ALARM, SA, CO.M	Event promoting devices for elderly people	Safety of elderly lady, living alone	7 months	None

Key: SA - Smoke Alarm, CO.M - CO Monitor

Table 6.4: Telecare Equipment Details

The types of devices used by this cohort of patients would fall under first generation telecare systems, as they are mainly personal alarm systems for emergencies (Celler, Lovell and Chan, 1999). Nottingham City Council is supplying second generation telecare systems too, which include fall detectors and door sensors, unobtrusive to the patients, but are triggered on suspicion that something is wrong (Celler, Lovell and Chan, 1999). The patients interviewed however were not currently using these, although some had been given the option.

The preventative technology grant was quite open ended, although it did suggest telecare technology and a target age group of over 65's. This aim is understandable as 40% of health service expenditure in the UK is on people aged 65 and over (Celler, Lovell and Chan, 1999). After some further user analysis, the decision was taken by Nottingham to include all age groups. The first stages of incorporating these devices hence included user profiling in which the Nottingham City Council looked at the potential target user, knowing that they wanted to be a social care support service. 'The primary target audience, were people in receipt of social care, the majority being over 65. But there were also people under 65 that had got learning disability, mental health problems, physical disability, who would also benefit; so we started from that premise, and we did all our training and marketing and review on that basis' (ATM). Further to this they investigated another group of people, 'who were not within social care, who would be perhaps old and frail, and not ill enough to need social care, but they could do with this' (ATM). The literature confirms this, as falls for the elderly or frail are seen as the greatest obstacle for them to living independently (Doughty, Lewis and McIntosh, 2000). The data to decide on what the population needed was partly by looking up the data generated by the census, looking at the number aged over 65 and the people with long term health illnesses or disability. Population statistics were also used as a source of data 'so we knew that in Nottingham, for example, there are about 38,000 people over 65. There's also statistics that tell you that, as a ratio of people, this many people are likely to have dementia, so we think there's about 3,000 people in the City that have got dementia because of those kinds of ratios' (ATM). Further to this, the number receiving social care can be deduced, 'about 3,000 people' (ATM) it was mentioned that this did not include for example people that had conditions such as dementia, that were not receiving social care currently but seen as a potentially huge group that could benefit. Currently Nottingham have got '1,737 people using Telecare. So we're still not even halfway there, considering the number of people that could benefit from it' (ATM).

Before buying into the telecare product, the Nottingham city council were involved in testing the scope of these alarms in a smaller project. They had started looking into the potential of equipment to support people with dementia via a small team. 'They'd already started looking at some gadgets that might help people that were kind of losing some capacity around memory, around orientation, so they were already looking at some devices' (ATM). This gave Nottingham City Council the chance to work with the main call centre, 'the main call centre we operate with, does all the kind of normal care alarm business: they were also

exploring some of the extra gadgets that were around,’ (ATM) building up their confidence on how the care-alarm systems would work logistically. This is also different to the existing community care alarm systems, as the call centre workers are aware of telecare users condition, able to give them advice, and take the correct action i.e. call a member of the family rather than an ambulance when required. Initially this is how Nottingham City Council became aware of the need of such care alarm system, ‘we kind of knew roughly what benefit there could be’ (ATM). However, limited funds prevented them from investing in it properly until the ‘Preventative Technology Grant’ came about. Financial pressure on hospitals increased the demand on community based services. Dienemann and Castle (2003) explain that this area did start seeing greater funding, as a consequence of new devices and pharmaceuticals along with knowledge of disease and disability, moving patients out of inpatient overnight stay hospitals to at the home or same day service mode.

6.8.2 Determinants of Acceptance

Acceptance of the telecare devices can be seen through the positive and negative comments made in favour of or against these devices. Some participants were aware of or had tried other telecare devices first. ‘The first one I tried was from company xyz, they sent a box, and my son-in-law he’s in computing and he couldn’t get this damn box to work, so I sent it back to them and I got the council one instead’ (P7). Ease of installation was of course a big factor in this. The Nottingham City Council sends someone to install the alarms after doing an assessment of the premises and the needs of the individual. ‘The chap who came and installed it was very good, he was very good. He said all you need to do is press that - the button on the device’ (P7). Providing installation as part of the service, lead to a better experience of the device from the offset which the first experience had failed to do. Service user questionnaire summarise that 95% of users were pleased with the installation service, rating it good or above (D1, D3).

The added trigger alarms, in the form of necklace or wristwatch that can be kept on your person, are seen as advantageous compared to other non-mobile alarms. ‘I know I’m satisfied with it and, but I don’t know what’s going to happen if I do get my flat round there because they’ve got their own alarms, pull-cords, but I’d rather have this one, wherever I am with this, I can press it and I’m through, you know’ (P6). So acceptance in this case can be to do with the flexibility this product provides, compared to others on the market or in this case the care home. This is reflected in the literature in that health and social care need to

coordinate with housing policy makers, ensuring effective allocation of resources (Tang and Venables, 2000). Comments from the service user feedback questionnaire also reflected the advantage of flexibility of these devices, seen as especially useful ‘when I go up and down the stairs and am away from the phone’ (D1).

To determine acceptance the telecare devices have been introduced after the existing situation has been assessed, the target population identified and target behaviour monitored looking at a small scale telecare system, targeting dementia patients. This is in line with Sutton’s first steps looking at behavioural intentions - M1 to M5, (Sutton, 2002b, *cited in Ogden, 2007*). Due to the small scale test done previously on dementia patients, the council were confident in moving forward and providing these devices on a larger scale, as well as confident in reaching the potential population that have not yet been targeted. The Assistive Technology Manager said that the feedback they received at that point with the dementia patient group, was mostly from the care workers, ‘we only have worker feedback as to what they think will or won’t work for their users,’ or some anecdotal feedback from referrers. He admitted that ‘it would be great if we had a user forum where we could try out new devices and get their input as to user friendliness, functionality etc, but at this stage we don’t’ (ATM). Drawing on the feedback provided by care workers can be valuable in itself, as they experienced the interaction of the user with the device first hand through observation. The study by Hanson *et al.*, proves this, as the carers and healthcare professionals did note the same benefits and drawbacks of the device, as did the elderly people (Hanson *et al.*, 2007). Which means carers can provide useful insights. Hence care workers can assess the individual’s needs better, as well as prompt any action needed to change the device; in this case analogue over digital displays seemed to work better for this particular client group. This stage was useful to understanding users’ response to the device, as well as to the service, and meant the council could rectify any issues surrounding providing the service that came with the device, looking into reputable call centres for example.

The steps taken to ensure user buy in, was by choosing the right type of telecare devices, which were intuitive, and simple to use, bearing in mind the target age group in particular. This was done successfully as noted by the responses that came back from the telecare users; ‘It’s about as simple as you can get fortunately’ (P6), ‘there’s nothing to it really. If you’re in trouble, press the red button’ (P3) and ‘I know how to use it – it’s easy enough’ (P5). This echoed the findings of the service user feedback questionnaires, as explanations on using the

telecare were given good or above ratings for 95% of cases in February and 92% in November (D1, D3). Having access to data on the potential market of such devices also helps in targeting that market specifically, and any specific considerations e.g. dementia patients.

The assessment of the users' needs regarding a device was done by a number of people in the initial stages. The first assessment will be from social care and health 'they will make the assessment based on need' (ATM). From the patients perspective, experience of this assessment has been rated good or above by 95% of users (D1, D2). 'The OT (occupational therapist) who did the original assessment was very good and clearly had medical knowledge and experience of the difficulties of old age' (D1). The department of health was aiming for a single assessment process, i.e. either the NHS or social care make the first assessment (Brown, 2003), and this has been achieved in this case. Following this a member of the telecare team assess whether the equipment meets that need. After which the call centre will do another mini assessment when installing on the individuals personal circumstance 'when they've gone to install the fall detector, in talking to the user, they've realised at the outset it's inappropriate, because they're not going to wear it. So they will suggest other forms of managing fall prevention, or alerting to falls, such as a motion sensor or a bed sensor or what-have-you' (ATM). So a variety of expertise makes up the initial assessments on the users' needs. The call centre then review again within the first eight weeks, the individual will also have an annual social care assessment. There are also opportunities for the users to raise any concerns that will be followed up by a member of the care team. 'So at the initial stages there's several times or occasions or opportunities to review it, and then there's some on-going times. And obviously if the person themselves says, it's not working for me, we can look at it again' (ATM). Chen *et al.* (2005) express the importance of considering the user characteristics in the process, such as age as well as physical and mental conditions, as this can affect the correct use of the device.

Since these devices were targeting elderly people, who also suffered from chronic conditions, understandable some of these diseases were progressive. This meant that some of the telecare devices that were suitable originally were no longer as useful due to the individual's condition. In this case the acceptance of the device was no longer due to willingness to use, but also whether they had the ability or capacity to use the suggested device. 'We don't issue packages - we don't say, right, if you're prone to falling we'll put this equipment in; if you've

got memory problems because of dementia, we'll put this in. Every case is individually assessed' (ATM). It was important to reassess the user needs and make changes where appropriate. There is support for this view, that telecare should be approached in a tailor-made way, after underpinning the individual's needs. In this way complex needs can be further addressed (Hanson *et al.*, 2007).

The acceptance of these devices, has as much to do with the greater accessibility provided by the councils telecare service as it has to do with the usability of the device itself. Individual assessments and care programmes help provide the independent living the government aims for. Making them affordable as well as targeting a larger user group, not only the elderly but those with mental health problems and other disabilities has built awareness of the benefits of these devices.

6.8.3 Value of Telecare Participant Contribution

The department of health in the United Kingdom is committed to involving patients in the NHS (Simpson and House, 2002). In this particular case the contribution expected by the telecare user, was predominantly in the form of feedback. Either through questionnaires conducted by the council telecare service, or through noting any comments or concerns raised by individuals to their healthcare team member.

Some patients give their feedback, or voice a concern as they are hoping for a solution or change straight away. This was the case of Patient 1, who needed changes to the alarm trigger devices as her health deteriorated. As her mobility decreased, alongside her strength and dexterity in her hands, the device was changed from a necklace, to a push alarm on the table, to a pull cord. In this case patient contribution was of utmost importance, as without the patient's requirements being continually monitored, the telecare system would have become redundant to her needs. The patient or carer does have a role to play in ensuring they ask for the help they need. In this way the device or service provider can adapt and provide more completely for the user's needs.

Other feedback or comments from users can help to make the product better in the future, even if in the short term there may not be a solution. Although, this cohort of interviewees was pleased with the usability of the devices, and generally happy with the service, there were some concerns. The devices were considered by some as unattractive (P3, P8), and there were issues of over sensitivity, making the user conscious of pressing the alarm by

mistake (P3, P5, P8 and P10). These issues are concurrent with those expressed in Hanson et al. (2007) study, also finding design related criticisms of over sensitivity and fear of false alarm amongst other things. Currently the assistive technology manager is aware of these issues, and is looking into different more discrete necklaces; not white with a red button, but silver with a black button – looking more like an item of jewellery. This experience will be discussed in greater detail in the next section, but it is important to note that patients provide an important source of information regarding their subjective experience on quality of life and satisfaction of care as well as health status (Huang *et al.*, 2005), this information should be duly noted for refinements to the device and care for the future.

6.8.4 *Patient Experience of Telecare*

6.8.4.1 Positive Experience

The positive experiences surrounding the device were related to safety, security, ease of reaching emergency services and carers and increased independence. This means the aims of the telecare service and its associated devices is being achieved. The Assistive Technology Manager wants to promote this as a prevention/early intervention tool. The main aim is concerned with safety, keeping people safe, as well as independent i.e. ensuring they can live in their own homes for longer, and not needing residential care. ‘So we’ve done our own initial survey analysis, which showed on average we were delaying people going into residential care by a number of weeks’ (ATM), which also saves money. Increasing people’s options, so they can stay home for longer, without being obligated to friends and family for daily monitoring corresponds to Hanson’s positive findings on telecare too (Hanson *et al.*, 2007).

The response from the patients overall reflected experiencing the following situations. Firstly in relation to safety ‘It does give a sense of safety; yes.’ (P1, D1, D3) Patients recognised their role in keeping safe ‘It’s a person’s responsibility to stay safe you know, but at the same time it’s nice to have this backup’ (P3). There were also comments relating to the vulnerability some users had felt, and how this gave them added security. ‘In my present circumstances it’s an additional security feature, I guess most people living on their own feel as if they’re exposed’ (P6, D1, D3).

Secondly these devices acted as support for the users, enabling them to feel they can easily contact someone in their time of need. ‘It gives me confidence that I’m not on my own’ (P4,

D1, D3), I just feel if I have another fall I'll be able to contact somebody' (P2). Ease of use of the equipment was another positive feature 'I've got more phones now than I had before, but I can't always move that fast enough to get to the phone. We had an emergency and all I had to do was, reach my hand out and push it – I hadn't got to fiddle about with a phone' (P5). Potentially preventative benefits of reassurance and peace of mind have been seen favourably in Hanson's study of telecare too (Hanson *et al.*, 2007).

In terms of independence, there were mixed comments from carers, but on the whole users felt they were able to live in their own homes thanks to these devices. 'My main ambition, to try and stay alive so that I can look after my wife because she's getting very near the end, you know, and I'm trying to keep her out of a home, you know – I'll look after her here' (P3). Many have used these devices to help maintain independent living in their own homes, 'they asked me if I wanted to move out of here, I says no, I says. I mean, I've lived on this estate all my life and my Doctor's only just round the corner' (P4). It also helps give them the confidence to believe they can live independently 'I work hard in this country, very hard, and bring up the kids, it can help me because I'm sick, but I'm a very strong person, very strong, you know and as I say, I like to be independent... I try to be independent' (P8). Telecare is supported in the literature as not only a technique attempting to maintain people in their homes, but there to facilitate independent living (Tang and Venables, 2000).

The speed of response was again a very positive feature 'when I've done the testing, then very quickly, someone, a human being actually speaks, so you're not hanging around for ages and ages. So those kinds of things have been very encouraging' (P6). Further to this, comments on how quickly an ambulance was sent out - '10 minutes' (P7), was again admirable and reassuring to users who had had emergency situations. While waiting for help, the fact that call centre stayed on the phone to reassure telecare user, give advice or calm them down was seen as a further great benefit by carers as well as patients (D2, D4).

It is important to note down the positive experiences, as it acknowledges that the providers of medical devices are meeting the aims of their users, and the aims of the organisation – providing what they set out to do.

6.8.4.2 Concerns about the Technology

There were a few problems noted with the technology, mainly concerning the phone line connection. That's the only bugbear – if the phone line goes down, you've lost the alarm

and you've got no control over that. If you had a sort of a thunder storm and it took the phone line out, you lose your line' (P5). Participants were concerned where their phone lines had either been cut off, or detached temporarily and they were out of touch with the call centre. 'For four days I was out of touch on the phone and couldn't get outside help at all' (P3). Other than that, sensitivity of the device was also an issue for some, and was at times too sensitive. But I tell you why I'm a bit shy of it - I was wearing it and then I caught it and the alarm was going off – and it was accidental, you see, so it's almost too sensitive (P3). A similar comment was noted in the carer feedback questionnaires. 'My father has dementia and therefore does not realise what the alarm is. An ideal alarm would be connected to a socket which cannot be switched off easily' (D2). The issues of sensitivity and concerns about false alarms have been seen as problematic with telecare (Hanson *et al.*, 2007).

The need for the device to be even more discrete was also implied, 'I put it there (behind the photo frame – P8.O1) because I don't want everybody to see it, you see' (P8). There was a sense that this particular user was embarrassed of it, and did not want people to know she needed extra assistance. 'I worked hard, you know, I don't like to ask for things, I'm that sort of person, I try to be independent but sometimes you have to let go... When you're exhausted you have to say something' (P8). For many people it is a last resort to ask for assistance. The care-alarm hub itself was also commented on; 'it looked very unsightly – about six lots of wires (P3), so the gentlemen put it on the windowsill, behind the sofa (P3.O3). In both instances the convenience of reaching the alarm is compromised, due to visual discontent. Despite this, one gentleman with a pendant did comment that 'I haven't had to adapt to accommodate the device in any way as it's incredibly subtle and I haven't noticed' (P6). These comments disagree to an extent with organisations that are looking to move away from non-invasive sensors to body sensors that can monitor vital signs, as part of the next generation of telecare (Brown, 2003). It will become even more important to determine user acceptance if these were to go ahead and user involvement in the development of such devices would really need to be given attention.

These are the kind of concerns that are recorded by the city council in their twice annual feedback forms. From this there is a move towards looking into different suppliers that can provide a more discrete personal trigger. One company is offering a silver pendant with a black button, as opposed to a red button which is not very discrete and states 'I am

vulnerable!’ At the moment however these devices are supply led, so the Nottingham city council can take feedback to inform future design, but cannot quickly alter the design themselves as it is dependent on their suppliers.

6.8.5 Self-Management

The theme of self-management is being explored here, as it has become government policy to develop this area further in healthcare as a way to empower patients and carers, as well as to ultimately save on costs. Talking to the individuals receiving telecare and their associated carers already showed that these individuals were motivated in pursuing their independence, but their fears of being alone or vulnerable let them down. Telecare firstly helped to resolve some of these reservations. ‘Feeling of not being alone’ (D3), ‘good to have someone to turn to in an emergency’ (D2), ‘makes me feel safer’ (D3), ‘me and my son feel more secure’ (D1), ‘I feel very reassured that it is there if required’ (D1), and ‘we both feel confident’ (D2) are all the positive aspects telecare has brought to the individuals.

There are the possibilities that a bad experience can adversely affect the individual’s confidence in living independently (Brown, 2003). On the contrary a good experience, for example with patient 4, who has had 4 emergencies resulted in the comment ‘I enjoy having the device and I have been lucky’ (P4). Suffering from Sciatica, where pain can be felt in the back of the thigh, leg and foot as well as arthritis, she is prone to falling. She has lost three stones in order to keep her weight to manageable level, ensuring she can try and get up after a fall, which her physiotherapist has also been guiding her on. If she still cannot manage the telecare alarm is there. In this case the emergencies are taken as part of life now, ‘I go down once or twice’ so daily management is required as well as for the patient to know their limits and hence when to use the alarm. For this lady the determination to live independently also continues, and a person’s own home is a powerful symbol of independence (Fisk, 1998).

Once telecare can be seen to be providing reassurance, and giving individuals the confidence to look after themselves, the next step is making the equipment as intuitive as possible, easy to learn and use, so patients are able to use it to deal with an emergency. ‘Explanation made it very easy to use the equipment’ (D3).

This section looks at whether the participants are able to self-manage their condition or deal with an emergency, and the impact on the carers involved.

6.8.5.1 Dealing with an Emergency

Four of the participants have experienced emergency situations, in which they had to call for assistance using the device. Those patients or carers in these situations that have used the alarm, came across as confident in using it, and had positive experiences of the response. ‘When my wife... when I thought I’d lost her... I had to punch the alarm to get through... I said can I have an ambulance please? And it was here in ten minutes.’ (P5) This is consistent with the findings of the carer feedback ‘Ambulance response has been excellent’ (D2). Another lady was prone to falling and commented that she ‘really enjoyed having it really, it’s just that bit of thing that if I do fall, I’m on my own, but I’ve been lucky. Since I’ve had it, I’ve had four falls.’ (P4) Additionally the patient is at least aware of someone looking out for them, and this consistent monitoring of their wellbeing can itself be reassuring according to Fisk and motivate them to use the system (Fisk, 1998).

However there were a few patients that were unsure if whether they should call for help. Sometimes they are not sure if it is really an emergency. ‘There has been about three occasions where I’ve come in and I couldn’t wake her up... it really scares me; and the carers said to me, well, you should have pulled that’ (P1). Other times the users were hesitant in using the device, as they feel conscious of alerting someone in unsociable hours. ‘I’m not going to do this at half past three in the morning.’ (P7) This shows that perhaps it is not the need to train about using the equipment, but at times need to understand the patient’s disease. Carer needs the knowledge and training on the illness to be able to handle the emergency. The equipment is itself intuitive and those aware of the emergency are fully comfortable in using it.

6.8.5.2 Impact on Carer

Telecare devices serve two purposes. One to ensure early detection of a problem, early intervention may mean less recovery time in a hospital, reducing healthcare utility. The other can be seen to help carers. As mentioned previously one carer pointed out his ambition to stay alive to look after his sick wife (P3), in this case the device was an aid to the carer. Telecare can give patients and carers added security that they can be contacted if there is an emergency in-between visits. ‘If there is a problem, I know I can be called straight away’ (D4). It has been proven to reduce visits for 25% of carers (D2, D4). Comments such as; ‘It reduced visits, but not necessarily calls’ (D4) and ‘I don’t need to phone my parents as often knowing they have access to care-response’ (D2) were made. Family and friends are given

additional peace of mind. 'I have additional peace of mind when I cannot be there' (D2). Above 80% of carers stated that having telecare had reduced anxiety about the person they care for (D2, D4). Although in the past it has also been noted that many telecare users, are using these technologies due to insistence of relatives (Fisk, 1998), in these interviews only one patient decided to get the technology on the request of his daughter (P7), although other factors did influence this decision. Telecare users also stated the following reasons for requesting the device; a medical problem (P1, P3, P4, P5, P8, P9), experiencing a fall themselves (P2, P4, P7), or a fatality of a loved one (P7, P10).

The extent of the condition of the patient also determines the peace of mind the carers get from the device, as well as potentially the relationship of the carer to the patient. 'I feel sick every night when I lock her in... to think she's here on her own' (C1). This was evident in the feedback questionnaires too, as only 50% (D2, D4) were enthusiastic for telecare, the other 50% being worried or sceptical for the person trying telecare. Evidently these tools should supplement and not replace human carers (Ruggiero, Sacile and Giacomini, 1999; Brown 2003), be they members of the family or care providers.

6.8.6 Adherence

Despite all the positive comments from all of participants interviewed, it seemed that in the majority of cases the participants did not actually wear the devices they had been given. Many kept them about their person; others had a particular place in the house for the device, for example next to the bed or the bathroom. Some due to personal circumstances were consciously not wearing due to concern of setting alarms off accidentally, either because of partners that were also ill or due to the alarms being too sensitive.

6.8.6.1 Patients Responsibility

Although, all persons receiving telecare recognised that keeping safe was their own responsibility only some kept the devices to hand all the time; 'I just take it off when I'm going to bed, but I wear it all the time otherwise' (P2, P7). This device was an aid not a replacement for keeping safe, and prompted the comment from patient 3 'the Lord helps them who helps themselves.' Those that did not wear it accepted their liability if anything were to happen 'It's my fault if I don't wear them – not their fault; they've given me the tools' (P3). One gentleman, who kept the pendant on a shelf in the living room (P6.O1), commented 'well if something were to happen I'd honestly have to dive over there; whether I'd be quick

enough I don't know' (P6). One of the ways to get round this is if the user consciously puts the device on when they feel they could be at risk, for example at night, when going into the bathroom or kitchen (P10.O1, P10.O2) or the garden or when they feel particularly unwell. 'Yes, I have it on if I don't feel very well' (P8). Reluctance to use these devices in the manner intended to, does to an extent reflect the absolute right of people to choose, which was mentioned by Fisk (1998) in his study. Hanson's study echoed this finding, and saw the reluctance of healthcare professionals to impose any healthcare package on someone known to be at risk 'for their own good,' with only 2% of carers agreeing and 10% of older people (Hanson *et al.*, 2007), agreeing for such an imposition.

From these interviews it became apparent that as this was a preventative device it was the users' choice and responsibility of incorporating it into their daily lives. This may be different with medical devices used for the detection or cure of a disease. If not used correctly the care team would need to contact and educate the patient to ensure that the correct measures are being taken, at the right times to help in the care of the patient. In some cases more can be done to ensure the users of the telecare devices do use them i.e. keep them on their person, maybe through reminders 'I don't have it on. It's only because I keep forgetting to put it on. It's my fault entirely. It's not theirs. That watch should be on me permanently' (P5). Again the watch was kept on a shelf in the main living room (P5.O1).

6.9 Conclusion

In conclusion, the three phases of the study are brought together to summarise and reflect on the findings. The findings are used to further benefit the design of the user involvement framework of medical device development.

The case presented to provide a deeper understanding of the initial stages of medical device development and the value of user input was supported by industry in the exploratory phase of the research. The basic stages of product development are consistent with the literary findings. It can be concluded with certainty that manufacturers of medical devices are aware of their users and the need to understand them and their requirements from the start. Currently there exists a lack of consistency within companies, on the ergonomic methods employed to involve users. Expertise and the experience of the project leaders does dictate the methods used to an extent, which should be given greater importance. Extracting the user requirements effectively is the main competitive differentiator, and hence should be given rigorous attention.

The need for a more structured approach to user involvement in the early stages of MDD is also evident. Senior management interviewed expressed their support for user involvement and the value for patients and clinicians to be involved as early as possible. A look at their processes however, suggested that perhaps they were shy of embedding these methods fully and hence are not benefiting from them as much as they could. The use of focus groups, observations and expert reviews through advisory panels are popular methods used, with more laborious techniques such as contextual inquiry or ethnographies rarely being used. Business obligations, competition and resources mean that companies sometimes do take the least time consuming option. Companies also need to submit to obligatory regulatory requirements first and do not always have the time or resource to incorporate extra 'nice-to-haves' within the design.

The conflicts on user involvement arise as it varies from simply user identification to actually understanding user needs and gaining user feedback and incorporating that feedback within the design. Recognition of the user is sometimes confused with involvement and lack of education on ergonomic methods to involve users means some companies miss out on opportunities available to them. However user involvement is seen to address the softer usability side of development, and recognised as a competitive differentiator between companies. All companies were very conscious of reaping the benefits of receiving and incorporating user feedback, especially due to the evolutionary nature of most medical products. At the same time they were cautious when providing information on any product development due to confidentiality reasons in the competitive market place.

Difficulties in bringing new devices to market had been argued by this cohort of interviews, to be down to lengthy timescales, business objectives and predominantly cost. Regulation however, was not necessarily seen as an obstacle to bringing new devices to market. This may be as manufacturers now see the role regulation has to play and is seen as part of the necessary requirement of developing a medical product, and not as a hindrance.

Due to no real defined process of user involvement, there is a notable difference between companies on the importance they give to the different types of users. Clinicians have been given the opportunity of higher levels of involvement compared to patients, in the set of companies interviewed. This does not suggest that the clinical user is of greater importance, but rather is reflective of the types of devices being produced in industry. Despite the shift in healthcare towards patient self-management, and giving patients greater control of their

healthcare needs, many of the devices being produced for the care of the patient are largely used by clinicians and nursing staff. If the interviews had focused solely on companies that produce point of care diagnostics, the influence of the patient would have been far greater. Instead the companies ranged from safety critical, orthopaedic and wound therapeutics, to diagnostic, treatment and preventative devices. This range clearly outlined the differences present between companies on their view of user involvement, with those with extensive range of products reaching a far greater user clientele. The parting comments from all but one of the companies expressed their interest in greater and better user involvement for the future.

The in-depth explanatory case study with company G emphasised the business side of medical device manufacture, especially in relation to logistics of how to incorporate the user and who the responsibility to do so rests with. All the departments did have a role to play in the concept and feasibility phases, but that did not necessarily involve the user and not all departments were concerned with user involvement.

The marketing department had by far the greatest involvement with users. This involvement included assessing user needs at the market planning phase, followed by a more detailed look at the target group going forward. User involved studies such as; focus groups, global surveys, surveys by business area, questionnaires and clinical trials take place to include user views through feedback. Multi-user events were also organised, where healthcare professionals and patient representatives can meet to discuss their views. When taking on user feedback, it was recognised by the marketing department the importance of acknowledging this feedback, especially as relationships with customers are long term commitments for medical device companies. They hence ensure their customers are aware of any changes they make resulting from their feedback.

The marketing department also actively engage with users, in order to increase acceptance of the device in the market. They do this by providing customers with either a reference point, recommendation or a trial period, whichever is relevant. Again this is important due to the long term relationships they have with their customers, and customers need the chance to ask questions and understand new devices or systems before they take on long term agreements. As well as engaging with users for feedback, the marketing department are aware of the need to inform potential users of new devices in the market, and they start communicating this well in advance of the product coming to market. Patient charities are seen as the intermediary route to patients, and they are used to pass on information too.

Supply chain and distribution had to strategies their position in the concept and feasibility stages, so are involved at these early stages. These departments' needs to have an awareness of the user they are targeting so that they can decide logistically what level to target products at, but apart from user consideration there is no real user involvement, as described by the literature and the other departments. Customer services involvement is based on taking orders, addressing queries and problems. The technical department involvement with users is also from the complaint handling side. Any concerns raised are either forwarded to the relevant business area, or dealt with at technical support. Ensuring the customer is kept informed while the problem is being resolved, and effectively dealing with the problem plays a part in the user acceptance of the device. Customer focus plays a big role, not only by way of the device, but the service that goes alongside it.

The patient interviews in the interpretive phase were further used to support industry's take on involving users. Firstly they showed that it is very important to understand the target user group. In this case study the user group consisted of elderly patients, some with mobility issues or other health problems. This dictated the need for an intuitive device, as many users were either unable to use complicated devices or apprehensive of technology. Individual situations needed to be assessed for this range of medical device, again showing the need to really understand the user's needs. In this case the users' needs were assessed by a variety of experts; healthcare professional, device expert and service expert. User involvement is required in the developing of medical devices, as it helps to see the perspective of the user and how a device can really fit into patient's daily lives for the management of their condition.

Through these interviews it appeared that one cannot influence acceptance of the device through the actual development process, and sometimes individual circumstance plays a bigger part. For example telecare participants who were also carers for their partners, found it difficult to keep the device on them at all times, despite wanting to. Education on the disease and self-management is also an important part in ensuring the device is being used correctly, as participants need to understand the relevance of the device for their benefit. Patient responsibility and their understanding of that responsibility goes a long way in ensuring adherence to using a device, or following a set medical regime - again potentially through education. In the particular telecare device used it is evident that the device was discrete enough to naturally blend into the user's home and lifestyle. This is quite possibly

due to no strict medical regimes required when using the device, being a device for emergencies and intervention, rather than diagnostic or treatment.

User feedback once the device is in the market is more useful on a bigger scale, as can influence development of products going forward. This is very important in the way medical device companies operate now with their evolutionary product development. It is perhaps more beneficial then, to get subjective opinions from users, to help in the improvement of devices going forward. For telecare devices, the call centre function is crucial to the device; this effectively means that the need for the service is just as important as the device itself and should be given equal consideration when developing medical devices.

Overall it can be concluded that the user certainly has a role to play in the development of medical devices. Manufacturers of medical devices are doing much to involve users in the development of devices, be it clinicians, patients or both – not only because of government policy, or regulation pushing towards usability, but because they themselves can see the benefits of this. Users willingness to take part in trials, focus groups, inform representatives of their user group, will also go a long way in informing medical device companies of what users want. Much is being done currently in making sure all types of users are involved in the process. As devices are starting to follow a consumer model of technology, patient involvement is being sought to higher level than before, especially in relation to self-management devices. User involvement can really be pushed for, if the user takes an active interest as well as responsibility in the care of their health.

6.10 Design Action

In light of the evidence presented from the empirical findings, the preliminary conceptual framework required enhancement. The original framework which is presented in chapter three was based on theoretical research alone. The following diagram (figure 6.13) shows the preliminary conceptual framework of user involvement, with areas that are now felt to either be unsuitable or wrongly positioned greyed out with an explanation to follow.

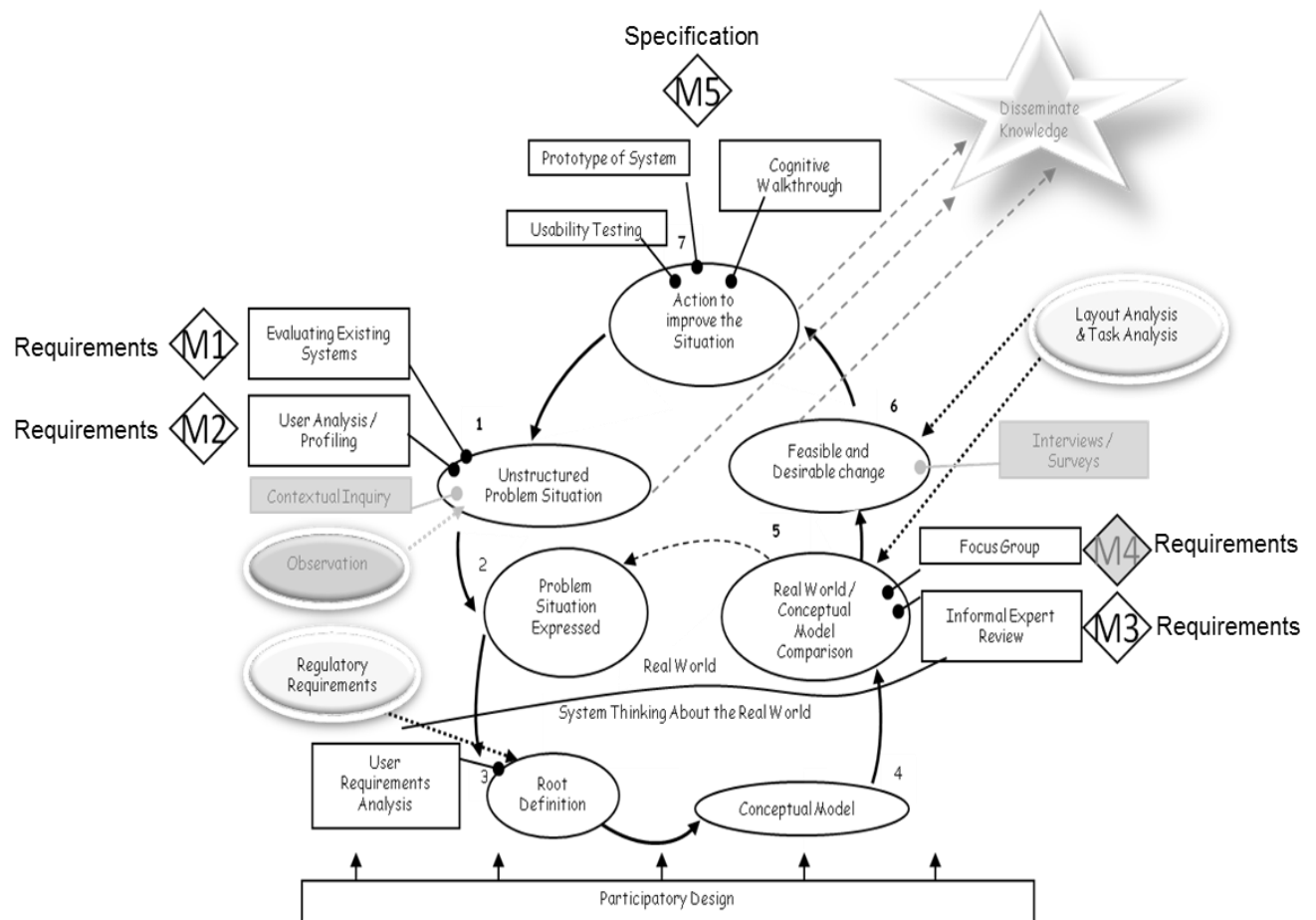


Figure 6.13: Redundant Areas in the Conceptual Framework Of User Involvement

Through the findings in industry, it became clear that methods such as observation and contextual inquiry were not relied on very much by the manufacturers interviewed and in instances where they are, use was irregular and informal. Some of the smaller manufacturing companies incorporated observational studies, but concrete feedback in document form was what was needed to get the concept off the ground. The other ergonomic methods which seem a little out of place are the interviews and surveys. They were initially included as part of the feasibility phase, when deciding on the feasibility of the design going forward. However many companies refer to survey data very early on, as in the case of the in-depth case study. Interviews and interview data is also something that is collected very early on, perhaps at the back end of a product that has already gone out to inform the new design concept, rather than feasibility. These methods were re-aligned in the model or replaced by methods which are given greater importance in today's medical device industry, in line with user requirements.

Another main area of concern in this model is the ‘knowledge dissemination’ area, represented by a star. It became very clear that despite the benefit of keeping users informed, competition and other business related concerns meant that this was not done very early on. It hence seemed appropriate to only inform users of what is to come at stage 7. For some manufacturers this still may be too early, and they may want to be quite selective of the type of user they decide to disclose information regarding new developments to.

Due to changes required in the ergonomics methods initially used in the model, the user acceptance steps (M1 to M5) need also to be altered in terms of their positioning. To begin with M3 is positioned to take place in conjunction with stage 5. It is proposed that a study should be conducted to determine beliefs for step M3, and originally the idea of using focus groups to elicit these beliefs was deemed suitable. After discussions in industry it became clear that participatory design methods like mock-ups and prototypes, however simple, could take place all the way up to stage 7, rather than just at stage 7, which the theoretical conceptual framework had portrayed. This brought about the idea that beliefs of users could be studied by looking at their reactions to prototypes, and stage 5 was modified accordingly (figure 6.14). This would potentially require greater analyses.

Step M4 looks at measuring the intentions between intenders and non-intenders. Stage 5 looks at stakeholder’s views of the conceptual model against the problem situation, so the initial rational had been that intentions of users could be measured here on their intent to use the device, especially as stakeholders are being consulted. However this now seems too early, considering the changes being made at this stage regarding prototyping. Realistically step M4 cannot be used to influence the decision of the stakeholders; it very much plays an analysis role. M4 would hence fit better in stage 6, which looks more at the feasibility side of development. This would allow enough room for analyses and potentially a final concept, before measuring intentions of users, rather than trying to measure intentions while the design is still uncertain. Here it is ideally positioned to influence any changes that are needed to make the device more acceptable, and can help towards making a decision on the type of interventions needed to make the device more acceptable at stage 7, through step M5. The development of the intervention is related to areas of informing, persuading or training, which ties in quite well to the knowledge dissemination star at stage 7, as it could potentially be a part of the intervention in getting peoples acceptance of the device.

These adjustments were made, followed by a few more additions and a final framework of user involvement in medical device development was produced (figure 6.14). As explained earlier, surveys were conducted much earlier on and have now been repositioned to stage 1. Step M4 has been moved up next to stage 6, and the idea of initial prototype has been introduced at stage 5.

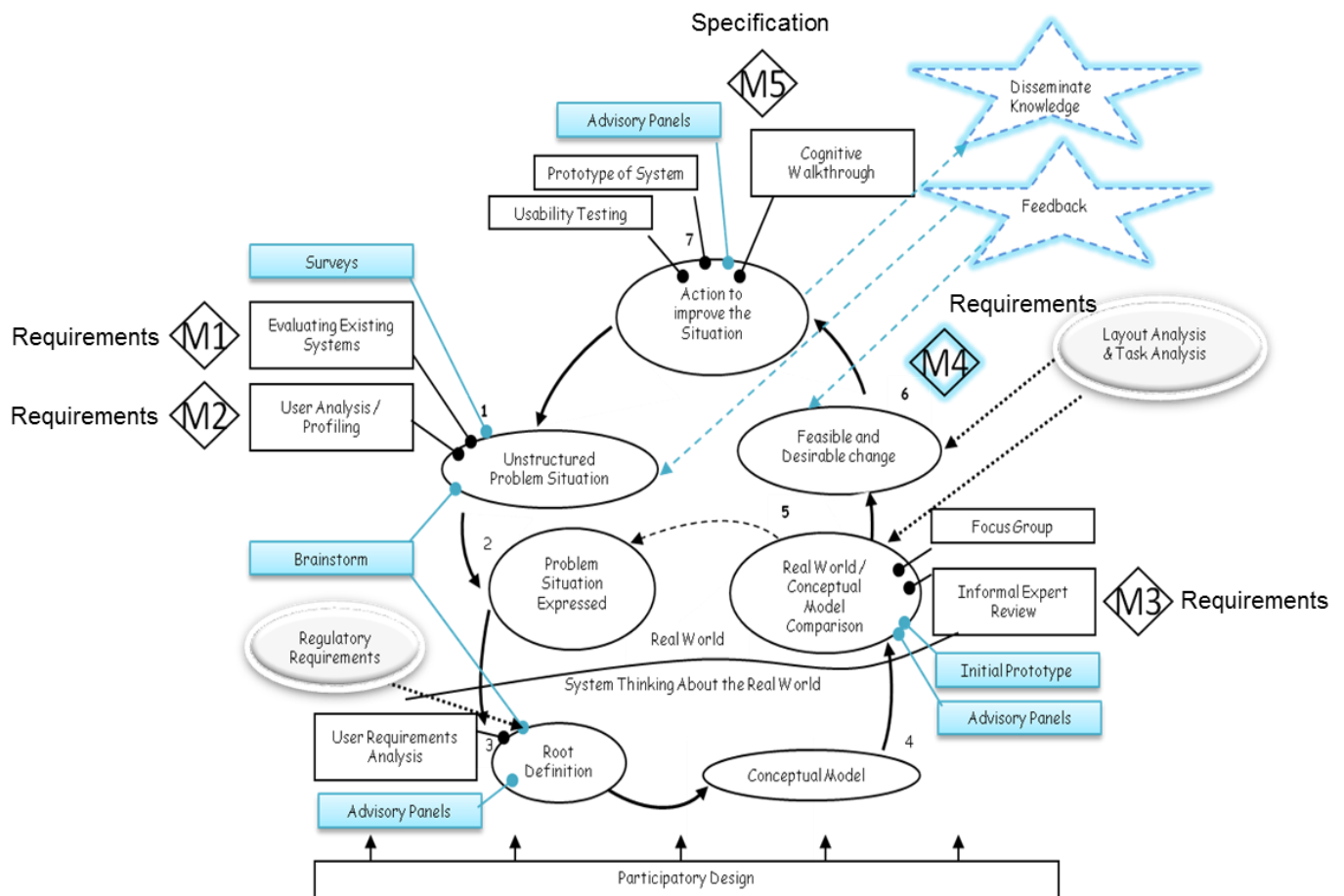


Figure 6.14: Additions to the Conceptual Framework of User Involvement

The grey areas were removed and any new additions are shown highlighted in blue in figure 6.14. Brainstorming of ideas was seen as important, and although the stages 1 and 2 look at defining the problem, with stage 3 the potential solution, there still seems to be no room for innovative design ideas. Brainstorming ideas and innovation is an important part of device development, even if the process does come across as quite stringent.

The idea of advisory panels is an important one in the manufacturing of medical devices. Across industry manufacturers rely on their advisory groups which can be made up of a whole host of people, including; clinicians, patients, policy makers and engineers to consult

with. Hence advisory panels appear at three different places in this framework, and represent a collaborative focus group. Advisory panels need to be consulted when potential solutions are being drawn up in the root definition stage (stage 3), especially as requirements are being gathered at this stage, and they can advise on whether all users requirements have been considered. They again should be consulted with when the potential solution is being compared with the problem at stage 5, as again can help to ensure all problems are solved for all those involved, or at least a consensus is reached on any trade-offs needed to be made. In this way users are involved, yet competitive information is not disclosed to any users that may have competing interests. Finally advisory groups can also be consulted in stage 7, when action to improve the current situation is taken. They can review how well the final prototype meets user needs, and solves the problem.

In this framework, the idea of feedback is highlighted by adding it separately to the model, despite the idea of feedback being quite visible in this iterative process of development. This mainly came about due to the importance of evolutionary design practice that takes place in the medical device industry. It is quite often feedback relating to other devices, or earlier version of devices or trends in the consumer market which inform the development of new or next generation devices. The feedback star represents the user or market feedback that comes from elsewhere, and can be used in stage 1, not specifically collected for the purpose of this development. Similarly such feedback can be useful when looking at feasible and desirable changes. The designers need to know what they can and should do in terms of their business requirements, and this should be addressed into the system at this point, so that the feasibility in terms of business functions and their strategies are understood and incorporated in the plan towards the device design solution.

The final framework is presented in figure 6.15.

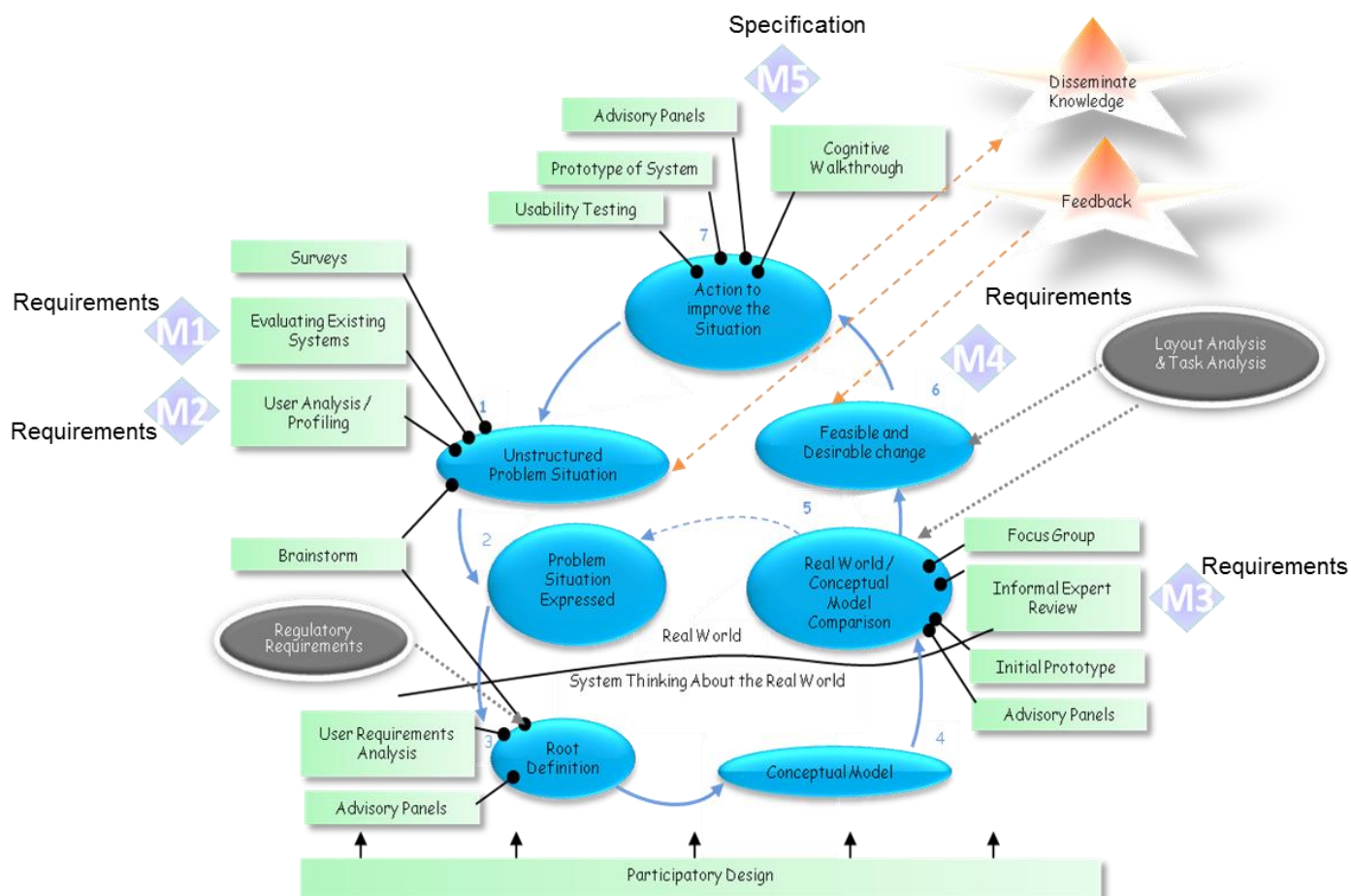


Figure 6.15: Final User Involvement Framework for Medical Device Development (MDD)

7 CHAPTER SEVEN: *Conclusion*

7.1 Introduction

This thesis has argued throughout that there are different aspects to user involvement in terms of methods, users and their behaviours. User involvement can only really take place if a structure is given to the problem which involves the user, understands the user and appeals to the user. In final conclusion when user involvement is done correctly i.e. the right information is exchanged between the right users at the right time and feedback is acknowledged and incorporated into the process of medical device development, then the acceptance of medical devices should increase and so should their success.

This chapter looks to conclude this research by summarising the progress made while achieving the aims and objectives of the research. The different threads of the argument are drawn together, followed by a discussion on the extent to which the research aims and objectives were met. This is followed by expressing the contribution this research has made to knowledge, its limitations as well as any further research possibilities and recommendations.

7.2 Overview of the Argument

This research has concentrated its efforts on deciphering exactly what the role of the user is in the development of medical devices. Findings of the theoretical literature search showed at first glance that users were clearly a part of many paradigms and academic subjects of study, with multiple theories and methodologies on whom the users are, how to involve them, their behaviours, motivations, intentions and emotions. Yet merging these views in a complementary fashion, gave an insight of what *should* be the role of the user, and how users should be involved specifically for the development of medical devices, from a single standpoint. The exploratory research in industry gave clear indications of how users were being involved currently in industry, to which extent and to meet what end. The explanatory study supplemented on this, with an explanation of which business areas were specifically involved and how. In addition the interpretive study was devised to incorporate the experience of patients as users, to understand their perceived level of involvement, and the importance of this involvement. Through the interpretive study, views of the carer's and local policy makers were also captured. These different research elements formed a multidisciplinary and multi-user study into the role of the user in medical device development.

Many medical device companies engage in evolutionary product development, predominantly modifying existing devices rather than creating new devices. Hence, although medical device development starts with the stages of concept and feasibility, much activity takes place prior to this, potentially on the back of existing devices. Through this companies develop their understanding of the target market and user needs, as well as how these requirements are changing. The relevant business functions strategize early in the feasibility stages, on how to market, supply, distribute and liaise with customers on these developments, depending on the target market and user needs. Clearly the target user is identified very early on, alongside sizing up the level of opportunity. Global companies further need to consider suitability on a global level, appealing to users across the world. With the telecare devices, the local council assessed potential users in their own geographical region, to understand the need before supporting implementation of the device.

The user involvement methods found in the literature and merged in the theoretical framework, were evident across the companies interviewed. It can be expected that some methods would be more popular than others, such as with the size of the company, the type of device and the target user group acting as influencing factors on the decision to incorporate certain methods would vary. On the departmental level it is marketing that engage more in user involvement techniques, and this would be specific to the product range in question. Before incorporating telecare devices, potential telecare users were assessed individually three times to ensure their requirements were being met according to their health needs, their device needs and service needs. Evidently a medical device cannot be seen in isolation from the users' situation, as the two are very much interrelated. This relates very well to user acceptance of the telecare example implored in this research. The tailor made packages of telecare are a very good example of user acceptance due to individuals' requirements being met. This relates to the importance of the service that is provided alongside the device, as in this case it gives users the confidence to use the device for their care. User acceptance is encouraged specifically by the marketing teams through providing information, education and training as necessary. From a business perspective dealing efficiently and effectively with problems and queries is helpful in ensuring user acceptance.

Willingness to take on board feedback and demonstrate to users the value of their input is vital to ensuring users feel valued, especially as medical device industries have long term relationships with their customers. Feedback sought through participatory design methods

was evident across the industry, as was a highly iterative process of design. All across industry, companies attempt to actively collect feedback. Even if this feedback was not incorporated immediately for a product, it was certainly considered for next generation versions. Intermediary groups such as patient charities are being used in industry to inform new designs, and get feedback. Companies engage in continual communication with users, after product launch, regarding modifications and upgrades, but shy away from parting with too much information on developments early on in design due to competition.

Meeting regulatory requirements are a necessary part of medical device development, and the industry is very much aware of its benefits. These requirements are usually included after the design specifications have been drawn up and the feasibility of the product going forward is being addressed. Global companies need to ensure legislation in all countries are met, and Company G combat that issue, by drawing up their own guidelines which incorporate standards from across their global market.

The business of medical device manufacture is a very competitive business, with its long development lifecycles, regulatory requirements and array of user needs all needing to be accounted for alongside the business objectives. Medical devices have started to mimic the consumer market, making product smaller and more mobile and being more aware of the service side of the business. Customer interactions and relationships are managed more thoroughly, and every business function attempts to differentiate itself from the competition. For some devices having backing by policy makers is crucial to their success. Company G work with the National Institute for Health and Clinical Excellence (NICE) to issue National Health Service (NHS) guidelines, for example the movement towards self-management and patient empowerment. Hence not only can the NHS become more aware of where device technology is moving, but medical device manufacturers can begin to gear its products towards the aims of the NHS. With telecare devices, it is apparent they could only really come into use once the government financially backed the scheme, seeing the benefits. Medical device manufacturers really need to be aware of where the market is moving and at the same time get backing from policy makers to aid the success of their devices.

Taking into consideration all of the threads of research investigated in order to address what role the user has to play in the development of medical devices, it can be seen that this role is dependent on the type of user. This research has outlined a role for the manufacturer, the patient, the carer and the policy maker as follows:

<p style="text-align: center;">The Role of the Manufacturer is to:</p> <p>Identify the user at the start</p> <p>Include different users via user involvement methods throughout the process of development</p> <p>Consider various perspectives as are in a position to incorporate everyone's view</p> <p>Regularly gather and analyse user feedback</p> <p style="text-align: right;">Ensure regulatory requirements are met for the safety of users</p> <p style="text-align: right;">Work with government and healthcare policy makers</p> <p>Consider the market trends, but in line with the needs of healthcare users.</p> <p>Manage and nurture long term relationships with customers i.e. patients and clinicians</p> <p>Have more links with information groups addressing and educating users about the disease</p>
<p style="text-align: center;">Patients</p> <p>Seek knowledge on illness as well as device</p> <p>Take Responsibility for Health</p> <p>Offer Feedback</p>
<p style="text-align: center;">Carers</p> <p>Seek knowledge on illness as well as device</p> <p>Offer Feedback</p>
<p style="text-align: center;">Service Providers: Local councils in this example</p> <p>Build understanding of the local users</p> <p>Provide information on device use</p> <p>Provide information regarding illness</p> <p>Provide feedback to associated manufacturers</p>

Table 7.1: Table of Users Roles in MDD

The role of the manufacturer in the process of development is by far the greatest; however the case studies undertaken in this research proved that patients, service providers and carers also play a part in this process. Even the small parts these users play affects the success of the product and in fact it is down to these users that has ensured manufacturers continuously

improve their designs to devices, their processes of gathering requirements and modifications to technology. This has not only been down to availability of new technology but because healthcare users are being perceived as consumers and want to be able to follow trends in the consumer markets, which they have already potentially adopted in their lives, mobile technology for instance being one such example.

Clinicians also clearly have a role which has been understood and elaborated upon through the manufacturer and patient perspective in this study, further research into the clinical perspective may well prove that clinicians do have a greater role to play in the development then perhaps the patients, as described by the manufacturers.

7.3 How the Aim and Objectives of the Research Have Been Met

In order to examine how well this research has met the aims and objectives set out at the beginning, each objective will be described and the extent to which this objective has been achieved and its contribution to the underlying aim of the research.

The first objective *‘To capture the significance of users, through the synthesis of existing methodologies in information technology and social science subject areas, by conducting a literature search’*, was met in a number of ways. Firstly by establishing through the literature, who these users potentially were and secondly discovering that various disciplines held their own assumptions of what is meant by user and user involvement. Many of these views were revealed as not dissimilar, rather they engaged in various user involvement methods that were designed to ultimately meet the same purpose. The second objective followed on from this, *‘to produce a theoretical framework of user encapsulation...’* by allowing for the construction of a theoretical framework to capture user involvement in medical development. Relevant aspects were merged, and efforts were concentrated on the early stages of the medical device development lifecycle. This contributed to the main aim by helping to understand the users and hence their roles better, what it means to be involved, and the process of medical device development from a theoretical standpoint. User requirements methodologies were investigated which in turn helped to produce a preliminary version of the theoretical framework from which the empirical research could begin. Meeting this objective significantly closed the gaps present in the literature relating to using theories from single disciplines in isolation.

The next objective was partly '*to examine the current process of medical device development in industry through empirical research.*' This objective was met by conducting interviews with the elite in industry as well as conducting an in-depth case study for one case. This helped to understand the process of medical device development at a practical level, and was revealing as to the level of user involvement currently present. This helped to define the role of the manufacturer of medical devices by developing an understanding of the manufacturers perspective on their obligations to the business, to regulation and to their customers, in light of which manifests their understanding of their responsibility to the user. Again this relates back to the aim, of understanding the process of development as well as the role of the user, in this case the manufacturer, better.

Following this, examination of '*the end user perspective, on their current level and their perceived benefit of involvement...*' was investigated through conducting a case study, which involved patients and carers as well as a representative of the local council backing the use of telecare for independent living. This case study ensured the perceived benefit by the council in backing this device was compared against the users experience and perception of it. This led to the *exploration and definition of the role of end users of medical devices,*' as again their role could be deduced by the interaction they had with the technology providers, their experience with the service and their view of their needs. Only by incorporating multiple users could this research understand the importance of the aim of this research of involving users in the development of medical devices, as it outlined the journey through the process of development, and the ongoing attention and interaction required throughout, so again met the main aim of understanding the role of the user by incorporating a variety of users in the empirical research.

This ultimately led to the final objective which was '*to produce an innovative process of user-involved-medical-device-development.*' The final construction of the framework for user involvement in the medical device development process was the outcome of this objective and in turn the aim of this research.

Through meeting these objectives, this research study was able to decipher the role for medical device users. The framework for user involvement in MDD took into consideration user requirements methodologies and was able to encapsulate and integrate the user more distinctively throughout the medical device development process, meeting the aim of this research.

7.4 Contribution to Knowledge

The original contributions of this study include its successful attempt to use a multidisciplinary approach to account for users and apply user involvement methods to specifically the early stages of the medical device development process. The literature showed limitations of involving users within the healthcare domain, in the theories across the different subject areas researched. The idea had been to tackle the idea of users, and understand their role in the development process from an IS perspective. The limitations of the chosen methodology within information systems quite naturally drew attention to the field of ergonomics and ergonomic methods. This provided some positive aspects to support the information systems methodology, but again drew some more light on the limitations of understanding user behaviours. The health psychology provided some insightful theories into covering that gap, but again was limited by its inability to transform the theory into a method to contribute to design. The design of medical devices gave an insight on how to deal with user behaviours by appealing to their emotions. It also contributed some tried and tested requirements to medical device development, including regulation, verification and validation, joining back to the IS methodology, with its structure and stages. In this way tackling the limitations of the literary gaps was a contribution of this research, the literature gaps being addressed as far as possible to enable the user involvement framework to stand autonomously. The research developed naturally to transcend and collaborate between these theories, which really contributed to the multidisciplinary approach it took.

Previous research claiming a multidisciplinary approach has dealt with combining two disciplines or methods at a time i.e. computer supported cooperative work (CSCW) with participatory research (Scandurra, Hagglund and Koch, 2008), used for requirements analysis, of healthcare-professionals. The collaboration between multidisciplinary user groups was emphasized here, rather than between the difference in the thoughts and needs of these users. This research added to the work by Scandurra, Hagglund and Koch (2008) as it produced a framework which is not only applicable to healthcare professionals, but also to patients and manufacturers. Furthermore many more theories were used in the multidisciplinary approach taken, ensuring a vast number of viewpoints were incorporated.

Johnson, Johnson and Zhang (2005) recognised the advantages 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 interface systems. Although Johnson, Johnson and Zhang (2005) proved redesign could be successful when collaborating across these fields, he concentrated his efforts on the redesign of software and interfaces rather than devices and drew for the most part on user centred design principles. This research also extended upon Johnson, Johnson and Zhang's (2005) work, as it was not limited to user centred design principles and is generic in that it is a useful framework for all medical devices not only the software elements. Furthermore it can be used for new product development as well as redesign or evolutionary product development.

This research made a further innovative contribution by developing a solution to the problem of inadequate user involvement in the medical device development process. It incorporated user involvement methods at the different stages of the process, specifically the early stages of concept and feasibility, ensuring consideration for the various types of users that may need to be included. This was especially significant as despite the enthusiasm for user involvement it has been lacking in industry practice. By incorporating user involvement within the process, its benefits can be attained by all. This could be even more beneficial considering user involvement may become a regulatory requirement, meaning all medical device manufacturers would need to incorporate and document any user involvement by law.

Further to this, validating the theoretical framework by eliciting manufacturer's views at both top level management and departmental management level, alongside the views of policy makers, patients and carers has provided various voices to this research. It has allowed different users to represent themselves in claiming their role within the development process. It has also enabled users to express the role they perceive other users to have, as well as themselves. For example the manufacturers also provided significant details on the role of the clinician, in relation to their own interactions they have with clinicians and experience on how the industry works. Unfortunately clinicians could not be interviewed for further investigation on their view in this particular research as a limitation of this research, outside the scope of this research. Nevertheless accommodating various voices in this research gave a more rigorous identification of the role of the user in medical device development.

7.5 Recommendations

Following the contributions to knowledge made by this research, there are a few practical recommendations that can be suggested. The first suggestion is for the medical device manufacturers to adopt user involvement methods within their development processes. This

is because; across the medical device industry, manufacturers are already aware of the benefits, the consumerist style healthcare users require it, and regulatory requirements are potentially looking to make it law. Manufacturers need to look at their own processes to recognise the extent to which they involve users and incorporate user views at the early stages of development, so that they may start to eliminate any gaps and inconsistencies in user involvement. This will prepare them to incorporate user engagement if and when this does become a regulatory requirement.

A further recommendation is made to policy makers. The national healthcare service is looking to support self-management and empower the user, giving power to local council authorities to rollout such schemes. It is important for policy makers to ensure the services they provide along with chosen devices are just as robust as the devices themselves, as this is what patients really value. The system surrounding the successful integration of a medical device in the life of the patient needs to be regarded in good esteem in order to aid the success of the medical device.

7.6 Limitations

Although this research was conducted as thoroughly as possible, it does have its limitations. Some of these objectives have not been met to the extent first anticipated. The in-depth industry case study was sought in order to supplement the understanding of the research and development departments. However, this became impossible as many of the companies interviewed had their research and development departments abroad. The company recruited for this explanatory work – Company G, predominantly undertook modifications to design rather than new designs which did offer some consolation, as a study by Rochford and Rudelius (1997) pointed out that the marketing function has almost an equal role to play as the research and development departments, when companies have an evolutionary process of development. Hence the marketing department was interviewed, and provided sufficient details on the company's activities to extend upon the elite interviews conducted at the exploratory phase. Additionally all the departments had some role to play in the initial research stages of the design, and developed strategies for the business as well as the device, giving a great working picture of how medical device manufacturers operate.

Further to this, the research objectives had intended to examine the end user perspective, on their level of involvement in device development and their perceived benefits of such involvement, in order to then define the end users role. Although this had been met through

interviewing telecare patients, carers as well as a representative of the service provider at the local council, there were more users involved that could have been interviewed. Carers were only interviewed if present and not actively invited to take part, yet it may have been useful to run a focus group listening to the carer's views to get a collective feel for their position and their experience and the degree of involvement they have or wish to have. Further to this there were also community nurses as well as a variety of clinical staff involved in the care of the telecare users, including GP's, occupational therapists, community nurses, physiotherapists and so on. Interviewing clinicians would definitely have provided another end user view on user involvement in the process of medical device development and how their involvement relates to their practice of using the device. It was decided from the offset however that manufacturers and patient end users were to be interviewed, as time would not give the luxury of collating information on every type of end user despite the benefits.

Through conducting the exploratory phase of the research and understanding the reliance of manufacturers on advocacy groups, patient charities and key opinion leaders, it seems that having been unable to interview such a group was also a limitation of this research. Some steps were taken to form contacts through the companies interviewed, however chasing down patients to interview had felt more important at the time, and the decision to pursue patients rather than the aforementioned groups was taken. With hindsight however, it seems that interviewing representative of patient groups and clinical advisory groups would have provided a high level view of the impact of these user groups, and may have increased the types of users interviewed for this research. At the same time the insight individual patients provide on their experience and how this relates to their acceptance of the devices, is best heard as first-hand accounts from patients, as the views can get diluted going up the hierarchy of influence.

The choice of device could have been selected differently. Initially the choice of device was made looking at devices that patients had the most interaction with, i.e. self-monitoring devices in the home. These devices were labelled telehealth devices, particularly used to monitor the vital signs of patient suffering from chronic diseases, either chronic heart failure (CHF) or chronic obstructive pulmonary disease (COPD). The extensive ethical review process meant getting the approval to interview these patients was very difficult, and in fact has only just been approved as this research comes to a close. Using telecare devices was a second option, not requiring the same level of ethical review, but it also meant the devices

were not as specific to certain patient groups either, with limited interaction required. Using telehealth device would have required the user's involvement on a daily basis, and their experience of living with the device may have provided even greater insight.

7.7 Further Research

Based on the limitations then, there are a number of possibilities for further research, with research specifically into the clinicians' involvement in the development of medical device being the obvious place to start. From the manufacturers perspective captured in this research it became obvious that clinicians can take part in many different ways to inform the design of a device. Hence, clinicians as users of the device need to be interviewed, as well as those who are part of advocacy groups specifically recruited by the manufacturers and those who present an idea according to their need in the practice of healthcare.

It may also be advantageous to take a particular device, and follow it in its modification lifecycle. This may help further establish where users interact and inform the development, and when in the process particular users are given importance. Long development lifecycle would mean that a longitudinal study is required; however the practical execution of developing a medical device is very significant in assessing the user's role, and pinpointing how to address user related issues at specific points through development.

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Appendix A: Exploratory Phase Appendix

Appendix A1: Ethical Approval Acceptance Letter for the Exploratory Study

School of Information Systems, Computing and Mathematics

David Gilbert, Head of School, Professor of Computing

Jasna Kuljis, Head of Information Systems and Computing, Professor of Computing

Tony Rawlins, Head of Mathematical Science, Professor of Mathematics

The use of e-learning to improve numeracy on Schools

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Date: 24th May 2010

STATEMENT OF ETHICS APPROVAL

Proposer: Anila Shah

Title: The Role of User Requirements Research in Medical Device Development

The school's research ethics committee has considered the proposal recently submitted by you. Acting under delegated authority, the committee is satisfied that there is no objection on ethical grounds to the proposed study. Approval is given on the understanding that you will adhere to the terms agreed with participants and to inform the committee of any change of plans in relations to the information provided in the application form.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Laurence Brooks', with a stylized flourish at the end.

**Dr. Laurence Brooks, Chair of the Research Ethics Committee
SISCM**

Appendix A2: Letter of Invitation for Medical Device Manufacturers

School of Information Systems, Computing and Mathematics

David Gilbert, Head of School, Professor of Computing

Jasna Kuljis, Head of Information Systems and Computing, Professor of Computing

Tony Rawlins, Head of Mathematical Science, Professor of Mathematics

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Date.....

Dear Sir/Madam,

I am a PhD student, currently undertaking my research at Brunel University, and working within MATCH, for further information visit the programme website www.match.ac.uk My research looks at the process of medical device development and in particular methods used at the design stages of development which require user involvement or input. The importance of the role of the user, and how user's needs and requirements are obtained and met, is a vital component of this research.

My research draws on the fact that medical device technologies are increasingly being designed for use in non hospital settings, by the patient and without assistance. However, it is evident that medical adherence and acceptance of the devices are lower amongst users than designers' expectations. Hence a greater need to close this gap and understand the emerging consumers of medical devices exists.

I am interested in speaking to yourself or a member of your research and development team to understand more about how the current process of medical device development takes place at your company, focusing primarily on the design stages of development. I want to understand whether my proposed theoretical framework can relate to or add value to the current process, and how much overlap there is between the theoretical framework and practical application. The findings will be analysed and communicated back to you after the study takes place.

Your interest would be very much appreciated and I look forward to hearing from you soon. Please contact me either by email (anila.shah@brunel.ac.uk) or by phone (07854217351) to confirm your interest and to hopefully set up a meeting.

Yours sincerely

Anila Shah

Information Sheet

Introduction

I am a PhD student, currently undertaking my research at Brunel University, and working within MATCH. My research looks at the process of medical device development and in particular methods used at the design stages of development which require user involvement or input. The importance of the role of the user, and how user's needs and requirements are obtained and met, is a vital component of this research.

My research draws on the fact that medical device technologies are increasingly being designed for use in non-hospital settings, by the patient and without assistance. However, it is evident that medical adherence and acceptance of the devices are falling lower than designers' expectations. Hence a greater need to close this gap and understand the emerging consumers of medical devices exists.

Participant's Tasks

The participant will be initially asked to answer some questions on medical device development, being asked to explain how their company undertakes this process. The second half of the interview will be an explanation of my theoretical model and a discussion on how the processes are similar / different and why.

Participation is not compulsory and you can withdraw at any time without consequence.

All personal details will be kept anonymous

If you have any concerns or complaints regarding the ethical aspects of this project please contact siscm.srec@brunel.ac.uk or Dr Laurence Brooks, Tel. 01895 266010

CONSENT FORM

Please complete all questions.

Please tick an appropriate box

	YES	NO
Have you read the Research Participant Information Sheet?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had an opportunity to ask questions and discuss this study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you received satisfactory answers to all your questions?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that you will not be referred to by name in any report concerning the study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that you are free to withdraw from the study?		
at any time	<input type="checkbox"/>	<input type="checkbox"/>
without having to give a reason for withdrawing	<input type="checkbox"/>	<input type="checkbox"/>
Do you agree to take part in this study?	<input type="checkbox"/>	<input type="checkbox"/>

Signature of Research Participant.....

Date.....

Name in Capitals.....

Interview Schedule

Introductory Questions:

- a. Please can you give a brief introduction to your company and what your job entails?
- b. What are the initial steps taken by your company in the process of medical device development?

Users

- a. Who are the target users for your products?
- b. Which users do you involve in your development process?
- c. Do different user types come together to discuss the product requirements as a group?
- d. How do you prioritise user needs if they are conflicting?
- e. Are the users involved in the early stages of the process?
- f. How are users involved at each of these stages?
- g. What methods of user participation or user involvement do you use in the development process?
- h. Do you think the users you do involve are satisfied with the level of their involvement and are able to see changes occurring according to their involvement? Please give examples
- i. WHY involve the users in your opinion?
 - i. What are the benefits and limitations of user involvement
- j. In the future do you plan for greater user involvement?
 - i. Are any users/stakeholders to be prioritised and at what stages?
- k. What is your opinion of the view 'Patients do not really know what they want anyway?'

Measurement of Success

- a. What is the success rate of devices designed by your company?
 - i. User acceptance rate
 - ii. User rejection rate
- b. If there is rejection then which stakeholders makes that decision
- c. Do you measure or plan for medical adherence (according to factors such as age, condition, background, health status, long term chronic patients, telemonitored patients).
- d. Do you provide training and information to your user?
 - iii. Does this influence the compliance of the device?
- e. What are your concerns when bringing new devices to market? (Research and development costs, regulatory requirements, cost of expansion in new markets, time pressures?)

Feedback

- a. How much iteration takes place in the design process and when?
- b. Are activities such as prototypes, mock-ups implemented as a long term strategy or used as and when required for a quick solution to an immediate problem?
- c. If there is a need for further modification after launch where does it relate back to for the need for improvement?
 - i. Is it a reflection of an issue in the requirements gathering phase?
- d. What is the latest stage you would make alterations or modifications to the device before launch?

Product Information

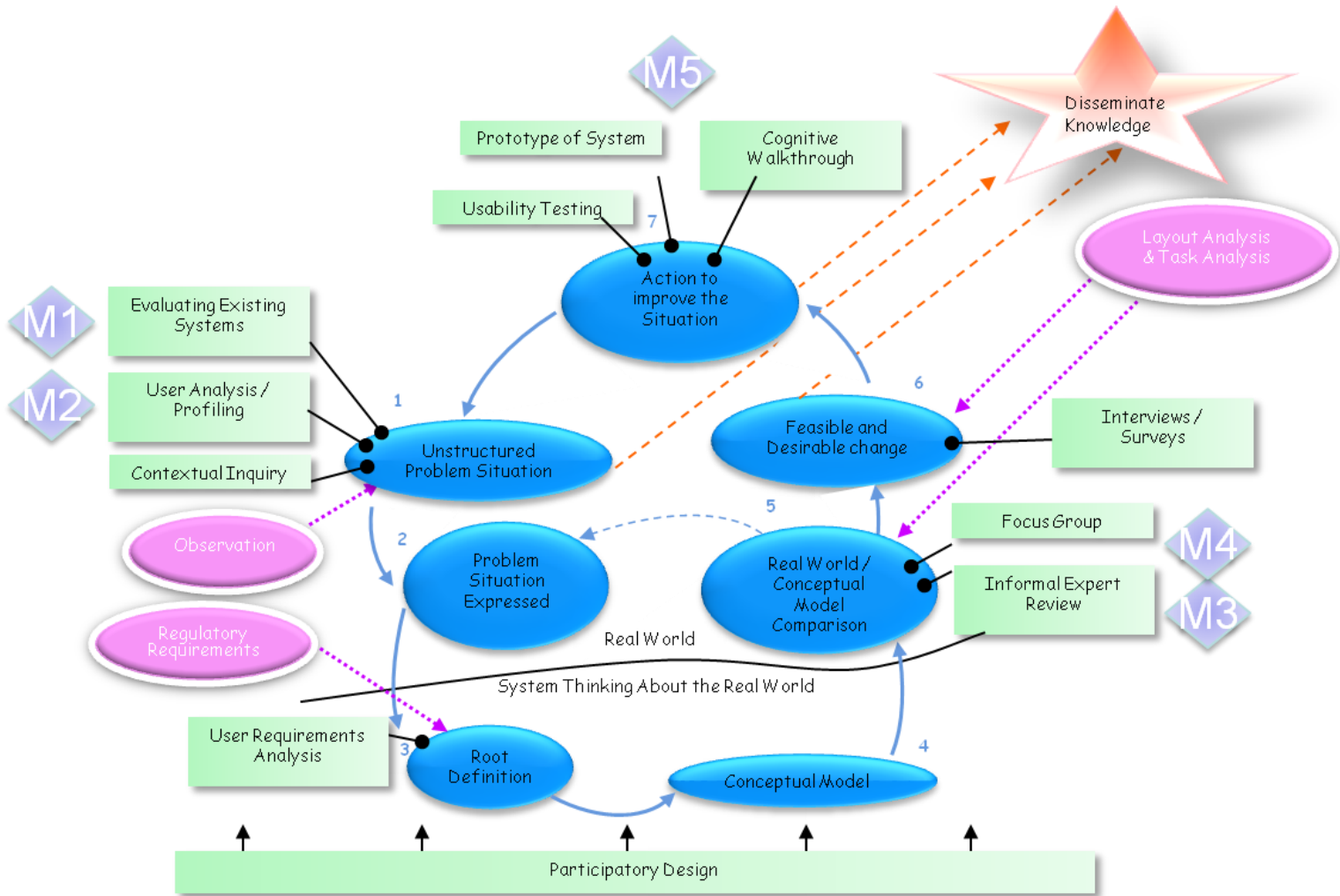
- a. At what stage would you be disseminating information to your users on new developments?
- b. What particular information is circulated?
- c. Which users in particular are given product information and does it vary depending on the type of user?

Regulatory Requirements

- a. At which stages of the process are regulatory requirements incorporated?
- b. Are these steps governed through any standards, at which stages and which ones does your company use?

End of Questions

Theoretical User Involvement Framework in MDD



APPENDIX B:

Interpretive Phase

Appendix

Telecare Service

Dear Sir / Madam,

Brunel University has been asked by Nottingham City Council to conduct a research study looking at the experiences and needs of individuals using telecare equipment within their home. Since you are enrolled on the 'Safe At Home' Telecare Service by Nottinghamshire County Council, we are very interested in your views about this.

We would be grateful if you would agree to participate in a short interview. The aim of the interview is to understand your experience of having telecare equipment installed in your home and how this may, or may not, have had an effect on your day to day life.

The interview will take up to 45 minutes. We would like to record the interview so that the interviewer can concentrate on listening to you rather than having to write things down. The interview will be transcribed and this document will be only be seen by the person who transcribes it and the researchers at Brunel University.

All information will be held in absolute confidence by the University research team. No one who takes part in the interviews will be able to be identified by anyone outside the research team.

We would be delighted if you are willing to be interviewed. If you have any further questions about taking part, please feel free to contact one of the members of the research team. If you wish to agree to take part please complete and sign the enclosed consent form and return it in the envelope provided. We will then contact you to order to arrange a convenient time for the interview. We will also ask if you are happy for the interviewer to come to your home or if you would prefer to come to a City Council building for the interview.

Thank you

Dave Miles, *Business Manager, Assistive Technology and Telecare, Nottingham City Council.* Email: Dave.Miles@nottinghamcity.gov.uk. Phone: 0115 8763478

Anila Shah, *PhD Researcher, Brunel University, Uxbridge.* Email: Anila.Shah@brunel.ac.uk. Phone: 07854217351

Thank you for agreeing to take part in this research

CONSENT FORM

Nottinghamshire County Council supports a 'Safe At Home' Telecare Service which combines technology and support to provide help in an emergency. Various sensors and detectors are installed in the home, providing the individual recipients as well as their family and carer's with added security and confidence while at home.

The study is designed to evaluate the impact of telecare for the patients involved.

Please complete all questions.

1. I confirm that I have read and understand the letter enclosed detailing the purpose of this research. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I agree to my information being collected and used for the purposes of this research project. ☐
4. I agree to take part in the above study. ☐

Signature of Research Participant.....

Date.....

Name in Capitals.....

Address.....

Telephone Number.....

Return to: Anila Shah, St Johns Building, Brunel University, Uxbridge, Middlesex, UB8 3PH

Interview Schedule

The aim of this study is to better understand the needs and requirements of individuals using telecare equipment within their home. The questions outlined look to understand the participants view of having such a device in their home and the impact this has on their lifestyle as well as health status. All interviews will be semi structured in-depth interviews. Ideas discussed will include ease of use of the equipment, ease of learning, self-management, feelings on health status, any concerns on the technology, aspects of self-management and knowledge about how to deal with an emergency and how patients have needed to adapt their lives.

Each participant will be individually interviewed once. The duration of each interview will be 45 minutes.

All participants will be asked to sign a consent form prior to taking part in an interview.

Question for the semi-structured interview:

The Equipment

1. How did it come about that you have got this equipment? (Prompts: Did someone mention it to you first or did you ask someone about it? What conversations did you have with people about it? Etc)
2. Why have you got this equipment? (Prompts: What is the aim of you having it? What does it help with?)
3. How long have you had the equipment installed?
4. What equipment have you got?
 - a. How often have you had to use it? / how often has it been activated?
 - b. Do you have to do anything (or does it work without any input from you)
5. Please describe how you would normally use the device / how it is activated/how it works?

Determinants of Acceptance

1. What are the best things about having this equipment?
2. What are the worst things about having this equipment?
3. What do your family and friends think about it?
4. Has having this equipment in your house worked out just as you thought it would or has there been anything that has surprised you at all? (Prompt – anything particularly pleased you or disappointed you?)

Value of Patient Contribution (some of this is covered in ‘The Equipment’ section)

1. Has anyone asked how you are getting on with this equipment?
 - a. What do they ask?

- b. What do you tell them?
 - c. Is there anything else you think they should ask?
- 2. Have any changes been made to the equipment since you first had it?
 - a. If yes Why? What? / If no, do you wish any changes could be made? It doing more/less/different? Have you mentioned this to anyone? If not why not?

Patient experience of Telecare

- 1. How does it make you feel having this equipment?
- 2. Have you had any emergency situations since this equipment was installed?
- 3. When does the equipment avoid or alert a possible emergency?
- 4. Think back to before you had this equipment, tell me how it has made a difference.

Self-Management

- 1. Have you needed to adapt your lifestyle in any way to accommodate for this equipment?
 - a. Has this equipment helped you to go about your usual activities or does it make it more difficult?
- 2. How do you feel when you are in other people's houses that don't have this equipment?

Adherence

- 1. What kind of instructions or training were you given to use the equipment?
 - a. Who gave you the instructions / training?
- 2. Have you found your own way around using the equipment, or do you feel you need to follow the instructions precisely?
- 3. So do you feel the equipment keeps you safe, or is keeping safe your responsibility?

End of Questions

D1: Service User Feedback - February 2010

TELECARE IN NOTTINGHAM

Independence without Isolation

Summary of service user feedback questionnaires **(as of February 2010 – 163 replies)**

1. How satisfied were you with the process of assessing your need for Telecare equipment?

Excellent = 48%	Very Good = 28%	Good = 19%
Average = 3%	Poor = 1%	Not answered = 1%

2. How would you rate the installation of the Telecare equipment?

Excellent = 49%	Very Good = 31%	Good = 15%
Average = 3%	Poor = 1%	Not answered = 1%

3. How did you find the explanation on how to use the Telecare equipment?

Excellent = 37%	Very Good = 33%	Good = 20%
Average = 2%	Poor = 2%	Not answered = 1%

4. Overall, how have you found the Telecare equipment?

Excellent = 43%	Very Good = 32%	Good = 17%
Average = 4%	Poor = 1%	Not answered = 3%

5. Has the installation of Telecare equipment given you more confidence/peace of mind?

Yes = 88%	No = 4%	Not answered = 8%
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6. Has the installation of Telecare changed the amount of care and support you receive?

Yes = 23%	No = 69%	Not answered = 8%
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7. Have you had any medication / health problems in the past 6 months, for example needing a hospital admission, use of ambulance service or new medication.

Yes = 51%	No = 42%	Not answered = 7%
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8. Have you experienced any problems with the use of the Telecare equipment?

Yes = 15%	No = 77%	Not answered = 8%
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TELECARE IN NOTTINGHAM

Independence without Isolation

Sample responses from service user feedback questionnaires (as at February 2010)

1. How satisfied were you with the process of assessing your need for Telecare equipment?

"The OT who did the original assessment was very good and clearly had medical knowledge and experience of the difficulties of old age."

"Very well explained".

"Very satisfactory, makes me feel safer".

"The person who came to assess me was polite and helpful"

2. How would you rate the installation of the Telecare equipment?

"Installation very satisfactory".

"Installed in very quick time with no upheaval".

"Explained well. Dealt sensitively with Mrs Smith".

"The installation was very good indeed on instructing me how to use the equipment. Thank you".

3. How did you find the explanation on how to use the Telecare equipment?

"Very Good".

"Helped to understand how to use it".

"Gentleman showed her what to do and tested it. Don't mind paying for it."

4. Overall, how have you found the Telecare equipment?

"Have not needed it yet thanks god"

"There was an initial technical glitch that lead to it being disconnected but resolved the following day."

"I'm very happy to say that I have not had cause to use it!! However, I feel very much safer knowing it is there if ever I do need it."

5. Has the installation of Telecare equipment given you more confidence/peace of mind?

"Definitely, as we know of acquaintances who were in trouble without it".

"My friends and relations are relieved that I have it".

"Especially when I go up and down stairs and am away from the phone".

"Takes away the stress of having to sort my meds out daily which is a great relief knowing that someone is there, at any time of the day or night."

"Done wonders for my peace-of-mind."

6. Has the installation of Telecare changed the amount of care and support you receive?

"I still have people asking me if I am alright".

"The installation of Telecare is itself support".

"Whilst used on very few occasions, its presence is a boon to my well-being."

7. Have you had any medication / health problems in the past 6 months, for example needing a hospital admission, use of ambulance service or new medication.

"This was before the equipment was installed".

"Mum fetched ambulance for dad with button, he had got out of bed and couldn't get back in".

8. Have you experienced any problems with the use of the Telecare equipment?

"No problems".

"Haven't yet only to thank you for care".

"Because I'm nearly deaf, I can't tell what the operator is saying".

9. Do you have any other comments about your needs?

"Feeling now of not being alone, which is all to the good".

"After a few days of receiving the equipment i accidentally pressed the red button and received helpful and immediate response".

"Installation was very quick and well explained and tested. Have not had to use the system yet but feel very reassured that it is there if required".

"Very helpful, me and my son feel more secure. Don't know how we'd do without it."

"Haven't used it yet, good to know its there."

"The installation of the equipment has done wonders for my peace-of-mind and I am very grateful. I am required to attend hospital on a 6-monthly occasion for my problems, but grateful for your kindness".

"A pair of new legs would do nicely. Many thanks."

TELECARE IN NOTTINGHAM

Independence without Isolation

Summary of carers feedback questionnaires **(as of February 2010 - 138 replies)**

1. Are you the named Carer/Responder (delete as necessary) in the event of an alarm being triggered?

Yes = 83% No = 12% Not stated = 5%

2. Has it been necessary to respond to any alarms?

Yes = 41% No = 56% Not stated = 3%

3. How did you feel about the person trying new Telecare equipment?

Worried = 5% Apprehensive = 22% Sceptical = 10%
Enthusiastic = 52% Other - 3% Not stated = 8%

4. Has Telecare reduced any anxiety you may have had about the person you care for?

Yes = 83% No = 12% Not stated = 5%

5. Has Telecare reduced or changed the number of visits/telephone calls you were making to the person you care for?

Yes = 25% No = 62% Not stated = 13%

TELECARE IN NOTTINGHAM

Independence without Isolation

Sample responses from carers feedback questionnaires **(as at February 2010)**

1. Are you the named Carer/Responder (delete as necessary) in the event of an alarm being triggered?

"I am the daughter living 1.25 hours away by car".

"My wife is the user and I live with her"

"We are the family carers who are also the responders".

"I am both carer and responder although my mother's neighbour when not at work can deal with things".

2. Has it been necessary to respond to any alarms?

"Fortunately have had no reason to use it".

"I have been in the house when he fell and able to help him up".

"Excellent, good advice received. Paramedics arrived within fifteen minutes".

"The operator was very calm and helpful which calmed me down".

"When you could not get any response from my father"

"Very good stayed on the phone to mum until I got there".

3. How did you feel about the person trying new Telecare equipment?

"As a health professional I knew it was essential".

4. Has Telecare reduced any anxiety you may have had about the person you care for?

"We both feel more confident".

"Good to have someone to turn to in an emergency".

"Now I have peace of mind when I cannot be there".

"Considerably, allows me to leave the house with greater freedom knowing Telecare is there".

"I feel I can go out for a day trip knowing he can get help".

"Ambulance response has been excellent"

"I know if anything happened the call would get to me straight away".

"Very much needed as service user was very isolated and didn't have many visitors".

"As I don't live locally and don't drive, having Telecare is a great relief".

"If there is a problem I know I can be called straightaway and will be there in fifteen minutes".

"My father-in-law has had a few falls, I know he will receive help if needed quickly".

"re: Taking of medication which are controlled pain analgesia and sleeping tablets".

"I am comforted in the knowledge my father has the independent means of communication if needed".

5. Has Telecare reduced or changed the number of visits/telephone calls you were making to the person you care for?

"Just gives us added peace of mind".

"At first - when I was still working - no longer applies but may in future".

"It reduced visits but not necessarily calls".

"I make more visits because I have to respond to alarms being activated".

"Yes, by half".

"I don't need to phone my parents as often knowing that they have access to care-response".

"Telephone calls reduced but not visits".

"We still phone at least once a day for social interaction".

6. Do you have any further comments on any issues that have arisen?

"No - I am feeling safer with Telecare".

"My father has dementia and therefore he does not realise what the alarm is. An ideal alarm would be connected to a socket which cannot be switched off easily".

"Just thank you on behalf of Irene and myself".

"The equipment and service are very good. They are all we hoped for".

"Telecare has given us all peace of mind, knowing that mum is safe if she falls or needs anything".

"My parents feel safer".

"I find the service very helpful, thank you".

"The equipment and service are very good, they are all we hoped for"

"Telecare is a good idea for old people with illness that affect them. We care because you do".

TELECARE IN NOTTINGHAM

Independence without Isolation

Summary of service user feedback questionnaires **(as of November 2010 – 222 replies)**

1. How satisfied were you with the process of assessing your need for Telecare equipment?

Excellent = 45%	Very Good = 31%	Good = 19%
Average = 2%	Poor = 1%	Not answered = 2%

2. How would you rate the installation of the Telecare equipment?

Excellent = 47%	Very Good = 34%	Good = 13%
Average = 3%	Poor = 1%	Not answered = 2%

3. How did you find the explanation on how to use the Telecare equipment?

Excellent = 36%	Very Good = 36%	Good = 18%
Average = 3%	Poor = 2%	Not answered = 3%

4. Overall, how have you found the Telecare equipment?

Excellent = 43%	Very Good = 34%	Good = 16%
Average = 3%	Poor = 1%	Not answered = 3%

5. Has the installation of Telecare equipment given you more confidence / peace of mind?

Yes = 86%	No = 4%	Not answered = 10%
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6. Has the installation of Telecare changed the amount of care and support you receive?

Yes = 24%	No = 66%	Not answered = 10%
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7. Have you had any medication / health problems in the past 6 months, for example needing a hospital admission, use of ambulance service or new medication.

Yes = 51%	No = 42%	Not answered = 7%
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8. Have you experienced any problems with the use of the Telecare equipment?

Yes = 14%	No = 76%	Not answered = 10%
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TELECARE IN NOTTINGHAM

Independence without Isolation

Sample responses from service user feedback questionnaires (as at November 2010)

1. How satisfied were you with the process of assessing your need for Telecare equipment?

"The OT who did the original assessment was very good and clearly had medical knowledge and experience of the difficulties of old age."

"Very well explained".

"Very satisfactory, makes me feel safer".

"The person who came to assess me was polite and helpful"

"It has given me peace of mind knowing I only press button and help is there".

2. How would you rate the installation of the Telecare equipment?

"Installation very satisfactory".

"Installed in very quick time with no upheaval".

"Explained well. Dealt sensitively with Mrs Smith".

"The installation was very good indeed on instructing me how to use the equipment. Thank you".

"Very professional, good communication skills".

3. How did you find the explanation on how to use the Telecare equipment?

"Very Good".

"Helped to understand how to use it".

"Gentleman showed her what to do and tested it. Don't mind paying for it."

"Explanation made it very easy for us to use equipment".

4. Overall, how have you found the Telecare equipment?

"Have not needed it yet thanks god"

"There was an initial technical glitch that lead to it being disconnected but resolved the following day."

"I'm very happy to say that I have not had cause to use it!! However, I feel very much safer knowing it is there if ever I do need it."

"Without it I would be lost. Great service!".

"I am more than satisfied with the equipment, it makes me feel safer and not so on my own".

5. Has the installation of Telecare equipment given you more confidence/peace of mind?

"Definitely, as we know of acquaintances who were in trouble without it".

"My friends and relations are relieved that I have it".

"Especially when I go up and down stairs and am away from the phone".

"Takes away the stress of having to sort my meds out daily which is a great relief knowing that someone is there, at any time of the day or night."

"Done wonders for my peace-of-mind."

6. Has the installation of Telecare changed the amount of care and support you receive?

"I still have people asking me if I am alright".

"The installation of Telecare is itself support".

"Whilst used on very few occasions, its presence is a boon to my well-being."

7. Have you had any medication / health problems in the past 6 months, for example needing a hospital admission, use of ambulance service or new medication.

"This was before the equipment was installed".

"Mum fetched ambulance for dad with button, he had got out of bed and couldn't get back in".

"My GP changed my medication 2 to 3 times. I've got more tablets than Boots".

8. Have you experienced any problems with the use of the Telecare equipment?

"No problems".

"Haven't yet only to thank you for care".

"Because I'm nearly deaf, I can't tell what the operator is saying".

9. Do you have any other comments about your needs?

"Feeling now of not being alone, which is all to the good".

"After a few days of receiving the equipment i accidentally pressed the red button and received helpful and immediate response".

"Installation was very quick and well explained and tested. Have not had to use the system yet but feel very reassured that it is there if required".

"Very helpful, me and my son feel more secure. Don't know how we'd do without it."

"Haven't used it yet, good to know its there."

"The installation of the equipment has done wonders for my peace-of-mind and I am very grateful. I am required to attend hospital on a 6-monthly occasion for my problems, but grateful for your kindness".

"From the time the equipment was installed until now I cannot fault the service given to me - Thank you all".

"A pair of new legs would do nicely. Many thanks."

TELECARE IN NOTTINGHAM

Independence without Isolation

Summary of carers feedback questionnaires **(as of November - 185 replies)**

1. Are you the named Carer/Responder (delete as necessary) in the event of an alarm being triggered?

Yes = 85% No = 11% Not stated = 4%

2. Has it been necessary to respond to any alarms?

Yes = 42% No = 54% Not stated = 4%

3. How did you feel about the person trying new Telecare equipment?

Worried = 5% Apprehensive = 21% Sceptical = 11%
Enthusiastic = 51% Other - 3% Not stated = 9%

4. Has Telecare reduced any anxiety you may have had about the person you care for?

Yes = 82% No = 14% Not stated = 4%

5. Has Telecare reduced or changed the number of visits/telephone calls you were making to the person you care for?

Yes = 25% No = 63% Not stated = 12%

TELECARE IN NOTTINGHAM

Independence without Isolation

Sample responses from carers feedback questionnaires **(as at November 2010)**

1. Are you the named Carer/Responder (delete as necessary) in the event of an alarm being triggered?

"I am the daughter living 1.25 hours away by car".

"My wife is the user and I live with her"

"We are the family carers who are also the responders".

"I am both carer and responder although my mother's neighbour when not at work can deal with things".

2. Has it been necessary to respond to any alarms?

"Fortunately have had no reason to use it".

"I have been in the house when he fell and able to help him up".

"Excellent, good advice received. Paramedics arrived within fifteen minutes".

"The operator was very calm and helpful which calmed me down".

"When you could not get any response from my father"

"Very good stayed on the phone to mum until I got there".

3. How did you feel about the person trying new Telecare equipment?

"As a health professional I knew it was essential".

"It is reassuring to know he has more security".

"Very professional. Mother has set off alarm twice by accident. Response by care team – immediate".

4. Has Telecare reduced any anxiety you may have had about the person you care for?

"We both feel more confident".

"Good to have someone to turn to in an emergency".

"Now I have peace of mind when I cannot be there".

"Considerably, allows me to leave the house with greater freedom knowing Telecare is there".

"I feel I can go out for a day trip knowing he can get help".

"Ambulance response has been excellent"

"I know if anything happened the call would get to me straight away".

"Very much needed as service user was very isolated and didn't have many visitors".

"As I don't live locally and don't drive, having Telecare is a great relief".

"If there is a problem I know I can be called straightaway and will be there in fifteen minutes".

"My father-in-law has had a few falls, I know he will receive help if needed quickly".

"re: Taking of medication which are controlled pain analgesia and sleeping tablets".

"I am comforted in the knowledge my father has the independent means of communication if needed".

5. Has Telecare reduced or changed the number of visits/telephone calls you were making to the person you care for?

"Just gives us added peace of mind".

"At first - when I was still working - no longer applies but may in future".

"It reduced visits but not necessarily calls".

"I make more visits because I have to respond to alarms being activated".

"Yes, by half".

"I don't need to phone my parents as often knowing that they have access to care-response".

"Telephone calls reduced but not visits".

"We still phone at least once a day for social interaction".

6. Do you have any further comments on any issues that have arisen?

"No - I am feeling safer with Telecare".

"My father has dementia and therefore he does not realise what the alarm is. An ideal alarm would be connected to a socket which cannot be switched off easily".

"Just thank you on behalf of Irene and myself".

"The equipment and service are very good. They are all we hoped for".

"Telecare has given us all peace of mind, knowing that mum is safe if she falls or needs anything".

"My parents feel safer".

"I find the service very helpful, thank you".

"The equipment and service are very good, they are all we hoped for"

"Telecare is a good idea for old people with illness that affect them. We care because you do".

"My father-in-law triggered the alarm (ineligible) smoke alarm going off which because of his deafness he didn't hear. The fire brigade attended. Many Thanks".

"I would like to add that the Telecare operation is excellent from the fitters to the operators. Thanks".

Appendix B5: Table of Observations

Patient	Observation 1	Observation 2	Observation 3	Observation 4
1	Pull Cord 1 in living room	Pull Cord 2 in bedroom	Hub in living room	Patient almost immobile
2	Pendant Worn around neck		Hub in hallway	
3	Pendant not on person, Wristwatch not on person	Pendant upstairs in bedroom	Hub behind sofa on windowsill	Telecare user is also a carer for partner
4	Pendant Worn around neck		Hub in living room	
5	Wristwatch on shelf		Hub in hallway	Telecare user is also a carer for partner
6	Pendant on shelf		Hub in bedroom	
7	Pendant worn around neck		Hub in living room	
8	Pendant on table behind photo frame	Belt used for going to garden		
9	Wristwatch taken from designated shelf and worn.	Used when going into garden, or when carer (wife) is not home	Hub in hallway	Carer is also a telecare user.
10	Pendant in kitchen	One pendant in bathroom	Carries across to whichever room she is in, doesn't wear.	

Interview Schedule

1. *Stages of development*

- a. How did you decide that this was the problem you were going to address?
- b. Where / how did you collect the data on the potential market and make the decision to invest in Telecare specifically?

2. *Identifying the user*

- a. How did you collect the data on the potential user?
- b. Where did you collect the data on the potential user from?

3. *User involvement*

- a. Where the users involved in the rollout of telecare and how?
- b. What methods of user participation or user involvement did you use in the development process?
- c. Do you think the users you do involve are satisfied with the level of their involvement and are able to see changes occurring according to their involvement?

4. *User acceptance*

- a. How successful would you say the device is in achieving its aims?
- b. Do you provide training and information to your user?

5. *Feedback and iterative design methods*

- a. What feedback is collected from users?
- b. How often is feedback collected?

6. *Knowledge dissemination and feedback*

- a. At what stage would you be disseminating information to your users on new developments?
- b. What particular information is circulated and how?
- c. Which users in particular are given product information?

7. *Regulatory requirements*

- a. Is there any regulation or ethical consideration you need to ensure?

8. *Business requirements*

- a. What are your future plans?

End of Questions