This item was submitted to Loughborough's Research Repository by the author.
Items in Figshare are protected by copyright, with all rights reserved, unless otherwise indicated.

# The involvement of users in the design of home use medical devices: challenges and incentives for change

PLEASE CITE THE PUBLISHED VERSION

PUBLISHER

© Thomas Grant

PUBLISHER STATEMENT

This work is made available according to the conditions of the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International (CC BY-NC-ND 4.0) licence. Full details of this licence are available at: https://creativecommons.org/licenses/by-nc-nd/4.0/

LICENCE

CC BY-NC-ND 4.0

REPOSITORY RECORD

Grant, Tom. 2019. “The Involvement of Users in the Design of Home Use Medical Devices: Challenges and Incentives for Change”. figshare. https://hdl.handle.net/2134/16283.

**Loughborough University**

# The Involvement of Users in the Design of Home Use Medical Devices: Challenges and Incentives for Change.

**by**

**Thomas Grant**

**Loughborough Design School**

**Submitted in partial fulfilment of the requirements for the award of Doctor of Philosophy of Loughborough University**

**June 2014**

**© by Thomas Grant 2014**

**The views expressed in this thesis are not necessarily that of Loughborough University**

# Abstract

The prevalence and use of medical devices in the home environment continues to grow in the United Kingdom (UK) and Worldwide. It is recognised that such devices offer significant benefits to both patients and the National Health Service in the UK.

The design of home use medical devices however represents a considerable challenge to designers and manufacturers alike. Developing devices that are usable and understandable by inexperienced, lay or dexterity impaired users requires an understanding across a breadth of disciplines. Previous research in this field has explored these challenges in attempt to offer support for developers of home use medical devices.

There have been very few studies however that have explored whether the design community actually need, want or use such guidance, before considering whether this literature is adopted correctly.

Through case studies, an online survey and in depth interviews this thesis suggests that industry practitioners are sceptical of the value of design guidance towards user involvement in home use medical device design. Consequently the practitioners in this research make little or no use of the formal design methods and supportive guidance documents available to them. More typically, practitioners in the home use medical device field use their own personal experiences and knowledge from working in the industry to adapt their own approaches to design.

This thesis reports that the greatest challenge to involving users in the design of home use medical devices are the internal corporate and traditionally hierarchical barriers between stakeholders within the design process. In contrast to previous research offering support for designers and developers of home use medical devices this thesis calls for a wider change in design practice to facilitate the application of usability principles.

As a conclusion to this thesis, recommendations for further research to address these changes in practice are proposed to industry professionals in the medical device industry. This thesis is submitted as part of the requirement for the Degree of Doctor of Philosophy at Loughborough University.

# Acknowledgements

I owe considerable thanks to many individuals, companies and organisations to which without their contributions, this research would not have been possible.

I would like to firstly express my deepest thanks and gratitude to my supervisor Laurence Clift, for his invaluable input, guidance and support throughout my three years of postgraduate study. His direction and insights have kept me motivated at times of difficulty.

I would also like to thank Dr Richard Bibb, my second supervisor who has again provided valuable support throughout my study. Dr Bibb has significantly contributed to the links with both industry and academia in this research.

I am very grateful for all the contributing companies who participated in the studies for this research, including manufacturers, designers, buyers and suppliers, whose names cannot be disclosed for confidentiality reasons.

I really appreciate the contributions of my internal examiner, Dr Val Mitchell, who provided considerable insight and challenged the research at each review, which benefited the direction of the studies.

Finally, I would like to thank Loughborough University and particularly the Design School for supporting my studies and providing the financial backing to make this research possible.

# Glossary

The following terms are used repeatedly throughout this thesis and their context and definitions are integral to the reportage of this document. For clarity to readers, the definitions of these terms in the context of this research are provided here.

**Designer –** A person who plans the look or workings of something prior to it being made, by preparing drawings or plans (Oxford Dictionaries, 2013). In the context of this research the term 'designer' extends to individuals involved in the design and development process that ultimately influence the appearance, function and performance of a home use medical device.

**Home Use Medical Device -** A device intended for use in a non-clinical or transitory environment, is managed partly or wholly by the user, requires adequate labelling for the user, and may require training for the user by a health care professional in order to be used safely and effectively."(FDA, 2013).

**Human Factors Engineering –** The application of knowledge about human capabilities (physical, sensory, emotional and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organisations (ANSI/AAMI HE75: 2009).

**Medical Device –** 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,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or [disability],
- 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. (EC, 2007; in accordance with Council Directive 2007/47/EC).

**Usability –** Characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction (IEC BS EN 62366: 2007).

**Usability Engineering –** Application of knowledge about human behaviour, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs and environments to achieve adequate usability (IEC BS EN 62366: 2007).

**Use Error –** Act or omission of an act that results in a different medical device response that intended by the manufacturer or expected by the user (IEC BS EN 62366: 2007).

**User –** Person using, i.e. operating or handling, the medical device. Note one: This includes, but is not limited to, cleaners, maintainers and installers. Note two: Patients or other laypersons can be users (IEC BS EN 62366: 2007).

**User Involvement –** The involvement of 'representative intended users' within the design process of a home use medical device (IEC BS EN 62366: 2007).

**User Centred Design –** A philosophy based on the needs of and interests of the user, with an emphasis on making products usable and understandable (Norman, 1998).

# Table of Contents

Chapter 1 Introduction ..... 15
1.1 Background ..... 15
1.2 Motivation ..... 16
1.3 Existing Knowledge ..... 19
1.4 Scope ..... 23
1.5 Research Aim, Questions and Objectives ..... 23
1.6 Overview of Research Methodology ..... 25
1.7 Thesis Structure ..... 26
1.8 Thesis Framework ..... 28
Chapter 2 Literature Review ..... 29
2.1 Introduction ..... 29
2.2 Literature Review Methodology ..... 30
2.2 Design ..... 32
2.3 Medical Device Regulation ..... 37
2.3.1 The Differences between EU and US Regulation ..... 39
2.3.2 Medical Device Classification ..... 40
2.3.3 Notified Bodies ..... 44
2.3.4 Adverse Incidents ..... 47
2.4 Home Use Medical Devices ..... 55
2.4.1 Defining Home Use Medical Devices ..... 59
2.4.2 Taxonomy of Home Use Medical Devices ..... 62
2.4.3 IEC BS EN 62366:2007 - Application of Usability Engineering to Medical Devices 64
2.5 Design Methods for Medical Device Development ..... 67
2.6 Design Process ..... 73
2.7 Medical Device Design and Development Process ..... 76
2.8 Design Guidance ..... 83
2.9 User Centred Design ..... 92
2.9.1 Towards User Centred Design for Medical Devices ..... 93
2.10 Researcher Identity Memo ..... 96
2.11 Summary ..... 96
Chapter 3 Research Methodology ..... 99
3.1 Introduction ..... 99

3.2 Research Design ..... 100
3.2.1 Research Design Framework ..... 100
3.3 Research Philosophy and Approach ..... 105
3.4 Epistemology and Ontology ..... 107
3.4.1 Positivist Paradigm ..... 109
3.4.2 Interpretivist Paradigm ..... 110
3.5 Inductive vs. Deductive Reasoning ..... 112
3.5.1 Theory Testing vs. Theory Building Research ..... 112
3.6 Quantitative Research ..... 113
3.7 Qualitative Research ..... 114
3.8 Mixed Methods Research ..... 115
3.9 Research Strategies ..... 118
3.10 Sampling Strategy and Methods ..... 125
3.11 Ethics for Research ..... 128
3.12 Data Analysis ..... 131
3.12.1 Triangulation ..... 131
3.12.2 Validity and Reliability ..... 131
3.12.3 Dealing with Bias ..... 134
3.13 Research Methodology for Design Research ..... 135
3.13.1 Design Research Methodology (DRM) ..... 135
3.14 Methodology: Final Design ..... 139
3.15 Summary ..... 141
Chapter 4 Case Study One: Towards Idealised Practice ..... 143
4.1 Introduction ..... 143
4.2 Background ..... 144
4.3 Rationale ..... 145
4.4 Methodology ..... 146
4.5 Discussion ..... 147
4.6 Challenges to Applying Usability Principles to Home Use Medical Devices ..... 151
4.7 Step Factors for Improved Usability of Home Use Medical Devices ..... 154
4.8 Theoretical Idealised Design Process ..... 158
4.9 Verified Idealised Design Process ..... 164
4.10 Conclusion ..... 168
Chapter 5 Case Study Two: A Stakeholder Network ..... 169

5.1 Introduction ..... 169
5.2 Rationale ..... 170
5.3 Methodology ..... 170
5.4 Discussion ..... 172
5.5 Conclusion ..... 178
Chapter 6 Designers' and Manufacturers' Perspectives ..... 179
6.1 Introduction ..... 179
6.2 Rationale ..... 180
6.3 Methodology ..... 183
6.3.1 Paper-based Questionnaires ..... 185
6.3.2 Internet and Web-based Questionnaires ..... 185
6.3.3 Chosen Method ..... 186
6.4 Pre-testing ..... 187
6.5 Design ..... 189
6.6 Piloting ..... 190
6.7 Distribution and Sampling ..... 191
6.8 Recruitment ..... 193
6.9 Results ..... 195
6.10 Analysis ..... 209
6.11 Discussion ..... 213
6.12 Summary ..... 228
6.13 Ethical Considerations ..... 229
6.14 Reliability and Validity ..... 229
6.15 Limitations ..... 231
6.16 Future Work ..... 232
6.17 Conclusion ..... 233
Chapter 7 Understanding Current Practice ..... 235
7.1 Introduction ..... 235
7.2 Rationale ..... 236
7.3 Methodology ..... 237
7.3.1 Structured Interviews ..... 241
7.3.2 Semi-structured Interviews ..... 242
7.3.3 Face-to-Face Interviews ..... 242
7.3.4 Telephone Interviews ..... 243

7.3.5 Interview Strategy ..... 243
7.4 Design ..... 244
7.5 Pre-piloting ..... 247
7.6 Piloting ..... 248
7.7 Final Design ..... 249
7.8 Recruitment ..... 249
7.9 Analysis ..... 250
7.10 Results ..... 253
7.10.1 Drivers for the Selection and Development of Home Use Medical Devices 255
7.10.2 The Challenges to Involving Users in the Design Process of a Home Use Medical Device ..... 257
7.10.3 The Design Process of a Home Use Medical Device ..... 264
7.10.4 The Methods for Involving Users. ..... 269
7.11 Discussion ..... 270
7.11.1 The Challenges to Involving Users in the Design Process of a Home Use Medical Device ..... 271
7.11.2 The Perceptions of Design Guidance ..... 295
7.11.3 The Design Process ..... 303
7.11.4 The Understanding of Users and their Needs ..... 303
7.11.5 The Use of Design Feedback ..... 307
7.12 Proposed Interventions ..... 309
7.13 Ethical Considerations ..... 311
7.14 Reliability and Validity ..... 312
7.15 Limitations ..... 313
7.16 Future Work ..... 313
7.17 Conclusions ..... 314
Chapter 8 Proposed Interventions: Stakeholder Workshop ..... 317
8.1 Introduction ..... 317
8.2 Rationale ..... 318
8.3 Proposed Interventions ..... 319
8.3.1 Intervention One: Regulatory Update ..... 319
8.3.2 Intervention Two: Endorsing Usability ..... 321
8.3.3 Intervention Three: Patient User Review Forum ..... 322
8.4 Methodology ..... 323
8.4.1 Opinionnaire ..... 327

8.4.2 Group Interview ..... 328
8.5 Design ..... 329
8.6 Piloting ..... 331
8.8 Recruitment ..... 331
8.9 Analysis ..... 332
8.10 Results ..... 333
8.11 Discussion ..... 341
8.12 Ethical Considerations ..... 345
8.13 Risk Assessments ..... 346
8.14 Limitations ..... 346
8.15 Conclusions ..... 347
Chapter 9 Overview and Synthesis ..... 349
9.1 Introduction ..... 349
9.2 Regional Considerations ..... 349
9.3 National Considerations ..... 354
9.4 International Considerations ..... 360
9.5 Barriers to Implementation ..... 362
Chapter 10 Conclusions and Future Work ..... 365
10.1 Introduction ..... 365
10.2 Conclusions and Contributions to Knowledge ..... 365
10.2.1 An Understanding of Design Practice towards User Involvement in Home Use Medical Device Design. ..... 365
10.2.2 The Challenges of Involving Users in the Design Process of a Home Use Medical Device. ..... 367
10.2.3 A Proposed Intervention to Change Current Perspectives and Practice of Usability for Home Use Medical Devices. ..... 369
10.3 Future Work ..... 371
10.3.1 Development of Requirements for a Usability Assessment for Home Use Medical Devices. ..... 371
10.3.2 Development of a Social Media Platform for Patient Users of Home Use Medical Devices. ..... 372
10.3.3 Exploration of Challenges towards User Involvement with a Wider Population of Designers and Developers. ..... 372
10.4 Critique of Study Chapters ..... 373
10.5 Concluding Summary ..... 376
Chapter 11 References ..... 377

Chapter 12 Appendix ..... 393

# Table of Figures

Figure 1.1: Thesis Framework ..... 28
Figure 2.1: Example of a Citation Map used within this Literature Review..... 30
Figure 2.2: Pfizer Exubera Inhaled Insulin Device (Johnson, 2007). ..... 35
Figure 2.3: Adverse Event Reports Submitted to the FDA (QMED, 2012). ..... 49
Figure 2.4: Types of Use Error (Adapted from BSI 62366:2007 and ANSI/AAMI HE75:2009)..... 52
Figure 2.5: Gupta's Relationship between Medical Devices and Consumer Products (Gupta, 2007). ..... 57
Figure 2.6: French's Model of the Design Process (Adapted from French, 2010)..... 75
Figure 2.7: Simplified Depiction of the Design Process (Adapted from Gilman, Brewer & Kroll, 2009)..... 76
Figure 2.8: FDA's Waterfall Model. ..... 79
Figure 2.9: Cifter's Dual Verification Process for Home Use Medical Devices (Cifter, 2011). ..... 80
Figure 2.10: Website Guidance for Designers developed by Cifter (Cifter, 2011)..... 85
Figure 2.11: User Centred Design Process for Medical Devices (MATCH, 2010)..... 95
Figure 3.1: Framework for Research Design (Robson, 2011). ..... 101
Figure 3.2: The Research 'Onion' (Saunders *et al*, 2009)..... 106
Figure 3.3: The Relationship between Epistemology, Theoretical Perspectives, Methodology and Methods (Adapted from Crotty, 1998)..... 107
Figure 3.4: Four Mixed Methods Models (Gray, 2009)..... 116
Figure 3.5: Main Types of Case Study Design (Adapted from Gray, 2009). ..... 121
Figure 3.6: Ethical issues at different stages of research (Adapted from Saunders *et al*, 2009). ..... 130
Figure 3.7: DRM Design Research Methodology (Blessing & Chakrabarti, 2009). ..... 137
Figure 3.8: Final Design Methodology including strategies, studies and outcomes. ..... 140
Figure 4.1: Step Factors for Improved Usability of Home Use Medical Devices. ..... 154
Figure 4.2: Theoretical Idealised Design Process for a Home Use Medical Device. (Non-verified Model). ..... 163
Figure 4.3: Theoretical Idealised Design Process for a Home Use Medical Device (Verified Model)..... 167
Figure 5.1: An Example of a Home Use Medical Device Stakeholder Network..... 177
Figure 6.1: Types of Devices Designed by Respondents..... 198
Figure 6.2: Perceived Importance of Selected Drivers for Home Use Medical Device development..... 199
Figure 6.3: Perceived Challenges Towards Involving Users in the Design Process of a Home Use Medical Device..... 200
Figure 6.4: Designers' Perspectives of Perceived Users for Home Use Medical Devices. . 201
Figure 6.5: Designers' Perspectives on Priority Users of Home Use Medical Devices..... 201
Figure 6.6: Different Design Processes Followed by Respondents. ..... 204

Figure 6.7: Is Design Feedback from End Users Actively Collected by Designers..... 205
Figure 6.8: Designers' Measures of Success for Home Use Medical Devices. ..... 206
Figure 6.9: The Level of User Involvement at Different Stages within the Design Process of a Home Use Medical Device..... 207
Figure 6.10: Pairwise Comparison Test Results for Question Five. ..... 211
Figure 7.1: Early Tag Cloud during Content Analysis..... 258
Figure 7.2: Participant Design Processes (Guidance Followed). ..... 268
Figure 7.3: Participant Design Processes (Guidance Not Followed). ..... 268
Figure 8.1: Types of Evaluation (Adapted from Easterby-Smith, 1994) ..... 324
Figure 8.2: Stakeholder Workshop Design ..... 330

# List of Tables

Table 1.1: Range of challenges to home use medical device design and development (Adapted from Gupta, 2007). ..... 20
Table 2.1: Additional Online Resources. ..... 31
Table 2.2: Examples of Search Terms used with the Online Databases and Library Catalogue. ..... 32
Table 2.3: Three Levels of Design (Norman, 2004). ..... 33
Table 2.4: Medical Device Classifications (Adapted from MHRA, 2013). ..... 41
Table 2.5: Current Roles of Notified Bodies (Adapted from MHRA, 2006). ..... 45
Table 2.6: Adverse Incident Reports Received in the UK (MHRA, 2011b). ..... 48
Table 2.7: Cifter's Unique Aspects to Home Use Medical Devices (Cifter, 2011). ..... 58
Table 2.8: References to Users within the CDRH Definition of a Home Use Medical Device (FDA, 2013). ..... 61
Table 2.9: Home Use Medical Device Taxonomy (Adapted from Gupta, 2007 and National Research Council, 2011). ..... 63
Table 2.10: Potential Design Methods for Medical Device Development. (Adapted from IDEO, 2002) ..... 72
Table 3.1: Types of Research Questions. ..... 103
Table 3.2: Positivist Paradigm Vs. Interpretivist Paradigm (Adapted from Easterby-Smith *et al*, 2002). ..... 111
Table 3.3: Characteristics of Qualitative Research (Gray, 2009). ..... 115
Table 3.4: Sampling Methods (Adapted from Gray, 2009). ..... 127
Table 4.1: Identified Challenges to applying a User Centred Approach to Home Use Medical Device Design. ..... 153
Table 6.1: Conclusions from Eatock *et al* (Eatock *et al*, 2009). ..... 182
Table 6.2: Defining Small and Medium Enterprises (Adapted from EC 2003/361/EC). ..... 196
Table 6.3: Company Sizes Represented in the Study. ..... 196
Table 6.4: Descriptive responses provided for Question Nine. ..... 202
Table 6.5: 'Other' Responses for Question Five. ..... 208
Table 7.1: General advice for interviewers conducting interviews (Adapted from Robson, 2011). ..... 241
Table 7.2: Interview sequences (Adapted from Robson, 2011 and Gillham, 2005). ..... 245
Table 7.3: Themes and Probes for interview. ..... 246
Table 7.4: Primary Classes for Content Analysis. ..... 251
Table 7.5: Common Class Profiles. ..... 254
Table 7.6: Responses to Drivers for Development. ..... 255
Table 7.7: Responses to Challenges for Involving Users. ..... 259
Table 7.8: Experience of Participants in Years. ..... 261
Table 7.9: Matrix Query Results to show the Effect of Experience on the Perceived Challenges towards the Involvement of Users in the Design Process of Home Use Medical Devices. ..... 261
Table 7.10: Matrix Query Results to show the Effect of Qualification Level on the Perceived Challenges towards the Involvement of Users in the Design Process of Home Use Medical Devices. ..... 262

Table 7.11: Matrix Query Results to show the Effect of whether Design Guidance is followed on the Perceived Challenges towards User Involvement for Home Use Medical Devices. 264
Table 7.12: Participant Design Processes. 266
Table 7.13: Comparisons of Participant Design Processes. 267
Table 7.14: Responses to User Needs Identification Methods. 269
Table 7.15: The Five Fundamental Fallacies (Pheasant & Haslegrave, 2006). 296
Table 8.1: Leading Intervention (Short Term). 340
Table 8.2: Leading Intervention (Long Term). 341

# Chapter 1 Introduction

## 1.1 Background

In recent years patient use of medical devices in the home environment has grown considerably. Changes in the age demographics of society and a cultural shift towards early discharge from hospital are recognised as key contributors to this recent trend (FDA, 2010). The trend is expected to continue into the future with the use of increasingly complex and sophisticated medical devices finding their way into patient's homes (National Research Council, 2011).

It is reported that home healthcare can provide significant benefits to both patients and society due to an improved quality of life and financial savings that can be made by providing care outside of the institutional environment (FDA, 2010). For ventilator-dependent adults savings of up to 66% can be achieved per month when care is delivered in the home (NAHC, 2008). These savings not only apply to high-risk devices such as complex therapeutic and respiratory devices. The increased use of monitoring and diagnostic equipment in the home can reduce the number of hospital visits and re-admissions, which provides significant savings to the National Health Service (NHS) in the United Kingdom (UK).

Aside from the cost savings that can be made, home healthcare provides increased comfort and convenience to patients and their families (FDA, 2010). In many cases patients are able to remain independent through the use of home healthcare devices and equipment (National Research Council, 2011). Advances in technology and miniaturisation have enabled devices that were previously only used by experienced and trained healthcare professionals to be used by inexperienced and lay users in the home environment (Cifter, 2011; FDA, 2010; Gupta, 2007).

It is recognised however that market migration in any field of design presents challenges to the role of the designer, and the medical device industry is no exception (Martin *et al*, 2008). It has been argued that home use medical devices are often

simplistic and smaller, more ‘colourful’ versions of medical equipment used by professionals in the hospital (Bogner, 1999 Wilcox, 2005). The key therefore to design in this sector is making the technology accessible, usable and understandable by patients who are often vulnerable and inexperienced.

In the past decade there has been an increased focus on research towards understanding the interaction between users and medical devices. Usability has been one of the primary foci in this research movement. In 2008, the British Standards Institute (BSI) introduced IEC BS EN 62366: 2008, an internationally harmonised standard under current medical device regulation, which refers to the *Application of Usability Engineering to Medical Devices*. (IEC BS EN 62366: 2008).

In the US, the Food and Drug Administration (FDA) refer to usability as one of the unique challenges in their guidance document the Medical Device Home Use Initiative (FDA, 2010). The initiative, first introduced by the FDA in the US in 2010, was developed to address the safety and safe use of medical devices used in the home environment. Within this document the FDA outline the benefits of the cultural shift towards home care whilst also recognising the challenges this rapidly growing market presents.

## 1.2 Motivation

It is recognised that a number of key contributing factors are driving the rise in the increased use and development of home use medical devices. Cifter posited that the three most cited reasons within the literature behind the rise in home use medical devices are (Cifter, 2011);

I. The increased proportion of older people in the adult population.
II. The trend towards reducing the patient time in hospitals.
III. The advances in technology.

**The Ageing Population**

It is widely understood that the demographics of society are changing and in recent times have encountered a cultural shift. Population changes are attributable to births, deaths and migration. In a recent publication by the Office for National Statistics (ONS) the national census for England and Wales revealed that there were 6.6

million births and 5.0 million deaths representing an increase in population of 1.6 million (ONS, 2012). The statistics show a decline in birth rates and increase in life expectancy as people are living longer. The figures from the ONS report a decline in the younger population between the ages of 0-14 years and increase in population of persons aged 65 and over.

In 2011, the percentage of the population aged 65 and over was the highest seen in any census at 16.4 per cent, denoting one in six people in the population were 65 and over (ONS, 2012). This represents a dramatic change in population demographics over the last century. In 1911, the data for England and Wales suggested that one in twenty residents were aged 65 and over (ONS, 2012). The percentage increase in population aged 65 and over has increased by approximately 10.6% between 2001 and 2011.

With a recognised ageing population there is subsequent demand for relevant health services and devices to accommodate for conditions associated with ageing. It is estimated that by the year 2050 in Europe, the population over 60 years of age will be approximately 253 million in comparison to 96 million under the age of 14.

**Early Patient Discharge from Hospitals**

Increasingly hospitals are discharging patients earlier than in previous years. The impact of early discharge presents the need for increased devices and technologies to treat patients outside of the hospital environment. Currently there are on-going changes to the NHS in the UK that have seen the introduction of targets to reduce the time patients spend in hospitals (e.g. Length of Stay) resulting in patients being discharged early from hospital to continue complex care regimes in the home environment (NHS Improving Quality, 2013).

**The Advancements in Technology**

Arguably a driving factor for all industrial development, from the automotive industry to mobile telecommunications, is the ever-increasing sophistication and capability of modern technology. New technologies enable consumers to perform tasks that were not possible in previous years. A consequence of this phenomenon being the associated level of expectation of technology available on the market today. With a rapid growth in the capability of technology, users become more

educated and aware of the technologies available to them. Thus there can be a rise in expectations for products and services. In the foreseeable future this may also be true and applicable to medical devices as increasing numbers of previously recognised professional use devices find their way into the home environment (Bogner, 1999 Wilcox, 2005).

**The Rising Costs of Healthcare in Hospitals**

The cost of healthcare is under the continuous scrutiny of government and media**.** It is widely understood that the cost of healthcare is rising globally (Bodenheimer, 2005). Simultaneously, cut backs on spending are occurring in all industry sectors since the economic downturn in 2008. These two compounding issues facing society today represent significant business drivers and incentives behind the transition towards home use medical devices.

**Adverse Incidents are on the Rise**

In a recent device bulletin by the Medicines and Healthcare products Regulatory Agency (MHRA), it was reported that adverse incidents (see Section 2.3.4) have seen a rise by approximately 13% for 2009-2010 (MHRA, 2011). According to the MHRA this figure has been increasing year on year in recent times (MHRA, 2011). A range of contributing factors need to be considered with these figures, however it is believed that the design of medical devices has a pivotal role to play moving forward in order to see a reduction in these incidents; particularly where home use medical devices are concerned. Further information regarding adverse incidents and their reporting is presented in Chapter Two.

**The Prevalence of Chronic Conditions**

There has been a significant increase in the prevalence of chronic conditions across the entire age spectrum particularly for conditions related to obesity such as diabetes. Consequently, there is an increasing demand placed upon healthcare services and the devices for patients. In light of the increasingly ageing population, people are now living longer with complex medical and social needs that foreseeably require treatment within the home environment (Gupta, 2007).

**Lifestyle Choices**

Increasing emphasis is now placed upon improving the overall wellbeing and quality of life across all ages and into older age. There is a drive towards improved health management with the goal of improved independence to monitor one's own health. Marketing campaigns for sports and health brands typically target this phenomenon that again could be argued contribute to the expectations of users for home use medical devices.

The range of tasks performed by patients in the home varies significantly in complexity and care requirements. Devices are used for monitoring, diagnostics, drug delivery and even emergency care. It is estimated that there are at least 10,000 different families of medical device types (Quotec, 2012). Given the variations in features of each of these device families, it is believed there are over 400,000 different medical devices on the market today (Quotec, 2012).

The combination of all of the factors described above demonstrates the rise in demand for home use medical devices. The dependence of society globally upon home use medical devices in the future is without question. In light of this, the intention of this thesis is to explore the practice of design by industry towards making home use medical devices usable and understandable for their users.

## 1.3 Existing Knowledge

It is recognised that there is currently a wealth of on-going research in the field of medical device design. Much of the previous research in this space has addressed the challenges of designing and delivering professional use medical devices (Brigdelal Ram *et al*, 2008; Martin *et al*, 2008; MATCH, 2003; Money *et al*, 2011; Sharples *et al*, 2012).

The specific focus of this research is upon home use medical device design. The most notable and in-depth of studies within this field in the UK is the work of Suresh Gupta (2007) and Abdusselam Cifter (2011). Both completed PhD theses in the home use medical device arena and the following section provides a brief introduction to their findings and how this research aims to build on their contributions to knowledge.

In his thesis, *Design and Delivery of Medical Devices for Home-Use: Drivers and Challenges*, Gupta explored the challenges to designing home use medical devices (Gupta, 2007). Gupta carried out a study with industrial design consultants and manufacturers to determine why the process of designing home use medical devices is both unique and challenging. Table 1.1 below presents the range of challenges identified by Gupta towards the development of home use medical devices (Gupta, 2007).

**Table 1.1: Range of challenges to home use medical device design and development (Adapted from Gupta, 2007).**

| |
|---|
| **Regulatory Issues** |
| **Manufacturing Issues** |
| **Point-of-provision Issues** |
| **Use Issues** |
| **Support Issues** |
| **Liability Issues** |
| **Disposal Issues** |
| **Business Issues** |
| **Technological Issues** |
| **Design and Development Issues** |

Gupta identified that designing home use medical devices requires a depth of understanding across a broad range of issues. The range of issues presented in Table 1.1, reflect the unique nature of home use medical devices holistically. The recognised trend towards increasing home use medical devices has resulted in a rapid period of growth for the field and a shift in paradigm towards commercialisation and consumerism. This change in paradigm has seen a blurring between the end users (i.e. typically patients for home use medical devices), as customers, which highlights the pertinence of commerciality in a medical context. Gupta referred to this shift as the crossing of boundaries between consumer products and home use medical devices. Gupta posited that while home use medical devices by necessity have to fulfil the legal regulatory requirements of medical devices, they may have to simultaneously meet the requirements of consumer products (Gupta, 2007).

The work of Abdusselam Cifter also explored home use medical device design in the thesis titled: *An Inclusive Approach Towards Designing Medical Devices for Use in the Home Environment* (Cifter, 2011). Cifter's work suggests three significant challenges specific to home use medical devices (Cifter, 2011).

- The knowledge level of lay users when using products.
- The usability of home use medical devices.
- The context of use of home use medical devices.

The themes highlighted by Cifter address a multitude of issues that increase the list of challenges and considerations for designers and developers of home use medical devices. Further challenges have also been cited within the literature, adding to the complexity of the field and the role of the designer. Some of these themes are introduced below:

- **The use of out-dated equipment** – Inexperienced and vulnerable users are increasingly using what is referred to as 'legacy' equipment in the home environment without technical support or instructions. The avenues for which medical equipment can now be accessed in the home are so vast that it would be almost impossible to monitor and control such movements (National Research Council, 2011; Turieo *et al*, 2004). It is becoming increasingly common for people to pass on devices and equipment to friends and family removing the healthcare professional out of the device provision process. This is compounded by the fact that these devices are often provided without instructions or packaging to offer guidance to the users and a reference of whom to seek when difficulties occur. Furthermore where instructions are available they are often not written for a lay audience and it is widely recognised that people do not refer to instruction manuals.
- **Usability –** Presently the user rarely chooses many of the devices used in the home themselves (UL, 2012). Devices are regularly prescribed or selected by healthcare professionals based on clinical effectiveness and purchasing decisions, with little consideration for the needs of the end users (UL, 2012).
- **The unpredictability of the home environment** – The hospital environment is regarded as predominantly controlled and hygienic. In contrast, the home environment can be the antithesis. The performance of devices is impeded or

compromised by noise, poor lighting, glare-producing surfaces, heat, dirt, improper cleaning products, electrical interference, humidity and moisture (Sawyer, 1996). The compounding of such factors and the interactions with users become integral considerations when designing a medical device for use in the home. The safe use of medical devices can only be achieved through careful consideration of the operating environment, user capabilities, device design and the interactions between them.

To counteract the challenges of designing home use medical devices it is advocated that users are involved early and often in the design process (IEC BS EN 62366: 2008). Sawyer posits that the end user population should be involved early and throughout the design process with 'hands-on' testing at the development stage (Sawyer, 1996). Sawyer states that the correct application of methods and attention focused on the needs of users leads to safer, more usable devices that consequently deliver reduced user errors (Sawyer, 1996). Good design practice for home use medical devices therefore can deliver considerable benefits to patients, the NHS and government in the United Kingdom.

The purpose of this thesis is to build on this existing knowledge of the field and make contributions to new knowledge that is of practical value to industry.

Both the works of Cifter and Gupta shared the overall aim of supporting designers in the design and development of home use medical devices. In his thesis, Gupta set out to 'support' product developers in designing 'better home use medical devices' (Gupta, 2007). In contrast, the aim of Cifter's thesis called for 'supportive information and suggestions regarding lay users' and how designers should address their needs and expectations (Cifter, 2011). In this respect, both bodies of research assert that designers need support in the design of home use medical devices.

However, both researchers identified that some designers in the context of their research were sceptical of the value of 'academic' design guidance, stating that they would not use such guidance in practice. Therefore, this research steps back from the position of offering designers further guidance and pursues whether designers do, in fact, require support in the design of home use medical devices. After all, developing further design guidance that is not utilised by practicing designers will not influence a change in current design practice.

To this end, the research described in this thesis aims to identify ways in which incentivising a change in industry's approach to design can be realistically achieved. In contrast to the work of Gupta and Cifter, this research seeks to identify designers' perspectives on the available guidance and information relating to the involvement of users in the design process of a home use medical device. The research aspires to ascertain whether practicing designers do in fact need support in the design of home use medical devices and whether they use the types of supportive information and guidance currently available. In addition, should it be found that designers do not make use of the available design guidance, the research explores what approaches can realistically be taken in order to change current design practice by industry towards home use medical devices.

## 1.4 Scope

The scope of this research is to identify current designer and developer perspectives towards usability guidance, specifically relating to user involvement, in the design of home use medical devices. This research is focused specifically on companies based within the United Kingdom (UK). The reason for this being that each country (Member State) has specific regulations and guidance towards medical device development. The locality of this research is in the UK and it is not within the scope of this research to address home use medical device design globally. That said, the findings of this research may possibly have implications for other member states and could be applicable to other fields. Where appropriate, any such findings will be indicated and described.

With this scope in mind the following section will now outline the aim of the research, the research questions and objectives of this thesis.

## 1.5 Research Aim, Questions and Objectives

It is understood that designing medical devices for use in the home is both a growing and challenging market. Previous research has addressed the need to support designers in this process (Cifter, 2011 Gupta, 2007). Much less research however has explored whether designers need, want or use such support.

The increasing body of research advocating user involvement in the design process of home use medical devices has not been matched by an increase in studies

addressing the practicalities of adopting such principles. Previous research has suggested that informal processes of user requirements research are still dominant in this field (Cifter, 2011; Gupta, 2007; Martin *et al*, 2008; Money *et al*, 2012). There is a need to explore and understand the design practice for home use medical devices more holistically prior to the development of any further support for designers.

The purpose of this research is to explore current design practice by home use medical device companies within the United Kingdom to understand their perceptions and application of current guidance and information.

With this is mind the aim of this research is:

*To incentivise the adoption of usability principles and the practice of user involvement in home use medical device design in the United Kingdom.*

To achieve the aim of this research, three research questions and corresponding objectives have been identified.

**Research Question One: How do designers consider and involve users in home use medical device development?**

**Objectives:** To ascertain how home use medical devices are designed for the needs of their users it is necessary to understand current design practice. This will be achieved through the following objectives:

I. Conducting a literature review of user involvement in home use medical device design.
II. Conducting a case study within industry to understand idealised practice for home use medical devices in the UK.
III. Identifying the design processes and methods currently used by industry in the UK.

**Research Question Two: What are the challenges for industry to involving users in the design process of home use medical devices?**

**Objectives:** To understand the challenges faced by designers it is necessary to both explore existing research and current practice on the nature of user involvement within Industry. This will be achieved through the following objectives:

I. Conducting a literature review on the challenges of usability for home use medical devices.
II. Conducting a case study to identify the range of stakeholders involved in home use medical device development.
III. Conducting an in-depth study with practicing designers to identify the challenges towards involving users in the design process of home use medical devices.

**Research Question Three: How can usability for home use medical devices be incentivised for industry?**

**Objectives:** In order to increase the uptake of usability principles for home use medical devices it is necessary to understand the perceived value of usability by industry. This research question will be answered through the following objectives:

I. Identifying the challenges for adopting usability principles and involving users in practice.
II. Developing intervention(s) based on these challenges to incentivise a change in industry's approach to design.
III. Evaluating the interventions with industry experts for future development opportunities.

The following section will now present a brief overview of the research methodology and introduce the structure of the thesis.

## 1.6 Overview of Research Methodology

This research follows a theory building methodology that applies the findings of each study to draw conclusions and add to the existing knowledge of the field. The principles of Design Research Methodology (DRM) were adapted for the context of this research and form the basis of the thesis structure and methodology (Blessing & Chakrabarti, 2009). A combination of exploratory, descriptive and prescriptive studies were used in this thesis to develop recommendations for current practice towards home use medical device design with respect to user involvement. A schematic of the thesis structure is presented in Section 1.8. Chapter Three of this thesis describes in detail how the methodology of this research was identified,

selected and developed. The following section provides a summary of each chapter presented in this thesis.

## 1.7 Thesis Structure

This thesis is comprised of ten chapters that support the recommendations and future work presented as a conclusion. The following section presents a short summary of the individual chapters as a quick reference for the reader:

**Chapter One** **Introduction:** Provides a brief synopsis of the topics and themes presented throughout this thesis. This chapter provides an overview of the research, a summary of the research methodology and a description of the research aims and objectives.

**Chapter Two** **Literature Review:** Presents a review of existing research relevant to the field of home use medical device design. The review explores medical device design as a practice from the perspectives of design processes, user centred design and current regulation. This chapter forms the foundation and context of the thesis.

**Chapter Three** **Research Methodology:** Describes the research designs, methods and strategies employed within this thesis. The epistemology and ontology of the researcher are described in relation to the theory within this thesis. The nature of quantitative and qualitative research is explored before the final design methodology is presented.

**Chapter Four** **Case Study One: Towards Idealised Design Practice:** Presents a theoretical idealised approach towards home use medical device design. The case study presents a range of preliminary challenges to involving users in the design process of a home use medical device. A series of step factors (drivers) behind the raised expectations for usability of home use medical devices are identified. A verified model for idealised practice towards home use medical device design is presented as a conclusion to the chapter.

**Chapter Five** **Case Study Two: Home Use Medical Device Stakeholder Network:** Provides an example of a current home use medical device stakeholder network from the diabetes market in the United Kingdom. The case study identifies

the range of stakeholders within a hierarchical structure that have different influences on the design and delivery of home use medical devices to their patients.

**Chapter Six Designers' and Manufacturers' Perspectives:** Presents the descriptive study of the thesis. The chapter presents an online survey of practicing designers' perspectives towards user involvement in home use medical device design in the United Kingdom. The chapter presents the methodology, analysis, results and discussion in relation to current literature. The chapter concludes with a summary of the main findings and the relevance to existing knowledge.

**Chapter Seven Understanding Current Practice:** Presents the explanatory study of the thesis. This chapter builds on the findings of Chapter six through in-depth interviews with participants from the previous study. Content analysis was performed on the interview transcripts using Nvivo software. The chapter presents a detailed description of the challenges towards user involvement in home use medical device design. The chapter concludes with the identification of three incentives to address current challenges towards the adoption of usability principles in home use medical device design.

**Chapter Eight Proposed Interventions:** Presents the validation study of the thesis. The chapter describes a stakeholder workshop conducted with a range of professionals from the field of home use medical devices. The chapter describes three interventions explored with stakeholders to identify improvements and potential for adoption in current practice. The chapter concludes with a discussion on the leading intervention identified during the workshop.

**Chapter Nine Overview and Synthesis:** Presents a discussion chapter on the findings and implications of this research on the wider research arena. The synthesis explores the implementation of the proposals within this research on a regional, national and international level.

**Chapter Ten Conclusions and Future Work:** Presents the conclusions of the thesis. The chapter describes the research contributions to knowledge in the field of home use medical device design and provides a summary of each of the chapters within the thesis. Finally the chapter concludes with a summary of future work to be conducted by others.

## 1.8 Thesis Framework

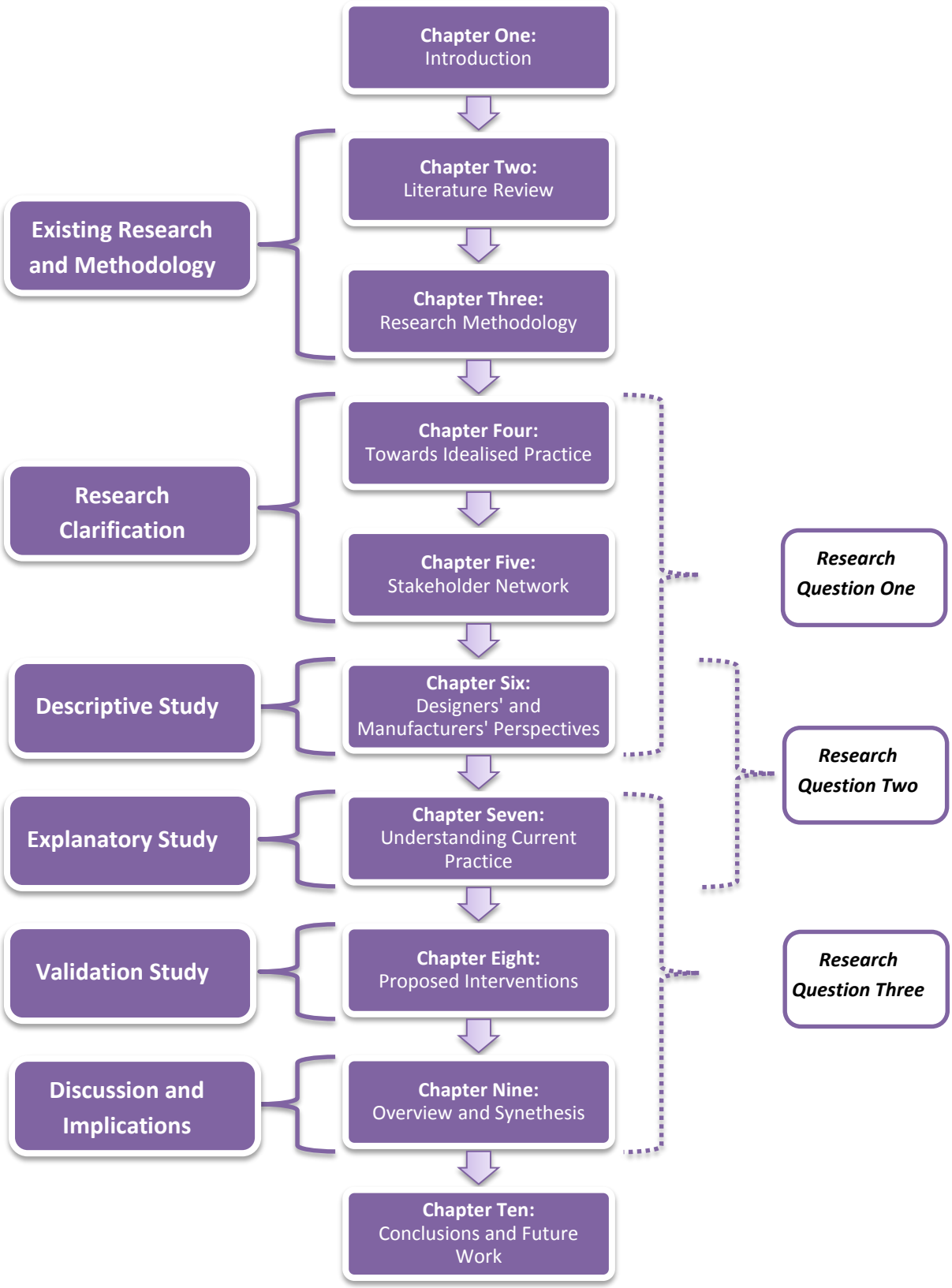



**Figure 1.1: Thesis Framework**

# Chapter 2
# Literature Review

In the previous chapter, an overview to the context of the research was presented. The research aim, questions and objectives were identified. The following chapter explores the existing literature on home use medical device design. The review will go into more depth behind the reasons for current practice in the Medical Technology (MedTech) sector and provide the foundation for the research methodology as a whole.

## 2.1 Introduction

Medical device design is a field of design that will affect us all at some point in our lifetimes. Almost everyone will experience the effects of ageing and capability loss when it comes to physical interaction with products and equipment. Furthermore, in recent years there has been a recognised cultural shift towards home healthcare that has seen a significant increase in the diversity and quantity of home use medical devices now available on the market. Recent estimates suggest there are approximately 400,000 different medical devices currently available on the market (Quotec, 2010). This figure demonstrates the considerable choice and variety for both professional and lay use of medical devices.

To understand the context of home use medical device design and usability it is necessary to explore topics such as industrial design, medical device regulation, user centred design and product design and how they all relate to the design of medical devices. This literature review is an essential component of the thesis framework to provide preliminary answers to the research questions.

For the purpose of this review a search strategy was applied to identify the relevant research papers, articles, journals and theses in the field. A summary of the methodology is provided here to bring clarity to the reader on how the literature was accessed and the search terms and sources used throughout this review.

## 2.2 Literature Review Methodology

The literature in this review was predominantly accessed through online databases that consist of peer reviewed full text articles. Initial searches for background reading and context of the field were conducted using the Loughborough University Library Catalogue. This online service provided by Loughborough University's library consists of resources available in the library and online in the University's repository.

The search process was then expanded using the Catalogue Plus facility, which broadens the literature access to a series of online databases consisting of peer-reviewed journals, articles and E-books. While some search terms used in one online database may have provided few or no results, the same terms in another database could be much more fruitful. Where specific and relevant sources were found the references within that article were explored further. The use of citation maps was considered particularly useful for this research to explore one article's relationship with other literature. An example of one such citation map is provided in the screenshot shown in Figure 2.1.

Figure 2.1 is an example of a backwards style citation map in which the cited references by the target article can be easily viewed to discover the wider relationships to other research. The particular screenshot shown in Figure 2.1 is a citation map developed during the very early stages on this research dated March 2011.

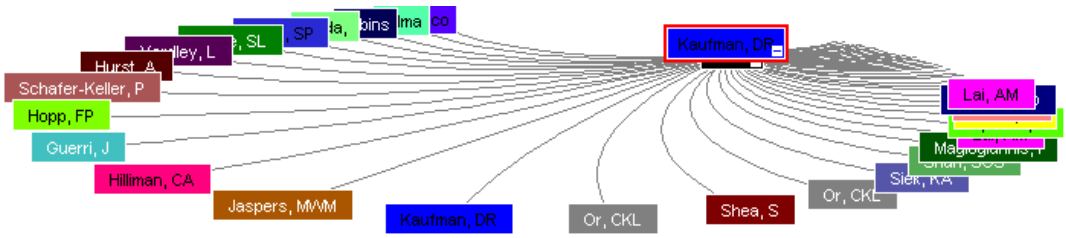



**Figure 2.1: Example of a Citation Map used within this Literature Review.**

In some cases, backward and forward citation maps were developed to explore not only cited articles and their relationships, but also more recent articles citing a particular target article. This method of literature searching helped develop a wide review of relevant literature for home use medical device design.

**Search Terms and Sources**

The broad range of topics and themes covered within home use medical device design called for an in-depth and expansive search of literature. By definition this need for a breadth of knowledge required the exploration of a multitude of literature sources and directories to inform the literature review. Table 2.1 presents a list of some of the additional online sources used throughout this research. While this list is by no means exhaustive, it does present of the main sources of information presented in this review. Note that the additional online sources of literature not present on the list were located through research avenues from the sources shown in Table 2.1.

**Table 2.1: Additional Online Resources.**

| |
|---|
| **www.bsigroup.co.uk** |
| **www.fda.gov** |
| **www.mendeley.com** |
| **www.mhra.gov.uk** |
| **www.nice.org.uk** |
| **www.sciencedirect.com** |
| **www.webofknowledge.com** |

Using these various sources of information the domain of home use medical device design was divided into specific research topics to simplify the process of searching. For the purpose and scope of this research seven research areas were defined: Design, Design Process, Design Research, Home Use Medical Devices, Medical Device Design, Usability and User Centred Design.

Table 2.2 presents a list of some of the search terms used for each research area within the online sources previously described. Note this list is not exhaustive and is provided to give an indication of how the literature in this review was found.

**Table 2.2: Examples of Search Terms used with the Online Databases and Library Catalogue.**

| Research Area Concerned | Search Terms (Including Boolean Operators and Wildcards) |
|---|---|
| Design | Design, Design* (Designing, Designers, Designs, Designed etc.) |
| Design Process | Design Process* (Design Processes) |
| Design Research | Design Research, Research Design, Research Method* (Research Methods, Research Methodologies etc.) |
| Home Use Medical Devices | Medical Devices AND Home, Home use Medical Devices, Design AND Medical Devices AND Home. |
| Medical Device Design | Medical Devices, Medical Devices AND Design, Medical Device Design, Medical Device AND Usability. |
| Usability | Usability, Ergonomics, Human Factors. |
| User Centred Design | User Centred Design, User Centered Design, UCD. |

The review will now be presented in accordance with the seven themes previously described.

## 2.2 Design

***"Design is the conscious and intuitive effort to impose meaningful order."***

***(Papanek, 1984).***

Many throughout history have defined the discipline of design. Pananek's definition refers to a state of order which design as a process aims to achieve. The term 'intuitive' used by Papanek is arguably one of the fundamental and desirable aspects of design today, particularly with the wealth of research on going in the field of User Centred Design (UCD). Furthermore, one could argue that intuitive design is even expected by users of modern products.

If products are intuitive to use then there are a range of associated benefits for the users themselves. The attainment of truly intuitive design however is undeniably a difficult task from the perspective of the designer.

A phrase familiar to many, whether involved in design or not, is that of 'Form Follows Function' first coined by Horatio Greenough in 1739 (Papanek, 1984). The definition however is often misinterpreted and the meaning behind the original statement is lost through modern translations. 'Form Follows Function' implies that as long as the functional requirements of a design are satisfied, form will follow and seem pleasing (Papanek, 1984). In contrast however, others have interpreted the phrase to mean that 'ideal' form will always work well. Papanek posited that this notion of thinking was responsible for many of the 'sterile, operating-room-like furniture and implements' from the early 20$^{th}$ century (Papanek, 1984). Simply designing for functionality does not result in good aesthetic or vice versa. As Papanek described design must be meaningful, which goes far beyond satisfying one aspect of a product's design (Papanek, 1984). Generating meaningful designs therefore must appeal to the users on a deeper level.

Designs that are meaningful to users evoke emotional responses or attractions to products. Concepts such as brand loyalty and the power of social image and acceptance have researched this topic considerably. More specific design research has addressed the concept of User Experience. Donald Norman explored the emotional effects of products on users in his book *Emotional Design* (Norman, 2004). Norman suggests that there are three levels of design namely: Visceral, Behavioural and Reflective (Norman, 2004). A description of the 'Three Levels of Design' are presented in Table 2.3.

**Table 2.3: Three Levels of Design (Norman, 2004).**

| Level of Design | Description |
|---|---|
| **Visceral** | Appearance, Automatic, Prewired emotional reaction. |
| **Behavioural** | Performance, Pleasure and effectiveness of use, Controls everyday behaviour. |
| **Reflective** | Self-image, Personal Satisfaction, Memories. Contemplative reaction. |

While Norman admits the description is perhaps a simplification of design and emotion, it raises the issues of 'trade-offs' in requirements and the translation of emotions into a final product (Norman, 2004). The level of importance attributed to each level evidently sits with the manufacturer, yet the outcome of the decisions will have the most significant impact on the end user. The principles of emotional design, user experience and design as a practice are important considerations in the design of home use medical devices.

Mary Beth Privitera *et al* posit that medical device design feature 'cross-functional properties which relate to function, appearance and value (Privitera *et al*, 2009a). According to Privitera *et al* these values are not necessarily equally weighed as there is an obvious emphasis upon clinical utility. Nevertheless the authors argue that there is an increasing awareness amongst user groups of the requirements relating to perceptions of value and appearance (Privitera *et al*, 2009a).

An example of a poor design in relation to Norman's Three Levels of Design is the Exubera inhaled insulin device, launched by Pfizer in July 2006. Exubera failed to meet the needs of the end user on a Visceral and Reflective level (Johnson, 2007; Norman, 2004). At the time, inhaled insulin devices were considered a dramatic leap forward in innovation and highly desirable by patients with Diabetes. In many respects the potential for this technology is still unattainable by manufacturers and the demand very much remains.

The prospect of administering insulin in a quick and pain free manner when compared with injectable devices meant that Pfizer's new product was highly sort after by patients and clinicians. When Pfizer launched the new device onto the market, the aesthetics of the final product was presented to healthcare professionals; including General Practitioners and Diabetes specialists, which instantly revealed problems. Note that these issues occurred following a challenging regulatory process for approval in which the efficacy and safety of the device was questioned.

The aesthetic of the device is provided Figure 2.2. At the final design stage prior to launch, medical devices represent a considerable financial investment to the company and shareholders. It is therefore often considered critical to attain approval and acceptance by the healthcare community at the early stage of the design process.

The Exubera device was criticised by healthcare professionals (HCPs) on an aesthetic and visceral level. The device invoked a negative emotional reaction to HCPs, which represent the medium between the designer and ultimate end users, the patients.

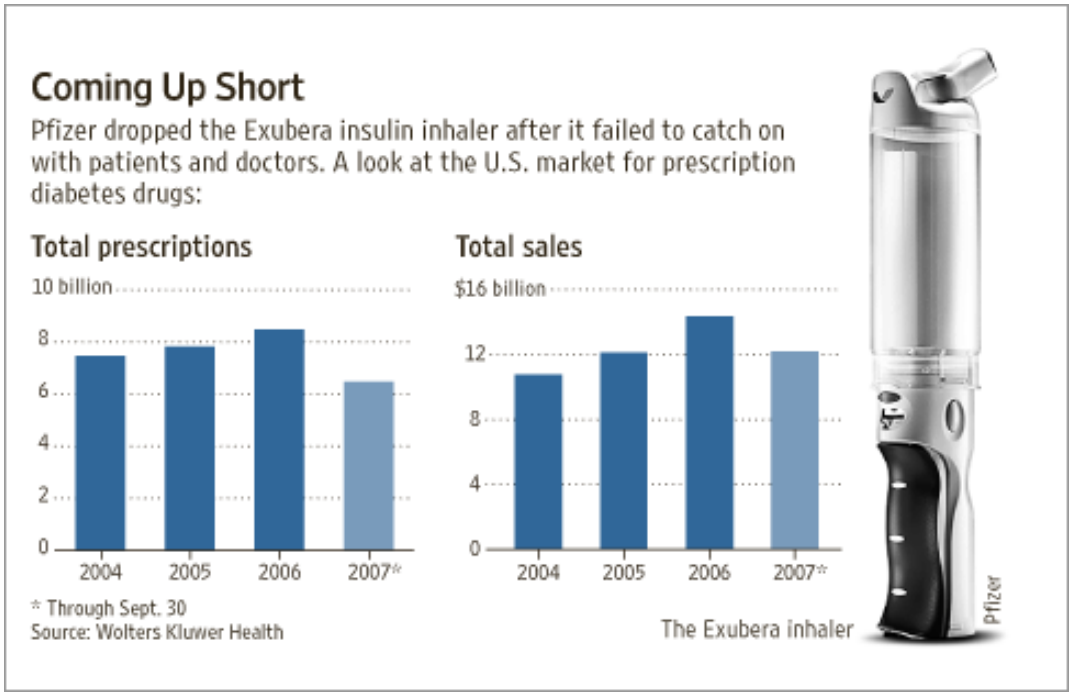



**Figure 2.2: Pfizer Exubera Inhaled Insulin Device (Johnson, 2007).**

It is recognised that one of the aspects patients like about injectable insulin devices is their discrete nature due to the associated stigma of a medical condition. The visceral aspects of the Exubera device failed to consider and meet the expectations and needs of device users. Similarly, with respect to Norman's reflective element of design appeal, the 'self-image' of patients was not addressed in the device design (Norman, 2004).

*"…the unwieldy device, a tube about the size of a flashlight, drew unfavorable reviews from the outset from doctors and investors." (Johnson, 2007)*

It would appear that during the conception and design stage of the Exubera device there was little consideration for the context and environment of device use. As a portable device intended for use in the home and public environments the design had failed to cater for the needs of its users. The look of the device had detrimental effects on the social image of patients making them feel uncomfortable in public.

*"The Exubera device, which some compared unflatteringly to a bong for smoking marijuana, could also be embarrassing to use in public" (Johnson, 2007)*

Aside from the aesthetical issues concerning Exubera, there were considerable safety concerns surrounding the device that resulted in a tough regulatory process for the company. At issue, only 10% of the insulin inhaled by the patient would get into the bloodstream (Johnson, 2007). The regulators took a strong stance against the device and when Pfizer finally received approval, the device had to be launched with a cautionary warning label against use of the device by smokers and asthmatics (Johnson, 2007). Furthermore, use of the Exubera device required patients to have regular lung examinations to ensure they were suitable to use the device and would be capable to inhale sufficient doses of insulin.

There were further issues surrounding the training of patients to use the device. One endocrinologist believed it could take up to one (1) hour to train a patient how to use inhaled insulin, significantly longer than that of insulin pens which would typically take around 5 minutes (Johnson, 2007). Alas, the costs to provide inhaled insulin devices are far greater than that of existing devices on the market.

From a functional and performance perspective, the aspects Norman describes as the behavioural level of design, Exubera also failed its users. Patients were required to insert packets of powder into the device measured in three or nine milligrams, which are not the units doctors typically used (Johnson, 2007). Consequently Pfizer had difficulty getting insurance to cover the treatment at a favourable rate and one British medical committee felt that the British health authorities should not pay for the device at all because it failed to offer any advantages over existing and less expensive therapies (Johnson, 2007). This example of medical device failure is particularly unique as it represents one of the few drug delivery products pulled from the market through lack of sales (Johnson, 2007). More typically this scenario would be seen for safety critical devices where reported incidents had been received and a subsequent device recall or alert had been called.

Evidently there were multiple failings with the Exubera device which were not limited to just the design and interactions with users. However, the failings in the design of the device resulted in a poor uptake and acceptance by both the healthcare sector and patients. The project is an example of a technology driven process that

perhaps with further consideration for the task, the users and the environment could have resulted in a final product more suited to the needs of end users. Reflecting on such a failing in the design of a medical device, and more specifically a home use medical device by definition, raises the question of how the design community prioritise the different levels of design.

This research aims to ascertain where the needs of end users sit alongside the other technical and commercial requirements for home use medical device development. One lesson that can be taken from the Exubera example is the essential requirement to satisfy relevant regulations in the design and development of any medical device. The following section will now explore the current regulations in relation to medical devices and home use medical devices before exploring the specific implications for design.

## 2.3 Medical Device Regulation

The medical device industry is arguably the most heavily regulated industry in the world today. The following section reviews the regulatory process for medical devices and in particular looks at the regulation of home use medical devices. To provide clarity for the reader the definition of a medical device is presented as a starting point to this section.

Due to the scope of this research, the definition used throughout this thesis is in line with the European Medical Device Directive 2007/47/EC or MDD as it shall now be referred.

According to the MDD, the definition of a medical device is as follows:

*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,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or [disability],*

- *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. (EC, 2007; in accordance with Council Directive 2007/47/EC).*

The definition by the MDD is very broad in its context and as previously described covers an estimated 400,000 different devices on the market today (Quotec. 2010).

The role of the MDD is to harmonise the regulations for all medical devices sold within the European market *(EC, 2007)*. The directive outlines essential safety and administrative requirements for all medical devices that fall into the scope of the directive. Compliance with the directives requirements must be shown through CE marking and only then can a medical device be freely sold throughout the European market without being subject to other national regulations.

Within Europe, medical devices are currently regulated and controlled through three directives known as the; Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC, Medical Devices Directive (MDD) 93/42/EEC and the In-Vitro Diagnostic Medical Devices Directive (IVDMDD) 98/79EC. In recent years these directives have been supplemented with updates in the form of modified and implemented directives with the most recent publication, at the time of writing, being the development of a technical revision Directive 2007/47/EC (EC, 2012).

As of the 26th September 2012 the European Commission announced a series of revisions for the regulatory framework (EC, 2012). The changes to the regulations, including home use devices, aim to ensure the products are safe and can be freely sold and fairly traded throughout the EU. It should be noted that changes and updates to the regulation of medical devices is an on-going process due to the evolving market shifts and capabilities of technology. The most recent updates aim to address the identified issues of medical device traceability to their suppliers, which is not always possible, and a lack of transparency on the evidence assessing medical device safety and efficacy (EC, 2012). It is proposed that the new regulations will be

implemented in 2014 however there is a recognised transition time during which the current regulations will remain in force (EC, 2013).

A Competent Authority (CA) ultimately determines the assessment of whether a medical device meets the applicable regulations. The recognised CA in the United Kingdom is the Medicines and Healthcare Products Regulatory Agency (MHRA). If a manufacturer is to consider developing a medical device to be distributed globally, for example outside of Europe, they must address international regulatory requirements.

The regulation of medical devices in the United States (US) is entirely separate of European regulatory system and comes with its own legislation and requirements. The recognised CA in the US is the Food and Drug Administration (FDA). The FDA uses the code of Federal Regulations to enforce the Federal Food, Drug and Cosmetic Act in the regulatory control of medical devices in the US market. The significance of the FDA for this research is particularly pertinent due to the size of the home use market in the US. As such, the impact of these regulations has global significance, particularly to the design community in the UK as many companies look to invest in this market demand. The following section will address the key differences between these two regulatory bodies and the necessary requirements to seek regulatory approval.

### 2.3.1 The Differences between EU and US Regulation

The regulatory authoritative bodies responsible for medical devices in EU and the US share some principles, however there are noticeable differences between them. Alexander and Clarkson refer to the differences in objectives established by the EU and US regulations (Alexander, K. & Clarkson, P.J, 2000). The objective of the EU regulations is to ensure that devices are safe and perform as the manufacturer intended. In contrast, the FDA's objective is to ensure finished devices will be safe, effective and thus present a benefit to the user (Alexander, K. & Clarkson, P.J, 2000).

One aspect that is shared by both regulatory bodies is the acknowledgement that safety and effectiveness in medical device development is an evolutionary process

and therefore cannot be simply assessed through final inspections or testing (Alexander, K. & Clarkson, P.J, 2000).

Due to the scope of this research, the review will not go into greater depth on the regulatory process adopted by the US and the FDA. Rather, the review will discuss the relevant similarities and where applicable refer to guidance developed by the FDA that is referred to in the UK guidance. For those interested in further information on FDA regulation, this can be found through the FDA website (http://www.fda.gov/).

### 2.3.2 Medical Device Classification

Within the EU, medical devices fall into one of four classifications that each has slightly different approaches for European Conformance (CE marking). These classifications are broadly dependent on the level of risk associated with a device and its use. The classifications for medical device regulation are as follows; Class I (including Is and Im), Class IIa, Class IIb and Class III.

The classification of any medical device will depend on the following factors:

- How long the device is intended to be in continuous use.
- Whether or not the device is invasive or surgically invasive.
- Whether the device is implantable or active.
- Whether or not the device contains a substance, which in its own right is considered to be a medicinal substance and has action ancillary to that of the device.

The intended purpose for use, defined by the manufacturer, will determine the classification of a medical device and ultimately the regulatory approval process necessary for conformity (EC, 2007). This was highlighted earlier in the definition of a medical device in the MDD whereby the medical purpose or ‘intended use’ is a statement assigned by the manufacturer (EC, 2007). Arguably, this presents an opportunity for manufacturers to avoid higher classifications through clearly defined purpose and device labelling. Such an approach would enable an easier route to market from a regulatory perspective and subsequently a quicker device launch.

Due to the size of the European conformance procedures copies of diagrams are presented in the appendix of this thesis (see Appendix 1) (MHRA, 2008). What follows is a description of the various approaches towards the attainment of a CE mark for a medical device.

**The Classifications**

The classifications and associated risks are presented in Table 2.4. Essentially, the conformity assessment procedures are more stringent for higher risk device classifications (MHRA, 2010).

**Table 2.4: Medical Device Classifications (Adapted from MHRA, 2013).**

| Medical Device Classifications |
|---|
| Class I – generally regarded as low risk |
| Class IIa – generally regarded as medium risk |
| Class IIb – generally regarded as medium risk |
| Class III – generally regarded as high risk |

**Class I Medical Devices**

For Class I medical devices, the initial responsibility falls upon the manufacturer to comply with all the essential requirements outlined in the MDD (MHRA, 2008). The manufacturer provides a self-declaration to this effect and records this in a written statement. The manufacturer must then follow a conformity assessment as shown in the flow diagram in Appendix 1 and compile a technical file for the declaration of conformity (MHRA, 2008). Finally, the manufacturer must register with a CA, the MHRA in the UK and only then can a CE mark be affixed to the medical device.

For medical devices that feature measuring functions or require sterilisation there are further considerations for the manufacturer:

- **Is Medical Devices (Sterility)**

The manufacturer must apply for certification through a Notified Body (NB) on aspects of manufacture relating to the securing and maintaining of a sterile barrier.

- **Im Medical Devices (Metrology)**

The manufacturer must apply for certification through a NB on aspects of manufacture relating to metrology for devices with a measuring function.

For those Class I medical devices without a measuring function or sterile requirement, certification by a NB is not necessary and conformity with the International and European standard ISO EN 13485 Medical Devices is voluntary (MHRA, 2008). For reference, ISO EN 13485 outlines requirements for a comprehensive quality management system for the design and development of medical devices, but is not a mandatory requirement for manufacturers to satisfy.

Note the role of notified bodies will be discussed later in this review.

**Class IIa and IIb Medical Devices**

In contrast to Class I devices, Class IIa requires further assessment in the form of a quality assurance audit by a NB. The declaration must be backed in all cases through a conformity assessment conducted by the chosen and qualified NB (MHRA, 2008).

Typically, the manufacturer has two potential routes to demonstrate compliance, what is referred to as an EC declaration of conformity. One approach is to follow the guidance set out in Annex II of the MDD, for a full quality assurance route incorporating an audit by a notified body to ISO EN 13485. The alternative route is to follow the declaration of conformity set out in Annex VII of the MDD coupled with one of the following options, defined in the MDD, at the manufacturer's discretion:

- EC Verification set out in Annex IV.
- Product Quality Assurance set out by the EC declaration of conformity in Annex V.
- Annex VI Product Quality Assurance declaration of conformity.

To further support the declaration of conformity, Class IIa devices must be assessed by a NB at all stages to assess and ultimately prove whether the manufactures claims are supported.

In many respects the route for class IIa and IIb are very similar as can be seen from the diagrams provided in Appendix 1.

In the case of Class II medical devices, the manufacturer has two potential routes to market. One approach as outlined in Annex II of the MDD is a full quality assurance audit. Alternatively manufacturers can follow an EC type examination outlined by Annex III of the MDD combined with one of the options described below:

- Examination and testing of each product or homogenous batch of products (**Annex IV**).

Or

- Audit of the production quality assurance system (**Annex V**) ISO 13485:2003 (excluding Design).

Or

- Audit of final inspection and testing (**Annex VI**) ISO 13485:2003 (excluding Design & Manufacture).

**Class III Medical Devices**

Class III medical devices represent the highest risk to device users and this is reflected in their regulatory approval process. Unquestionably such devices present considerable challenges to the manufacturer to gain conformance and approval. This is due to their complexity, invasiveness and in most cases risk to a patient's life. For these reasons the conformance route for Class III devices requires an additional design dossier examination by a notified body if the manufacturer opts for a full quality assurance audit by a NB in accordance with ISO 13485:2003. The alternative route is similar to a class II medical device through an Annex III of the MDD with an examination by a NB followed by either; a full production quality assurance audit or having every device/batch verified by a NB. The difference between class II and III being that class III medical device conformance does not allow manufacturers the route of mere inspection as described in Annex VI of the MDD, making the requirements and standards for medical devices, deservedly high.

Further information on the regulatory assessment procedures can be found in Appendix 1 of this thesis or by visiting the MHRA website at (http://www.mhra.gov.uk/Howweregulate/Devices/).

**Competent Authorities**

To reiterate, in the United Kingdom, the MHRA is the competent authority qualified to ensure medical devices comply with relevant regulations. There are currently four sets of Medical Device Regulations implementing all of the MDD amendments to date; Statutory Instrument No.618 Medical Device Regulations 2002 (Consolidated Legislation), 2003 No. 1697 (Amendments to cover the re-classification of breast implants and additional requirements covering devices utilising materials from TSE susceptible animal species), Medical Devices Regulations 2007 No.400 (Amendment to cover the re-classification of total hip, knee and shoulder joints) and the Medical Devices (Amendment) Regulations 2008 No. 2936 which transposes Directive 2007/47/EC into UK law (MHRA, 2013).

This section of the review has revealed that an integral aspect of the regulatory process is the role of the NB. The following section will address what notified bodies do and how they sit alongside the regulatory framework for medical devices.

### 2.3.3 Notified Bodies

Notified Bodies or NBs are certification organisations designated by the National authority (Competent Authority) of a Member State to carry out one or more of the conformity assessment procedures described in the annexes of the MDD (MHRA, 2006). The previous section highlighted that with the exception of some Class I medical devices, all medical devices require the intervention of a NB.

The chosen NB must be qualified to perform all the functions set out in any annex for which it is designated (MHRA, 2006). The designation may be restricted to specific types of devices and/or Annexes (MHRA, 2006). It is worth noting however that the NB might not necessarily conduct every part of the testing process. Third parties or subcontractors may be employed into the certification process to conduct testing in external laboratories or by specialists. In such cases the NB must be qualified and competent to analyse the results of any tests or audits conducted.

Despite this, the final responsibility very much sits with the NB concerned and therefore the competence of any subcontractors must be ensured by the NB themselves (MHRA, 2006).

**What will a Notified Body do?**

The tasks of the NB will vary according to the classification of the device concerned and the preferred assessment route selected by the manufacturer. Typical activities performed by notified bodies are described in Table 2.5.

**Table 2.5: Current Roles of Notified Bodies (Adapted from MHRA, 2006).**

| |
|---|
| **Full Quality Assurance** – The NB will carry out an assessment of the manufacturer's quality system, including design. They will sample across the range of products and processes to ensure that the requirements are being met. |
| **Examination of the Design** – The NB will assess the full design dossier relating to each type of product to ensure that they meet the requirements. |
| **Type Examination –** The NB will assess the full technical information relating to each type of product and carry out appropriate testing of a representative sample of production to ensure that it meets the requirements. |
| **Verification –** The NB will either test every unit or every batch of product to ensure that they are meeting the requirements before the manufacturer can place them onto the market. |
| **Production and Product Quality Assurance –** The NB will carry out an assessment of either the manufacturer's quality system covering production and inspection (Production QA) or final inspection (Product QA). They will sample across the range of products to ensure that relevant technical files are available as well as ensuring that the relevant processes being undertaken meet the requirements. |

Evidently, medical device regulation is critical to successful design in the sector. It has been argued however that regulation or rather over regulation can limit the ability and innovation of the designer (Braungart & McDonough, 2008). This can be drawn from the legislative procedures within the available guidance documents themselves, which are predominantly prescriptive, outlining a framework for the design process.

In contrast, design is inherently a creative and innovative process that could be considered the antithesis to the prescriptive requirements laid out in current legislation and guidance for designers.

Braungart and McDonough argue that regulation can be a sign that the design process has failed.

*"In a world where designs are unintelligent and destructive, regulations can reduce immediate deleterious effects. But ultimately a regulation is a signal of design failure." (Braungart & McDonough, 2008).*

Regulations therefore have potential to both mitigate risks from potentially hazardous devices but simultaneously inhibit the role of the designer to deliver devices that are truly innovative.

It has believed that if the process of design is sufficiently understood and implemented then regulation should not be so restrictive to innovation. Braungart and McDonough posited that 'good design can require no regulation at all' (Braungart & McDonough, 2008). This does not mean to say that there is no place for regulation in the control of medical device design. To the contrary, regulation of medical devices is unquestionably necessary in this expansive and diverse market where the needs of users and capabilities of technology are ever changing.

There is however a need to consider the shift in market demands for current and future devices used within the home environment, including the implications for medical device regulation (Cifter, 2011, Gupta, 2007). Modern devices used in the home environment represent a form of cultural shift towards commercially available 'consumer medical devices' (Cifter, 2011; Gupta, 2007). The implications of this shift have profound effects on device design, which will be discussed throughout the content of this thesis.

Devices that are now recognised as 'consumer medical devices', in that the consumer or user has the choice of which device to purchase, calls for additional design considerations beyond meeting the safety and efficacy requirements (Cifter, 2011; FDA, 2010; Gupta, 2007). Arguably, the designer needs an element of freedom and creativity to deliver designs that offer a greater experience for the end user.

Where regulations are too prohibitive to design then ultimately there will be no variation in the availability of devices to users. Perhaps for instances of safety critical devices such an approach is necessary and apposite.

Norman describes how a ‘standardised’ approach may be necessary when products cannot be designed without arbitrary mappings and difficulties to device users (Norman, 1998). By standardising the system, the problem or the task, the potential for error and requirement for learning is reduced. This approach does have the negative consequence however of stagnating innovation and designs that are desirable to their users. Furthermore, overregulation can have a negative consequence on industry’s perception towards regulation and subsequently have a detrimental effect on industry as a whole.

Aside from assessing regulatory approval, the MHRA also monitor medical devices post launch. Once a device is launched onto the market, issues of device use are put to real tests with potential users. The following section explores the importance and role of adverse incident reporting.

### 2.3.4 Adverse Incidents

As the UK’s CA the MHRA are responsible for the monitoring and regulation of any adverse incidents involving the use of medical devices. The MHRA define an adverse incident as follows (MHRA, 2011a):

*An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons.*

***Causes of adverse incidents involving devices may include:***

- *Design or manufacturing problems*
- *Inadequate servicing and maintenance*
- *Inappropriate local modifications*
- *Unsuitable storage and use conditions*
- *Selection of the incorrect device for the purpose*
- *Inappropriate management procedures*
- *Poor user instructions or training (which may result in incorrect user practice).*

***Conditions of use may also give rise to adverse incidents:***

- *Environmental conditions (e.g. electromagnetic interference)*
- *Location (e.g. devices designed for hospitals may not be suitable for a community or ambulance setting).*

Each year the MHRA produce a report that provides an overview of medical device related adverse incidents that are received during the preceding calendar year. The report presents the most recent incidents and significant actions taken in that year.

The most recent report available at the time of writing presents the data recorded in 2010 (MHRA, 2011b). In 2010 the MHRA received 10,280 adverse incidents reports involving medical devices, which represents a 13% increase on the previous year (see Table 2.6).

**Table 2.6: Adverse Incident Reports Received in the UK (MHRA, 2011b).**

| Data | 2008 | 2009 | 2010 |
|---|---|---|---|
| Incident Reports Received | 8,902 | 9,099 | 10,280 |
| % change over previous year | +3.1 | +2.2 | +13.0 |

The figures show a 42% increase over the past decade, which is in line with a global rise in adverse incidents. In the US, serious adverse events have tripled in as many years (QMED, 2012). As shown in Figure 2.3 below, the FDA received over 400,000 adverse events with more than 50,000 reported serious patient outcomes in 2011 (QMED, 2012). Serious patient outcomes are defined by hospitalisation or worse, including deaths. These figures represent an annual growth of 45% for adverse events associated with device malfunctions or defects in 2011 (QMED, 2012).

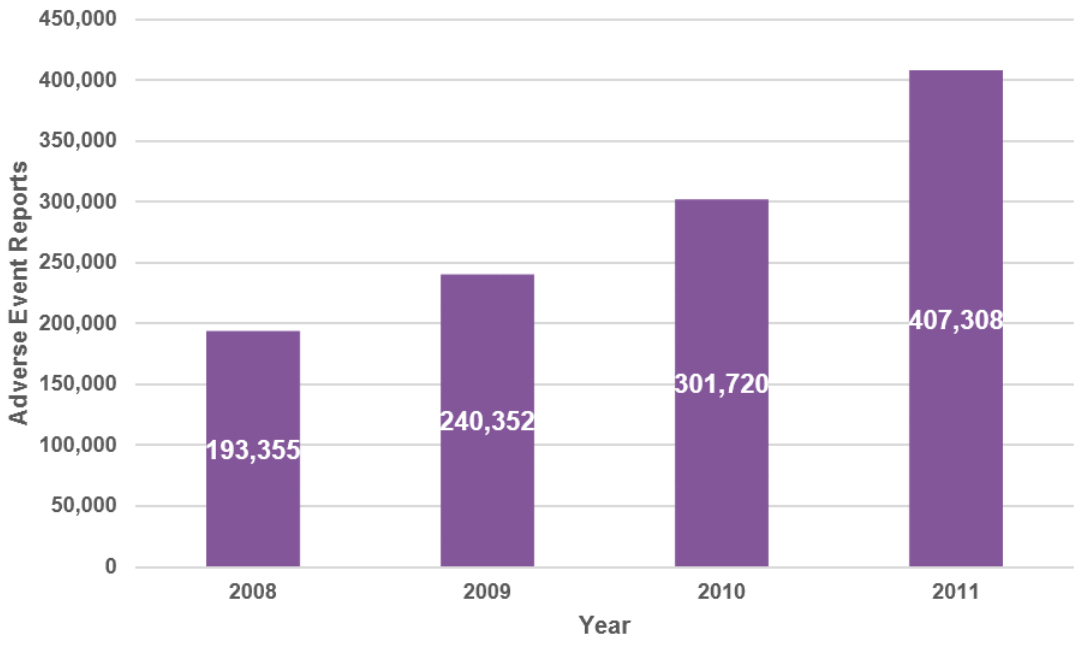



**Figure 2.3: Adverse Event Reports Submitted to the FDA (QMED, 2012).**

To refer back to the definition of an adverse incident by the MHRA it is evident that the design of medical devices plays a crucial role in these figures. From experience, the MHRA suggest that 'user error', as it is traditionally known, is sometimes the cause of adverse incidents or at least contributes to their cause (MHRA, 2011b). However the error on the users' part is often the result of underlying issues, such as device management, maintenance or the adequacy of training for users (MHRA, 2011b). As such, adverse incidents relating to 'user error' are considered a failure of the 'system' surrounding the use of medical devices, which includes all of training, maintenance and the delivery of the device to the patient. In a device bulletin available on the MHRA website, the organisation explicitly states the following (MHRA, 2011a):

*"…the MHRA is concerned with preventing the occurrence of adverse incidents, not with assigning blame or liability."*

It is believed that a blame neutral culture to adverse incident reporting will lead to increased accuracy and reporting of events involving medical devices through honest and open reporting. The failing of the system rather than the user is mirrored by the current definition of 'use error' adopted by the British Standards Institute (BSI) in

the internationally harmonised standard IEC BS EN 62366:2007. The standard adopts the term 'use error' as opposed to 'user error' within the usability standard for medical devices which is presented below:

*"Act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user."(IEC BS EN 62366:2007)*

Use error is preferred by the usability standard, as it is blame neutral on behalf of device users. Thus, the occurrence of errors is attributable to the use of the device as opposed to the user themselves. It has been identified that the number of errors attributable to use error caused by inadequate medical device usability are an increasing cause for concern (IEC BS EN 62366:2007). Typical examples of use errors can include slips, lapses and mistakes by the user (IEC BS EN 62366:2007).

The concept of use error is currently preferred over terms such as 'user error' and 'human error' as it is believed that not all errors associated with the use of medical devices are attributable to oversight or carelessness on the part of the user (IEC BS EN 62366:2007). Rather, as is more commonly the case, use errors are the direct result of poor user interface design. Here, the interface represents the point at which the user physically interacts with a device to achieve a desired, or as the case may be undesired, outcome. One of the most significant contributors to use error is attributed to non-intuitive or counter-intuitive displays and controls on devices.

In the US, the notion of a blame neutral term is shared by the American National Standards. The American National Standard ANSI/AAMI HE75:2009 defines use error as follows:

*"Undesirable or unexpected events resulting from the interaction between a user and a device; use error accurately indicates error but does not attribute fault to the user." (ANSI/AAMI HE75:2009).*

Use error however is not the same as abnormal use by users who actually intend to use a device correctly (ANSI/AAMI HE75, 2009). The American National Standard explores this topic further and refers to the different types of use errors that are

encountered with medical devices. They represent a mismatch between the needs of users and the design of the device and/or user interface. As such the consideration of the needs and expectations of users during the design process is advocated to develop safe and usable devices (IEC BS EN 62366:2007; ANSI/AAMI HE75:2009).

Ward and Clarkson posited that the concept of user errors raises the question of how the designer ensured 'trouble free use' through good design practice (Ward & Clarkson, 2004). It has long been understood that the there is a direct link between poor device design and what has traditionally been classified and understood as user error (Ward & Clarkson, 2004). IEC BS EN 62366, covered in more detail later in this review, outlines three types of use error that can occur with medical devices. The diagram shown in Figure 2.4 presents the relationships between the different types of use errors.

Actions performed by users can be either intended or unintended. Intended actions can refer to abnormal or correct use and mistakes, whereas unintended actions can be classified as either slips or lapses. Mistakes by users are intended but incorrect actions and therefore constitute use error. Use error specifically can be the result of mistakes, lapses or slips as shown in Figure 2.4. A slip or lapse is the result of some form of failure in the execution and/or memory recall when performing an action. Mistakes on the other hand are failures in judgement and/or inferential processes used to select an objective (ANSI/AAMI HE75:2009).

Abnormal use is generally the result of a malevolent action, actions that are intended that result in undesirable outcomes. Typically, this form of device use is not associated with use scenarios that designers can reasonably anticipate or prevent through application of risk control measures (ANSI/AAMI HE75, 2009). This makes reference to the regulatory requirement to make devices as safe as is reasonably practicable. It is important however for the designer to consider that abnormal does occur and ANSI/AAMI HE75:2009 recommends 'follow-up' assessments to determine whether instances of abnormal use and associated hazards can be avoided. This is again supported by IEC BS EN 62366:2007 and is mandated in ISO 14971 for Medical Devices and the Application of Risk Management (IEC 62366:2007; ISO 14971).

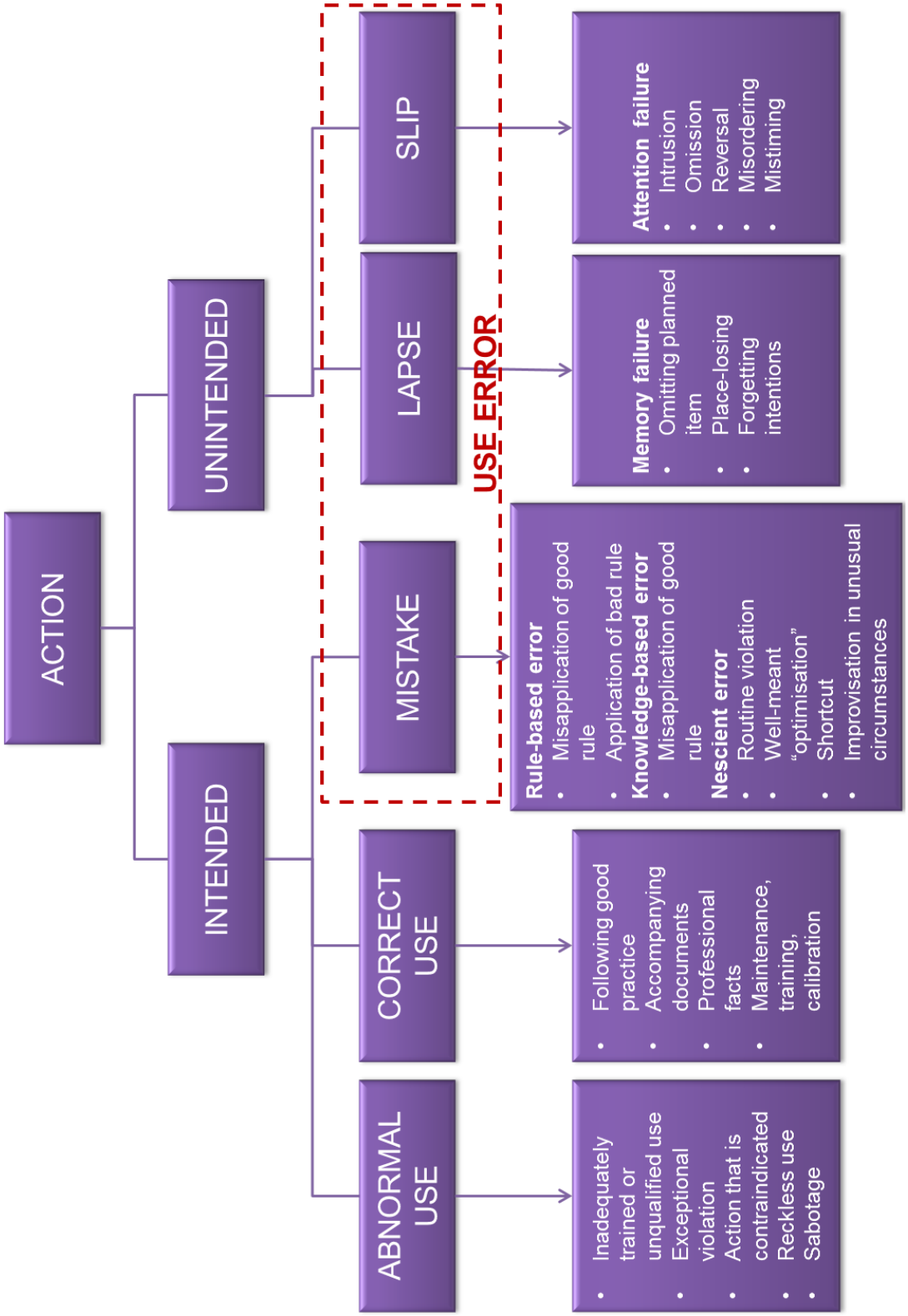



**Figure 2.4: Types of Use Error (Adapted from BSI 62366:2007 and ANSI/AAMI HE75:2009).**

The introduction of the harmonised usability standard in the UK represents the increased drive towards improved design in the Medical Technology (MedTech) sector (IEC BS EN 62366:2007). The standard and other supportive guidance represent 'push' factors upon manufacturers to develop intuitive and usable designs that meet the needs of end users.

For clarity to readers, the terms incident and event are used interchangeably in this section. Under the MHRA definition in the UK, such cases are referred to as 'Adverse Incidents' as per the definition shown previously. Under FDA regulation in the US however the term 'Adverse Event' is used to describe such cases. For clarity from this point forward and due to the context of this research, the MHRA term 'Adverse Incident' will be used throughout the thesis.

While there has been a recognised increase in the number of adverse incidents received by the regulatory authorities in both the UK and US, it does not necessarily mean that devices are less safe today than they have been previously. There is a range of hypotheses as to why recent figures have seen such a significant rise in the past decade and these are discussed below.

## Drivers in the Rise of Adverse Incident Reporting

According to a report by the Qualified Suppliers to the Medical Device Industry (QMED) there are four recognised key drivers that are responsible for the growth in adverse event reports received by the FDA in the US (QMED, 2012). While these drivers specifically address figures for the US market they refer to general principles that are arguably applicable to the overall rise in the adverse incidents with medical devices and therefore have implications for the UK market.

### *Driver One: Improved Reporting Compliance and Procedures*

The increasing regulation of medical devices, specifically focused on user error as previously described, has resulted in an increased emphasis on the reporting of adverse incidents. While many argue that adverse incidents are vastly underreported it is believed that a significant proportion of the growth in adverse incidents is indicative of improved reporting (QMED, 2012). The MHRA have developed an online facility through their website for anyone, whether manufacturer, clinician or

patient to report an incident at any time. There has also been an increase in device bulletins published by the MHRA each year that has led to a raised awareness amongst industry to report incidents.

***Driver Two: More Devices in Use***

The number of medical devices that can be bought directly in a commercial environment or over the internet is increasing (MHRA, 2013). There are more medical devices in circulation now than there ever has been and the variety and complexity continues to grow. Chapter One introduced some of the drivers for the home use market and these trends certainly look set to continue into the future (FDA, 2010). With more devices in use it can be expected that there will be a rise in the numbers of adverse incidents involving devices due to the significant increase in their prevalence.

***Driver Three: Increased Medical Device Complexity***

As devices become increasingly complex, errors will inevitably rise. Devices that were previously used by trained healthcare professionals are now accessible in the home environment for use by lay users with a lack of experience and familiarity with the technologies (Cifter, 2011). Inappropriate or poor design for the end user leads to a mismatch in the expectations of users and the use of a device. Affordances are a fine example of this in such cases where 'pull' handles are featured on a 'push' door. In this oversimplified example, the product (a door) is very simple to use however the poor consideration for users and their interaction with the product make use unnecessarily complex. Device complexity therefore does not only refer to the technological capability of a medical device but the interface with which the user interacts.

***Driver Four: Higher Risk Patient Groups and Procedures***

The final driver recognised for increased adverse incident reporting is the rise in high-risk patient groups now using medical devices (QMED, 2012). As manufacturers and designers alike attempt to innovate and expand markets, devices are increasingly targeting the most vulnerable users (QMED, 2012). In such cases the perceived benefits to the patient are considered 'worth the risk' for device use and as such the potential for adverse incidents to occur is considerably high.

With the current regulatory framework now presented the focus of this review will turn to home use medical devices specifically. The following section opens with a brief overview of home use medical devices, including definitions and a taxonomy of home use medical devices.

## 2.4 Home Use Medical Devices

Until recent times, designers of medical devices designed products that were intended largely for use in formal clinical environments by trained professionals (National Research Council, 2011). This allowed designers the opportunity to make numerous design related assumptions (ANSI/AAMI HE75:2009). These design assumptions included the environmental conditions, where typically the device would be used and the skills and abilities of the expected device users. It is now widely understood that medical devices originally designed for such instances are now migrating into the home (Gupta, 2007; Cifter, 2010; Martin *et al*, 2008). These devices present considerable challenges to the role of the designer and numerous additional considerations that need to be accounted for in the design and development process (Gupta, 2007; Cifter, 2010; Martin *et al*, 2008). One example of such challenges includes the defining and characteristics of home use medical device users.

The cognitive and physical abilities of home use medical device users are hugely diverse (Gupta, 2007; Cifter, 2010). To compare such users with healthcare professionals, for whom many of these migrated devices were originally designed, results in very different levels of training, experience and expectations of device use (ANSI/AAMI HE75:2009). Increasingly untrained and inexperienced users of medical devices in the home are interacting with complex and sophisticated medical technology. This is further compounded by the symptoms and capability loss that are associated with particular conditions.

In the FDA publication, *Do it By Design*, Sawyer *et al* posited that the population of home use medical device users represent a special challenge to designers (Sawyer, 1996). Sawyer *et al* explained that illness, poor reading ability, inadequate facilities, insufficient assistance and inexperience all add to this additional complexity of designing a medical device for home use (Sawyer, 1996). It is recognised that one of

the factors driving the increased complexity of devices used in the home is the push towards shorter stays in hospital and consequently patients are discharged with complex care regimens and thus require further care in the home (ANSI/AAMI HE75:2009). The very nature of the technology and considerations for the design process makes designing medical devices for this market particularly challenging for designers (Martin *et al*, 2008). The conditions of home use medical devices set the stage for problems in terms of usability and use errors that both compromise patient safety (ANSI/AAMI HE75:2009). Chapter One of this thesis introduced two significant bodies of research that have explored the topic of home use medical device design (Cifter, 2011; Gupta, 2007). The following section highlights some of the findings of these works in more detail before defining the term 'home use medical device' for the context of this research.

It has been posited that home use medical devices are particularly unique in the sense that they simultaneously represent forms of consumer products and medical devices (Gupta, 2007). As previously explained these devices sit between the boundaries of consumer products and medical devices (Asl, 2004; Gupta, 2007; Cifter, 2010). This connection between consumer products and medical devices forms part of the cultural shift towards commercialisation in the medical world. Figure 2.5 is an adaptation of the diagram developed by Gupta that demonstrates the relationship between medical devices and consumer products (Gupta, 2007).

In his thesis, Gupta found that the majority of designers did not distinguish between designing home use medical devices and consumer products (Gupta, 2007). In fact, the majority of designers in his study disagreed that home use medical devices are any different from either professional use medical devices or consumer products in terms of how their design process works (Gupta, 2007). From a purely design perspective this finding is concerning as home use medical devices represent a significantly safety critical domain.

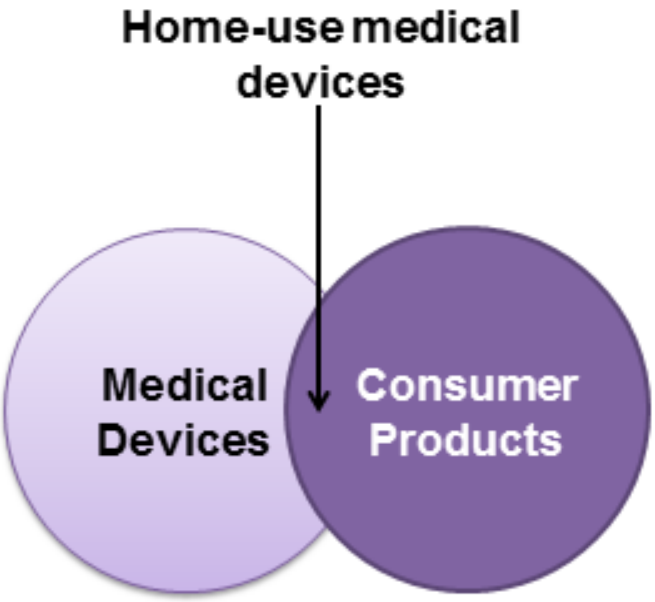



**Figure 2.5: Gupta's Relationship between Medical Devices and Consumer Products (Gupta, 2007).**

It would appear from the findings of this literature review that there is a real push towards commercial issues and much less emphasis put upon device usability. Previous research has reported that the consideration of usability within the design process is often an afterthought (Martin *et al*, 2008). Furthermore, the perceived costs in time and money outweigh the benefits gained by manufacturers, reportedly delaying the time to market (Martin *et al*, 2008, Money *et al*, 2011). Alas, the incentives for manufacturers to implement such practices within their own design process fail to be adopted, despite regular advocacy from researchers. Gupta's study identified that designers believed home use medical devices come with their own unique challenges and design issues. These challenges specifically related to device usability and risk management (Gupta, 2007). Interestingly, Cifter's research into home use medical device design found a contrasting view. In his thesis, Cifter found that designers did distinguish between designing home use medical devices and consumer products. Cifter identified four main aspects of design that were unique to home use medical devices. These are summarised in Table 2.7 (Cifter, 2011).

**Table 2.7: Cifter's Unique Aspects to Home Use Medical Devices (Cifter, 2011).**

| |
|---|
| Home use medical devices, by their nature require an intrinsically greater attention to matters of lay users' safety and risks to the lay users. |
| A considerable amount of attention should be given to lay users and their characteristics, in relation to demographic variety and diverse capabilities. |
| Home use medical devices are subject to medical device regulations. |
| The functionality and usability of home use medical devices should be optimised in order to prevent user errors, because misuse may have more serious implications than that of everyday products. |

Where Gupta and Cifter agree is that home use medical device design is a complex field that is comprised of numerous challenges for the designer (Gupta, 2007; Cifter, 2011). Delivering a device that is usable, safe and provides a benefit to the user is a very difficult task. Cynically, one could argue that any product is the result of compromises made throughout the design process to satisfy stakeholders and this is particularly interesting for medical device design and this research. By understanding designers and stakeholder perspectives of home use medical devices this research will ascertain how such compromises are prioritised to deliver safe, usable and effective medical devices for end users. This knowledge forms the basis of research question one of this research. Both the works of Gupta and Cifter revealed that defining a home use medical device in itself is difficult. Evidently there are a host of (consumer) products and devices that fall into the scope of home use medical devices. Certainly far too many to list here, however for clarity a taxonomy of medical devices currently used in the home is presented in Section 2.4.2.

As consumer products and medical devices merge, the expectations of users change. Traditionally home use medical devices would wholly have been developed to serve the purpose of a clinical need. However as described by the National Research Council in their *'Health Care Comes Home'* report, medical devices are now expected to meet the demands of modern lifestyles and consider the implications of consumer choice (National Research Council, 2011).

*"Some types of medical devices have become de facto consumer products, and more and more individuals expect to be able to choose products that suit their lifestyles and are convenient and easy to use." (National Research Council, 2011)*

For clarity purposes it is necessary to establish what is specifically meant by the term 'home use medical device' within the context of this thesis. The following section looks towards a recognised definition.

### 2.4.1 Defining Home Use Medical Devices

In order to identify potential users of home use medical devices it is necessary to establish a clear definition of what the term 'home use medical device' means. This is essential for the scope and context of this research. During this review a number of definitions were found in the literature.

In his thesis, Gupta explored the definition of a home use medical device. At the time of his research there was no recognised definition of a home use medical device (Gupta, 2007). As such Gupta developed a definition of a home use medical device within his literature review based on previous examples from the Global Medical Device Nomenclature and the FDA (Gupta, 2007). Gupta's definition of a home use medical device used within the context of his thesis was as follows:

*"A home-use medical device is a medical device that is or can be used and/or operated by non-professional users, such as patients and their carers, independently in the home environment or other non-clinical environments such as people's cars and places of work, etc."(Gupta, 2007).*

This definition recognises the multitude of potential users and environments that fall under the term 'home use medical device' (National Research Council, 2011). Compounding this issue is the recognition that medical devices currently used in the home may not have been originally designed for that intention (IEC BS EN 62366: 2007; Martin *et al*, 2008). The concept of independence in this definition implies that in some contexts of device use it will be necessary for users to be unsupervised. Therefore the designer must consider the expectations of device users to develop a device that is understandable and operable without assistance.

Gupta's definition makes another reference to the use of mobile or portable medical devices that are taken everywhere by their users. This represents a growing trend in medical device use. The Exubera device presented in Section 2.2 described an example of a portable device and some of the considerations for design.

Over the years that have passed since the publication of Gupta's work in this area there have been developments in the regulatory definitions of a home use medical device. This is largely attributable to the increasing recognition from the regulatory bodies of the rise in home use medical devices (Turieo *et al*, 2004; FDA, 2010; FDA, 2012).

One example of more recent research in this field was the thesis conducted by Cifter (Cifter, 2011). In the context of his research and the exploration of lay users for home use medical devices, Cifter refers to the current definition adopted by the Centre for Devices and Radiological Health (CDRH) in the US. The CDRH Home Health Care Committee (HHCC) was set up in 2001 to look at medical devices through the Total Product Life Cycle (FDA, 2013). Their current definition of a home use medical device is:

*"A device intended for use in a non-clinical or transitory environment, is managed partly or wholly by the user, requires adequate labelling for the user, and may require training for the user by a health care professional in order to be used safely and effectively."(FDA, 2013).*

This definition expands on the issues raised in Gupta's definition and makes specific reference to device labelling and training that may be required to use a device as intended by the manufacturer. Furthermore, there are four specific references to device use and users in a variety of contexts that ultimately impact on device safety. These are briefly summarised in Table 2.8.

**Table 2.8: References to Users within the CDRH Definition of a Home Use Medical Device (FDA, 2013).**

| |
|---|
| 1. **Environment of Use -** The first context refers to the environment of use and where the device is likely to be used by users. |
| 2. **Task -** The second context refers to the task directly. This demonstrates the importance of identifying the target users for whom the device is intended and addressing their needs. |
| 3. **Instructions and Labelling -** The third reference relates directly to instructions and labelling which must be readily accessible and legible for a lay audience. |
| 4. **Training -** The final reference refers to the necessary training, particularly by healthcare professionals, necessary to use a device safely and effectively. The need for training on the use of a device demonstrates a need for a level of required knowledge and experience beyond that of the capabilities of the user. Essential to designing home use medical devices effectively is the understanding of user needs and capabilities to make devices usable, safe and of benefit to the user. The design of home use medical devices in this context goes beyond designing a product alone and more specifically refers to the design of a system that compensates for user inexperience or capability loss. |

One final definition of a home use medical device was found during this review on the FDA website. On their specific Home Use Devices page, accessible from the FDA website, the definition of a home use medical device is as follows:

*"A home use medical device is a medical device intended for users in any environment outside of a professional healthcare facility. This includes devices intended for use in both professional healthcare facilities and homes." (FDA, 2013).*

Perhaps this last definition presents most clearly that a home use medical device has the potential to be vast array of devices used anywhere, by anyone. Thus the implications for design of such devices are significant. It is the role of this research to explore how such devices are designed in practice to deliver benefits to device users.

### 2.4.2 Taxonomy of Home Use Medical Devices

The range of definitions for home use medical devices revealed that there are a multitude of available devices that are potentially used in the home today. These devices could range from simple, understandable and common devices through to complex, rare and incomprehensible devices to a vast majority of device users. For the purpose of this research it was deemed necessary to gain an understanding of the range and complexity of devices that are currently used and are migrating into the home environment. As part of this review, a taxonomy of home use medical devices was constructed to benefit both the researcher and the readers build a visual understanding of the types of devices currently made available to the home use market (see Table 2.9).

The taxonomy structure is adapted from previous literature and taxonomies found while conducting this literature search. In particular the works of Gupta and the National Research Council were predominantly used to provide a basis for this taxonomy (Gupta, 2007; National Research Council, 2011). The taxonomy presented here is not exhaustive of all devices currently used in the home. Due to the nature in which devices are accessed today it would be almost impossible to determine every device that is used in the home environment. Therefore the list presented here provides a summary of the range of devices that are known to be in current use within the home environment. As such this taxonomy provides a context for the definitions of home use medical devices previously described.

For simplicity and legibility, the range of devices presented in this taxonomy have been categorised into three simplistic groups. The categories selected and presented in Table 2.9 include: Diagnostics and Monitoring, Therapeutic and Assistive Technology.

**Table 2.9: Home Use Medical Device Taxonomy (Adapted from Gupta, 2007 and National Research Council, 2011).**

| Category | Devices |
|---|---|
| **Diagnostic and Monitoring** – For home use these devices largely refer to test kits used in the self-diagnosis of a condition or devices used to monitor one's own health. | Allergy Test<br>Apnoea Monitor<br>Bladder Infection Test<br>Blood Coagulation Meter<br>Blood Glucose Meter<br>Blood Pressure Monitor<br>Cholesterol Test<br>Doppler<br>Drug, Alcohol, Nicotine Test<br>Electrocardiogram (ECG)/Heart Monitor<br>Electrocardiogram Monitor<br>Fetal Monitor<br>Gonorrhoea Test<br>Hepatitis C Test<br>HIV Test<br>Male Fertility Test Kits<br>Male/Female/Stress Hormone Test<br>Menopause Test<br>Ovulation Test<br>Peak Flow Meter<br>Pregnancy test<br>Pulse Oximeter<br>Stethoscope<br>Thermometer<br>Vaginal pH Test<br>Weight Scales |
| **Therapeutic** – In the context of the home these refer to devices and equipment used to treat or prevent a condition which may be delivered by the patient themselves or healthcare professional depending on the device. | Breast Pump<br>CPM<br>Defibrillator<br>Dosing Equipment<br>Feed Pump<br>First Aid Kit<br>Haemodialysis Equipment<br>Inhalers<br>Insulin Pens<br>Manual Resuscitation Bags<br>Massager<br>Medication Patches<br>Nasal Sprays<br>Nebulisers<br>Nebulisers<br>Oxygen Cylinders<br>Oxygen Therapy System<br>Suction Pumps<br>Syringe Drivers |

| Category | Devices |
|---|---|
| | Syringe Pumps<br>Syringes<br>TENS (Transcutaneous Electrical Nerve Stimulation) Machine<br>Tracheostomy Care<br>Ventilators<br>Volumetric Pumps<br>Wound Dressings |
| **Assistive Technology** – Within the home assistive technologies largely refer to aids that benefit patients with mobility issues and physical disabilities. | Bathing Aids<br>Beds, Mattresses and Cushions<br>Communication Aids<br>Eyeglasses<br>Hearing aids<br>Hoists<br>Incontinence Aids<br>Medicine Management Kits<br>Orthotic Devices<br>Prosthetics<br>Scooters<br>Stair Lifts<br>Vision Aids<br>Walking Aids |

The review will now discuss the current usability standard IEC BS EN 62366:2007 which is harmonised under the current Medical Device Directive (MDD).

### 2.4.3 IEC BS EN 62366:2007 - Application of Usability Engineering to Medical Devices

Recent developments in the literature and academic research have led to the increased recognition of usability and in 2007 IEC BS EN 62366 – Application of Usability Engineering to Medical Devices was harmonised. The internationally recognised standard details the application of usability engineering to medical devices (IEC 62366:2007).

The standard was first introduced to counteract the reported rise in use related errors caused by poor device usability. It was recognised that medical devices designed prior to the introduction of more formal processes were ‘non intuitive, difficult to learn and to use’ (IEC BS EN 62366:2007). As a result the standard describes a Usability Engineering Process (UEP) for manufacturers and designers alike to follow

as a methodology to improve device usability and minimise use related errors. The scope of the standard specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, and how it relates to the safety of a medical device (IEC BS EN 62366:2007). The definition of the term 'usability' will now be discussed. Within IEC BS EN 62366:2007, usability is recognised as a particular characteristic of device design itself. Thus usability is defined as a:

*"…characteristic of the user interface that establishes, effectiveness, efficiency, ease of user learning and user satisfaction" (IEC BS EN 62366:2007)*

However if the concept of usability is broadened out, the International Standards Organisation (ISO) also define usability as:

*"The effectiveness, efficiency and satisfaction with which specified users can achieve specified goals in particular environments" (ISO DIS 9241:2011)*

Therefore usability refers to a range of factors specific to design that determine the interactions made by users. Consequently good design is paramount to achieve improved and usable products for users.

Both ISO definitions make reference to three specific terms that define usability; *Effectiveness*, *Efficiency* and *Satisfaction*. To understand usability it is necessary to have a greater understanding of what these terms specifically mean and how they related to the use of a device.

Patrick Jordan, a renowned usability professional and researcher, defines these terms within his book, *An Introduction to Usability* (Jordan, 1998).

- "**Effectiveness** refers to the extent to which a goal, or task, is achieved"
- "**Efficiency**, meanwhile, refers to the amount of effort required to accomplish a goal"
- "**Satisfaction** refers to the level of comfort that the users feel when using a product and how acceptable the product is to users as a means of achieving their goals"

Jordan argues that it is possible to make the general assumption that users of products that are used voluntarily regard satisfaction as the most significant aspect of usability (Jordan, 1998). In the context of medical devices, the use of devices is predominantly mandatory as opposed to voluntary. It is typically more common for users of home use medical devices to be required to use a device for a particular condition rather than their own choice to do so. Alas, the subject of satisfaction or the 'pleasurability' of medical devices is often an issue for debate.

That is not to say that satisfaction for medical devices is not an important issue. To the contrary, as increasing numbers and varieties of professional medical devices migrate into the home the topic of satisfaction will become increasingly important. Particularly when we consider that user satisfaction is widely regarded as one of the critical factors behind medical adherence and commercial brand loyalty. For over-the-counter medical devices, where device users are both the purchasers and end users of the device, user satisfaction is both more an important and powerful consideration for manufacturers. If users are fond of a particular type of device produced by one manufacturer they are much more likely to repeat purchase or in the case of prescribed devices request them from their general practitioner. This model of accessing devices supports the commercial argument and business case for companies to invest in usability for medical devices.

For a manufacturer to meet the internationally harmonised standard there are certain steps that must be followed as part of the Usability Engineering Process (UEP) (IEC BS EN 62366:2007). A significant part of this process is the collation of the 'Application Specification' (IEC BS EN 62366:2007). This specification includes fundamental proponents of a 'User Centred' approach to design such as; the intended patient (user) population and an intended user profile.

The contents of an application specification include:

- Intended medical indication.
- Intended patient population – Examples include; age, weight, health and condition.
- Intended user profile.
- Intended conditions of use – Examples include; environment of use, hygienic requirements, frequency of use, location and mobility.

- Operating principle.

The standard requires that manufacturers identify characteristics that are related to safety, including the consideration of the user profile and the features previously described that form the application specification.

The aim of the UEP outlined in the standard is to assess and mitigate risk caused by usability problems associated with correct use and use errors (IEC BS EN 62366:2007). It is believed that by following the UEP, 'reasonable usability' can be achieved which in turn will lead to a reduction in use errors and minimise use-associated risk (IEC BS EN 62366:2007). With this in mind, research question one of this research aims to establish how usability guidance, specifically IEC BS EN 62366:2007 is received by practitioners in industry. To ascertain the perceived value of such guidance it is necessary to understand how designers consider and involved users in the design of home use medical devices, a fundamental principle of a usability engineering approach. The review will now turn towards the identification of specific design methods currently recognised and used to capture the needs and requirements of device users.

## 2.5 Design Methods for Medical Device Development

It is acknowledged that designing medical devices is a complex and multi-layered process that involves a diverse and skilled team (Lehoux *et al*, 2011). Understanding how individuals from different disciplines and perspectives come together is integral to any design process. Each member of the design team brings their own perspective to design based on their experience, knowledge and opinions. To ensure that the approaches and methods advocated by each member of the design team are considered and harnessed the correct design method must be chosen. Similarly, the research methods chosen in relation to identifying user needs must be suited to the context of the product being designed. This section explores previously used design methods in the development of medical devices specific to improving usability.

To explore the range of methods used in the development of home use medical devices, a review of the design method literature was conducted.

Martin *et al* conducted a literature review of methods used to capture user requirements to determine the value of such approaches for medical device development (Martin *et al*, 2008). A total of 120 papers were found and over thirty (30) methods were reviewed in relation to ergonomics and applications in medical device development. Many of the methods highlighted in the review shared similarities with one another and featured only slight variations from more established or well-known methods (Martin *et al*, 2008).

Martin *et al* presented methods, which were repeated in more than five (5) papers in terms of; the types of data generated, the specific considerations for medical device development and their potential for improved usability and user satisfaction (Martin *et al*, 2008). The list discussed by Martin *et al* included: Contextual Inquiry, Cognitive Task Analysis, Cognitive Walkthrough, Delphi Technique, Focus Groups, Heuristics and Usability Tests (Martin *et al*, 2008).

A brief summary of these techniques is presented below:

**Contextual Inquiry (CI) –** refers to a specific form of interview conducted within the context of use. Participants are asked to perform a task while an interviewer aims to extract as much raw data and information as possible through observation. The method is regarded as an adapted form of ethnographic research to meet the time and budget constraints of engineering (Holtzblatt & Beyer, 1993). Thus, some prefer contextual 'observation' in place of inquiry as the method refers to a form of ethnography. Martin *et al* believe the method to be particularly suited for medical device development during the design of a new, or re-design of an existing, medical device (Martin *et al*, 2008).

**Cognitive Task Analysis (CTA) –** refers to a method of data capture that studies the mental processes involved for a particular activity. The addition of 'cognitive' changes the focus of a simple task analysis to that of the mental processes involved (Cacciabue, 2004). Cacciabue defines CTA as 'a method that attempts to specify the interaction of mental procedures, factual knowledge, and task objectives in the process of job performance.' (Caccibue, 2004). Martin *et al* posit that CTA has potential value for medical device design. They suggest that through an understanding of the cognitive workload and identification of critical decision points,

the designs of devices can be informed and supportive of the tasks performed by users (Martin *et al*, 2008).

**Cognitive Walkthrough –** refers to a form of expert evaluation specific to the usability of a product or device. This method therefore does not include actual end users but rather evaluators, typically members of the development team or usability specialists, who look for usability issues through the sequence of a performed task (Martin *et al*, 2008). One limitation of this method is the use of experienced evaluators who may not necessary represent the actual end users and their likely interactions. Martin *et al* suggest that cognitive walkthrough may be more suited to the early stages in the design process whereby obvious usability issues could be identified before testing later with actual end users (Martin *et al*, 2008).

**Delphi Technique –** refers to a technique that aspires to gain a consensus of opinion from a group of people. This approach is particularly beneficial for prioritising requirements that may have been established through other user requirements research (Martin *et al*, 2008). Delphi Technique, shares some similarities with that of Nominal Group Technique in that individual estimates or data is initially collected prior to a group discussion on the subject and previous data collected (Robson, 2011). Revisions are then made to reach a 'group view' or consensus (Robson, 2011). Typically such an approach would involve a number of rounds in which questions are revised based on previous responses to clarify issues raised before the final round of questions which looks to establish a consensus on the relative importance or priority of issues raised in the previous rounds (Martin *et al*, 2008).

**Focus Groups –** are a widely recognised and adopted method for data capture in research and commercial business worldwide. Their application in medical device development is particularly attractive to designers due to relative low investments in time and money to collect data and information from device users (Martin *et al*, 2008). Robson defines focus groups as a 'group interview on a specific topic' featuring 'open-ended' discussions guided by the researcher (Robson, 2011). There are challenges associated with their use however. For example it can be common for one or two persons to dominate a discussion restricting involvement from participants who are less willing to share information (Robson, 2011). Furthermore, as with interviews, participants are only able to discuss issues that they are aware of

and that they can recall or articulate at the time of the interview (Martin *et al*, 2008). To combat these issues Martin *et al* suggest combining focus groups with observational techniques, such as those described in CI, to assess the contextual issues of device use (Martin *et al*, 2008).

**Heuristics –** refer to an evaluative usability technique, typically conducted by experienced individuals in Human Factors or Human Computer Interaction (HCI), which examines the user interface of a product or device against a set of established usability heuristics (Usability Net Website, 2003). According to Zhang *et al*, one reviewer can detect up to 35% of usability problems through a heuristics evaluation and add that using five reviewers will result in approximately 65-70% of usability issues being identified (Zhang *et al*, 2003). Thus, such an approach is not sufficient alone to capture all of the usability issues of a medical device. Martin *et al* add that a heuristics evaluation is potentially more valuable during the early stages as part of an iterative design approach (Martin *et al*, 2008).

**Usability Tests –** perhaps the most ubiquitous method associated with the development of medical devices today. They refer to the testing of device performance in terms of task completion times and rates, ease of use and amount of errors (Martin *et al*, 2008). Usability tests are commonly used during the medical device validation stage to demonstrate regulatory compliance (IEC BS EN 62366:2007). They have been shown to add value for design during the early stages of the design process however. Martin *et al* describe how usability tests can inform and help generate usability goals during the early stages and through iteration can lead to the refinement of device design (Martin *et al*, 2008).

Aside from the seven commonly cited methods for medical device development identified by Martin *et al*, there are alternative approaches available to designers. As Martin and Barnett posit it is not suitable to assume that cited methods in the literature necessarily reflect those used in practice (Martin & Barnett, 2012). They state:

*"It is difficult to know to what extent the published ergonomics research in this area reflects current industrial practice, given the heterogeneous nature of the medical device industry and the understandable reluctance of companies to publicise details of their development processes."(Martin & Barnett, 2012).*

Thus one of the aims of this research is to determine the current methods adopted by industrial practitioners operating in the home use medical device market today.

One alternative approach identified during this literature search for design methods includes the possibility of approaching a specialist design consultancy, such as IDEO for example. IDEO is a globally recognised design consultancy that specialise in 'human centred' design for the public and private sectors. Since previous research has reported that it is not uncommon for external companies or consultancies to conduct specific usability research, it could be considered foreseeable that a manufacturer might consider such an approach to identify design research methods (Gupta, 2007). Practicing designers could therefore approach IDEO to identify relevant or suitable methods for the design of a new or upgrade of an existing home use medical device.

To address this market need, IDEO developed a range of method cards that aim to simplify the process of data capture and improve the understanding of designers on usability issues. The IDEO method cards were developed as part of a research project that aimed to inspire practicing and/or aspiring designers to keep people at the centre of the design process (IDEO, 2002). The methods are grouped into four simplistic themes; Learn, Look, Ask and Try defined by the nature of the approach. The researcher reviewed the cards based on particular references suggested for improving the usability of a product. Table 2.10 lists the range of potential methods that might be considered suitable during the process of designing and developing a home use medical device.

It was recognised during this review that a range of the methods refer to techniques that are similar to those discussed by Martin *et al* (Martin *et al*, 2010). The IDEO method cards provide 'snippets' of information relating to a method offering suggested further reading for designers or developers to become more knowledgeable about a particular technique. The cards are admittedly intended as a guide or reference to the design community and are not intended as a definitive solution to usability. Despite this they still provide value in challenging one's own preconceptions of ways to approach a particular problem or design issue. For this reason the methods presented in Table 2.10 are listed and do not include a description of the techniques. This falls outside of the scope of this literature review,

which is specifically focused on the methods applied by industry and cited within the literature. For contextual reasons and potential for manufacturers to consider such methods it was considered relevant to present these methods here.

**Table 2.10: Potential Design Methods for Medical Device Development. (Adapted from IDEO, 2002)**

| |
|---|
| Role Playing, Competitive Product Survey, Error Analysis, Cultural Probes, Fly on the Wall, Guided Tours, Narration, A Day in the Life, Affinity Diagrams, Anthropometric Analysis, Behavioural Archaeology, Rapid Ethnography, Personal Inventory, Shadowing, Surveys and Questionnaires, Time Lapse Video, Try it Yourself, Camera Journal, Card Sort, Character Profiles, Cognitive Task Analysis, Activity Analysis, Empathy Tools, Five Whys, Extreme User Interviews, Unfocus Groups, Scenarios. |

Understandably there are a wealth of design methods or approaches within the literature that a manufacturer could use during the design of a product. Some of these methods are established formal techniques whereas others are less well known and refer to informal approaches. The purpose of this review is not to identify and explain every available design method suitable for improving the usability of a product. Rather, the aim of this review is to develop an understanding of the user research methods that have been used previously to ascertain current practice towards user involvement in home use medical device design.

The literature review conducted by Martin *et al* was found to be the most relevant study into the methods used for the design of medical devices and therefore forms the basis of this section. As previously stated however, this thesis is concerned with the actual methods used by designers in practice and therefore must be addressed through involvement with industry professionals specifically. As Martin *et al* explain:

*"Published papers do not necessarily reflect methods in practice" (Martin et al, 2008).*

According to Martin *et al* the selection of methods for user requirements capture will depend on the stage of development, the types of users, the time, cost and necessary

expertise available to conduct the research (Martin *et al*, 2008). Thus the process of designing a medical device will have significant implications for the consideration and involvement of device users within the design process. In order to determine the methods adopted by industry to capture the needs of their end users requires the involvement and questioning of currently practicing designers. Answering research question one with regards to current practice will establish whether methods cited within the literature reflect those that are used in practice.

To understand the range of user research methods used throughout the design process it is necessary to have an understanding of the design process of a home use medical device. The following section explores the design process as a whole from initial conception to launched product on the market. The section will begin with a brief description of recognised design processes for product development before addressing specific medical device processes.

## 2.6 Design Process

In order to understand the design processes used by the medical device industry it is necessary to have a detailed understanding and familiarity with general product design processes.

In the seminal text, *Design for Usability*, Gould and Lewis advocate three principles as a basis for a general methodology to design (Gould, J.D. & Lewis, C, 1987). These can be summarised as follows:

I. **Early Focus on Users and Tasks –** Critical to the design process of any physical and functional product is the identification of who the likely users will be. This is recognised as a fundamental principle of a 'user centred' approach to design described in Section 2.9 and supported by IEC BS EN 62366:2007 for medical devices. The designer must understand the user's cognitive, behavioural, anthropometric and attitudinal characteristics including the tasks to be performed (Gould, J.D. & Lewis, C, 1987).

II. **Empirical Measurement –** Gould and Lewis believe that users should actually use and interact with prototypes or simulations early in the development process. User's reactions and performance should be

recorded and analysed to assist the development process (Gould, J.D. & Lewis, C, 1987).

III. **Iterative Design -** Gould and Lewis refer to iterative design as a way of 'confronting the reality of unpredictable user needs and behaviours that can lead to sweeping and fundamental changes in a design.' (Gould, J.D. & Lewis, C, 1987). Through early and regular design iterations significant improvements for device users in terms of safety and usability can be made.

New innovations to market are less likely, if at all, to have an established user base and therefore understanding the exact users, their characteristics and other potential users can be very difficult. However as Gould and Lewis point out, this scenario strengthens the argument for empirical measurements and iterative design in industry's approach (Gould, J.D. & Lewis, C, 1987). In contrast, when modifications are made to an existing device, users and user groups should be readily identifiable and accessible. This is particularly common in the medical device industry where it has recently been reported that manufacturers often prefer to make major upgrades to devices rather than launching a completely new innovation (Eatock, J, Dixon, D. & Young, T, 2009). Following the principles of Gould and Lewis therefore suggests that design refers to a process that by necessity can require empirical methods and iteration to transfer an idea to a product (Gould, J.D. & Lewis, C, 1987). Papanek also supports this notion of applying a methodical approach to design in his quote presented at the beginning in Section 2.2 of this review.

*"Design is the conscious and intuitive effort to impose meaningful order" (Papanek, 1984).*

There is of course a wealth of research that has explored the depiction and understanding of the design process featuring linear processes to iterative cycles. One could argue however that in many cases, models of the design process largely follow similar principles when taking an initial concept to a manufactured product. One such representation of the design process that is familiar to many designers is the work of Michael French in what is commonly referred to as the 'French Model' (French, 2010). In his book, *Conceptual Design for Engineers*, French refers to design as all of the process from 'conception, invention, visualisation, calculation,

marshalling, refinement and specifying of details which determines the form of an engineering product' (French, 2010). French describes the 'anatomy of design' in the form of the process shown in Figure 2.6. The ovals within the model depict the stages reached while the rectangles represent work in progress (French, 2010).

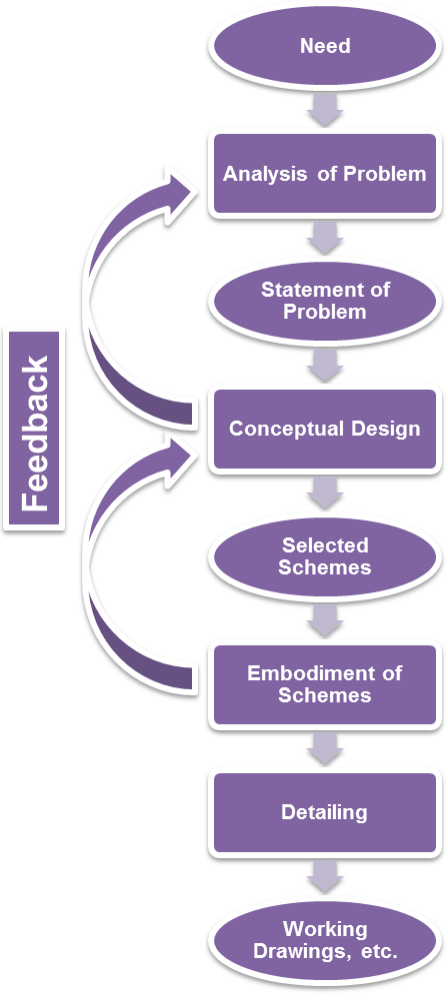



**Figure 2.6: French's Model of the Design Process (Adapted from French, 2010).**

The model developed by French signifies the importance of an early identification and analysis of the problem that from the outset dictates the process of design. There is also a 'Feedback loop' within the model that calls for the reflection of concepts and embodiment back to the original analysis of the problem about what the design is aiming to solve. Thus, the model developed by French supports the notion of the three principles defined by Gould and Lewis described previously.

Gilman *et al* suggest a simplification of a general design process can be depicted as Figure 2.7 (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009).

**Figure 2.7: Simplified Depiction of the Design Process (Adapted from Gilman, Brewer & Kroll, 2009).**

Both French's model and Gilman's simplification of the design process are recognised approaches to product development. An appreciation of specific stages involved in product development is fundamental to the process of designing a home use medical device. With this in mind the review will now explore design processes specific to medical devices used in the home environment.

## 2.7 Medical Device Design and Development Process

This review has highlighted that if a medical device is to be a success in the marketplace it is essential for a manufacturer to follow detailed and thorough design process towards delivering a quality, safe and effective device that meets the needs and expectations of device users (EC, 2007; IEC BS EN 62366:2007). A process that Gilman *et al* refer to as 'design controls' (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009).

According to Gilman *et al*, design controls are a set of defined systematic steps to be followed when designing medical devices to deliver a resulting product that is 'safe, effective and can be successful in a competitive marketplace' (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009). By virtue of the potential risks presented by medical devices it is of necessity that manufacturers have a rigorous design process in place. As Medina *et al* state that the regulatory governance of medical devices requires a separate and adaptive process for medical device development (Medina, 2012). In their study, Gilman *et al* refer to smaller companies and the approach taken for the medical device design process (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009). They posit that while smaller companies may have fewer product lines and can

potentially coordinate resources more easily, there is often a lack of time and money to conduct user requirements research in the first place (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009). The fact that individuals can interact more closely in smaller companies allows for simpler processes to function effectively. That said however, irrespective of whether the company is large or small, 'the process intricate or streamlined, there are specific steps that must be taken and documented to ensure that the result is a desired product that is safe, effective and profitable' alongside regulatory compliance (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009).

Figure 2.7 presents the Medical Device Design Process according to Gilman *et al* (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009). The authors describe this model of the design process as a detailed approach that might be typically followed by a large company developing a medical device. However in their paper, Gilman *et al* describe the design process of a medical device under four simpler stages namely: Concept, Development, Manufacturing and Distribution (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009). This would suggest that similar approaches are applied to medical devices as those described in Section 2.6 whereby an initial need is developed through a process of iteration towards a final product.

The Gilman *et al* design process suggests that medical device design is largely defined by the regulatory requirements described in Section 2.3 of this review. Gilman *et al* describe three critical tasks that are to be defined in the development phase of the design process: Clinical Testing Required, The Regulatory or Governmental Clearances Required and the Reimbursement Strategy (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009).

Gilman *et al* conclude that by following a systematic approach for the 'entire development life cycle' results in the optimisation 'of producing a reliable product that meets the needs of the customer and is successful in the market place' (Gilman, B.L, Brewer, J.E. & Kroll, M.W, 2009).

In another study, Eatock *et al* conducted a survey of the medical device industry to determine the tools and strategies towards medical device development dependent on the size of company. A summary of the findings is presented below under the headings defined by the authors (Eatock, J, Dixon, D. & Young, T, 2009).

- ***Expected and supported*** – Large companies use a wide variety of tools/strategies in parallel, while small companies lag in applying LEAN, Six Sigma, stage gates and TQM.
- ***Not-expected and supported*** – Large companies prefer known technologies, while small companies prefer new-to-the-world technologies.
- ***Surprising*** – Large companies prefer to perform major upgrades even though their success of major upgrades is lower, while small companies have a high success rate for new-to-the-world technologies.

The study by Eatock *et al* indicated that smaller companies typically develop 'new to world' technologies and it could therefore be argued that their products are possibly more innovative to that of their larger competitors (Eatock, J, Dixon, D. & Young, T, 2009). This is supported by the typical business model of the MedTech sector whereby larger companies often 'buy-out' smaller innovative companies. The study also suggests that smaller companies operating in the sector adopt less formal or well-established methods for development such as LEAN or Stage Gate processes and might therefore utilise flexible or adaptive processes based on the background and experience of the design team.

Another example of a medical device design process found within this review is that of the FDA's Waterfall Model (FDA, 1997). The Waterfall Model provides a simplified schematic of the device design process from the conversion of user needs requirements into a finished device. This process is depicted in Figure 2.8 and represents another example of the medical device design process as a design-controlled or systematic process. The FDA have omitted the inclusion of iterative 'feedback paths' between each phase of the process in this diagram, that they state would be required, in order to emphasise the influence of design controls in this particular model (FDA, 1997). Once the design input has been reviewed and determined to be acceptable, 'an iterative process of translating those requirements into a device design begins (FDA, 1997). The initial step of this process requires the conversion of the identified requirements into a higher-level specification. As such these specifications are classified as a design output using the FDA model. When the specifications have been verified to conform to the design input requirements they then become a design input for the next step in the design process and this is repeated

through the process (FDA, 1997). The Waterfall Model calls for a design review at each stage of the design process whilst also introducing for this research the concepts of '*Design for Verification'* and '*Design for Validation',* which are discussed later in this section.

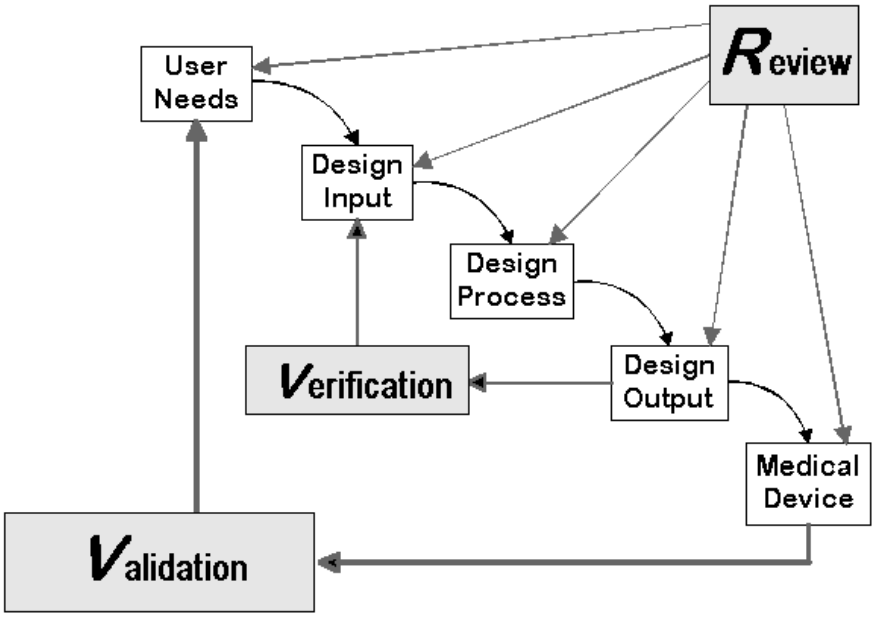



**Figure 2.8: FDA's Waterfall Model.**

In addition to these medical device design processes, one example of a specific design process for home use medical devices was found.

**Home Use Medical Device Design Process**

As part of the conclusion to his thesis, Cifter developed the 'Dual Verification Model Design Process', which he proposes as a suitable approach for home use medical devices (Cifter, 2011). The process, which can be found on his, website at: http://homeusemedicaldevices.com/design/dualverification.html is adapted and presented in Figure 2.9. The process appears to get its name from the verification of *'Essential Requirements'* and *'User Requirements'* when designing a concept. In doing so, Cifter makes a distinction in the design process between the regulatory requirements and the need to capture user requirements as part of a dual approach to design a home use medical device.

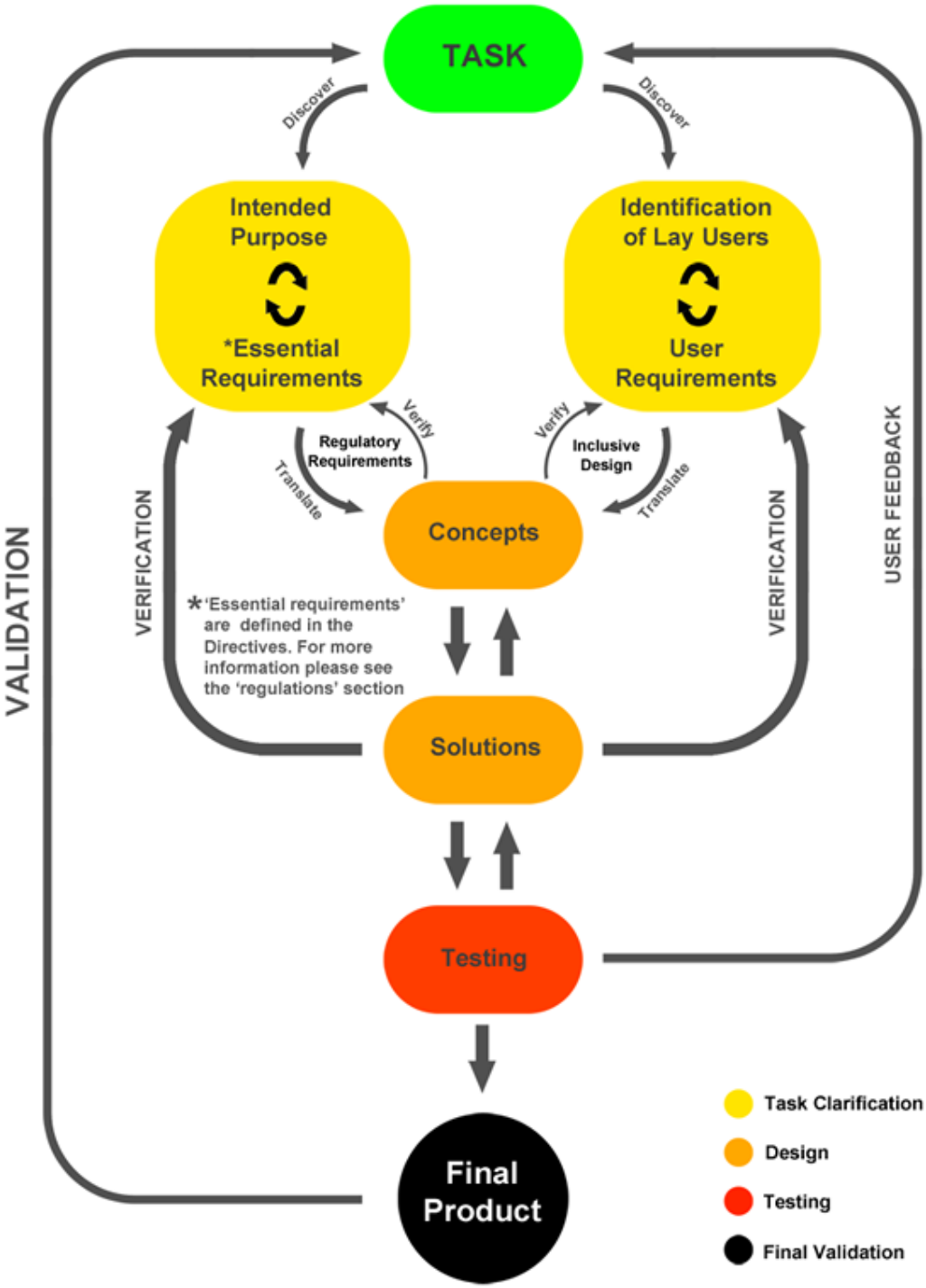



**Figure 2.9: Cifter's Dual Verification Process for Home Use Medical Devices (Cifter, 2011).**

According to Cifter, the Dual Verification Model has been developed to specifically support designers who do not have any prior experience in designing home use medical devices (Cifter, 2011). As Figure 2.9 shows, the process is comprised of five main stages: Discovering the Task, Task Clarification, Design, Testing and Final Validation, which are briefly summarised below.

1. **Discovering the Task –** Cifter defines the beginning of the design process for a home use medical device with the definition of the task and the desired outcomes of that task. In doing so, he suggests that two questions should be answered: '*Who are the target lay users of the device?*' and '*What is the intended purpose of the device?'* (Cifter, 2011).
2. **Task Clarification –** According to Cifter, at this stage the requirements of the task should be 'specified precisely' and consequently involves two simultaneous and parallel tasks (Cifter, 2011). Firstly, the needs identified with respect to the intended purpose of the device must be investigated against the Essential Requirements of the MDD (Cifter, 2011). Secondly, the requirements of target or intended users must be investigated with the users themselves. This task according to Cifter, will ensure the final product developed is designed inclusively and considers the capabilities of the target users (Cifter, 2011).
3. **Design –** With the requirements now specified and understood they must be initially translated into concepts and subsequently verified against the requirements. Hence, this stage refers to Design Verification asking the question of the designer *'Are we building the right thing?'* (Cifter, 2011). Consequently the best solution to meet the identified and verified requirements is selected.
4. **Testing –** With the best design selected, Cifter now calls for device testing to commence involving the lay users of the device and strongly recommends that this be carried out in the context of use (Cifter, 2011). Should necessary changes be required at this stage there is an iterative loop back to the design stage to improve the design (Cifter, 2011).
5. **Final Validation –** In the final stage of the Dual Verification Process, the validation of the device is carried out which is supported by the FDA waterfall model previously shown (Cifter, 2011; FDA, 1997). As a result this

stage of the process helps the designer answer the question *'Have we built the right thing?'* (Cifter, 2011)

To conclude this section of the review on medical device design processes, the concepts of *'Verification'* and *'Validation'* are defined to provide clarity for the reader.

**Design for Verification**

Design for Verification in the context of medical device design refers to the evaluative activity or process that checks whether a device design meets its requirements. "Specifically, verification involves checking that what has been designed (design outputs) meets its requirements (design inputs) (Alexander & Clarkson, 2000). Alexander and Clarkson describe this process as the posing of the following question "Are we building the thing right?" (Alexander &Clarkson, 2000). Thus verification consists of the detailed examination of specific aspects of the design, throughout the development process, assessing that outputs meet inputs.

**Design for Validation**

According to the FDA's design control guidance, Validation is the culmination of the design process including design verification and the assessment of user needs and intended users to determine the correct product has been built (FDA, 1997). In this definition there is a clear expectation for manufacturers to assess the needs of the user throughout the process to culminate in a resultant device that meets their needs. Ultimately, it is the validation process that ensures a device is fit for purpose throughout the evolutionary process of design and will therefore form the assessment of a medical device for regulatory approval. Alexander and Clarkson describe the process of validation with the following question: "Have we built the right thing?" (Alexander & Clarkson, 2000).

The processes identified in this section provide a guide for designers to follow when designing medical devices both for professional and home use. Supporting these processes are relevant guidance documents to assist designers and developers in meeting the regulatory requirements for medical devices. The following section of the review will now explore the relevant design guidance available to manufacturers to assist them in the design of home use medical devices.

## 2.8 Design Guidance

The depth and complexity of the regulatory process described in Section 2.3 highlighted some of the conformance procedures necessary to acquire a CE mark. The previous section revealed that the process of designing a medical device is multifaceted and complex (Lehoux, P. *et al*, 2011; Martin *et al*, 2008). This complexity has called for the development of detailed and descriptive design guidance to support the design and development of medical devices.

Of particular interest for this research is the recent trend towards usability for medical devices. Over the past 15 years there has been a significant increase in focus towards 'user centred design' and 'human factors' issues, principles and practices for medical devices (National Research Council, 2011).

Currently there are a number of available guidance documents and standards that have been produced in attempt to support manufacturers and designers in the attainment of such practices (ANSI/AAMI HE75:2009; IEC BS EN 62366:2007). Such documents endorse and advocate principles of 'user centred design', 'human factors', 'ergonomics' and 'usability', which depending on the document one refers too are all used interchangeably with respect to usable and understandable medical devices.

An over simplistic premise of their focus is that of identifying, capturing and addressing the needs of device users to deliver products that satisfy their requirements, needs and capabilities. A more detailed review of 'user centred design' and its application to medical devices will be discussed later in this review.

A list of some of the currently available guidance documents that specifically refer to usability and medical device design are summarised below:

- **ANSI/AAMI HE48:1993** – Human Factors and Engineering Guidelines and Preferred Practices for the Design of Medical Devices.
- **ANSI/AAMI HE74:2001** – Human Factors Design Process for Medical Devices.
- **ANSI/AAMI HE75:2009** – Human Factors Engineering – Design of Medical Devices.

- **IEC 60601-1-11:2010** – Medical Electrical Equipment parts 1-8 General Requirements for Safety. **(Replaced by: IEC BS EN 62366:2007)**
- **IEC BS EN 62366:2007 –** Medical Devices – Application of Usability Engineering to Medical Devices.
- **BS EN ISO 14971:2012** – Medical Devices – Application of Risk Management to Medical Devices.
- **BS 7000 Series** including **7000-6:2005** – Design Management Systems Managing Inclusive Design.

This list provided here is not exhaustive of all the available guidance open to designers but rather presents the most relevant and important guidance documents and standards at the time of writing this thesis. It is worth noting that the regulations and standards for medical devices are ever changing with the technological advancements of the field and therefore one should always refer to the latest publications sourced through the MHRA, FDA, BSI and ISO.

Evidently from the list above there is a wealth of available guidance documents for designers and manufacturers alike to refer to, follow and/or implement. Largely these documents are standards, which by their nature would imply that compliance is voluntary and not mandatory. As previously discussed however in Section 2.4.3, IEC BS EN 62366:2007 is harmonised under the MDD meaning manufacturers have a moral obligation to demonstrate how they have considered usability issues in the design of medical devices. It is therefore of interest to this research to determine what designers' perspectives of such guidance documents are and if indeed the principles outlined are followed and valued.

Many of the studies identified in this literature review have suggested or alluded to designers requiring support in the design and development process of both home and professional use medical devices (Buckle *et al*, 2006; Cifter, 2011; Gupta, 2007; Martin, 2008; Money *et al*, 2011; Vincent & Blandford, 2011). This research aims to establish how the guidance available to designers is actually received and whether the principles are valued and adopted. To explore this topic further, one must first consider that there is a wide range of design guidance and information available to designers from domains outside of design standards relevant to home use medical devices. The outputs of the work conducted by Gupta and Cifter addressed the need

to support designers in the design process of home use medical devices (Gupta, 2007; Cifter, 2011).

**Information Resource for Designers (Cifter, 2011).**

In conclusion to his thesis, Cifter developed an informative website or 'reference point' for designers to refer too when designing home use medical devices (Cifter, 2011). The website aimed to provide one point of reference that designers could visit to locate the necessary information concerned with the design of home use medical devices. The site includes tabs with links to the following: Design Considerations, Regulations, Documents and useful links for extra reading. A screenshot of the website is provided below in Figure 2.10.

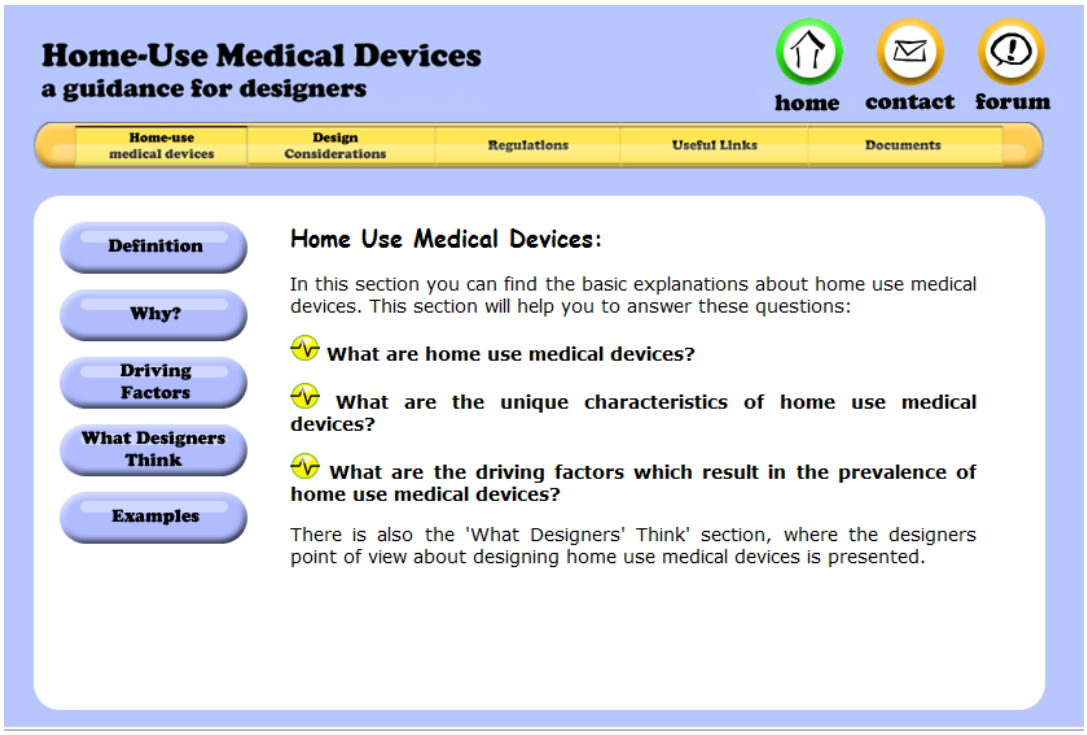



**Figure 2.10: Website Guidance for Designers developed by Cifter (Cifter, 2011).**

The site is undoubtedly a valuable resource in that designers or researchers can instantly access a large amount of information related to the design of home use medical devices. Such information could be particularly useful to a start-up company for example where contextual information may be missing due to a lack of experience in the field.

One must consider however that such a resource (i.e. an online site for information) is only truly useful to industry if practitioners are aware of them in the first instance

and secondly whether the information is legible and interpretable by the target audience. Furthermore, there is a need to explore with the intended audience whether the motivations to engage with such guidance exists.

On reviewing the website it would be reasonable to assume that designers or researchers, for whom the site is intended, would be able to interpret and understand the information presented. The information and language is clear and simple and the progression through the website follows a logical and systematic format in line with the design process of a home use medical device. What cannot be inferred from the viewing the site however is whether practitioners have an awareness of this resource and if indeed they value the content and information it displays. At the time of this review no evidence was found for the validation of the website and how it was perceived by the target audience. Cifter did however conduct his own validation of the website which covered the content and presentation of information (Cifter, 2011). Twelve interviews were conducted with designers, of whom 3 had experience in home use medical device design.

According to Cifter, the general feedback about the website was positive however a number of differences were raised in the perceived value of the information depending on the experience of the viewer (Cifter, 2011). Designers with experience in home use medical device design found that the information was too introductory however in contrast those with little to no experience preferred this format (Cifter, 2011).

The information was also perceived to be very academically orientated and did not include enough content on actual design practice. This can be a drawback and perception of much of the academic guidance across a range of fields. There seems to be a common perception from industry that academic work is naturally theoretical and as such lacks practical value in the real world setting. As such increasing research is conducted to address the gap between research and practice (e.g. Knowledge Transfer Partnerships or KTPs).

Cifter did propose to continue future work on the validation of the website with a redesign based on the comments provided by the designers at interview. Evidence of this work however was not found at the time of this literature review.

An earlier but equally significant body of research into home use medical devices is that of Gupta (Gupta, 2007).

As an output to his thesis, Gupta developed a Spidergram tool to support the design of home use medical devices (Gupta, 2007). The tool made use of Gough's design tool for packaging and aimed to address the challenges and considerations identified throughout his thesis (Gough, 2007). Gupta's tool included considerations for: The Lifecycle of a Home Use Medical Device; Design and Manufacture, Point of Provision and First Encounter, First Use and Familiarisation, On-going Use and Disposal, Business and Technology. The Spidergram included an assistive wheel to enable users to plot the scores for each issue accurately.

In total 58 key issues were clustered into 5 groups (Gupta, 2007). The tool was developed to have a dual purpose for designing home use medical devices. Firstly, designers could use the tool as a reference for the considerations and issues that need to be addressed when designing a home use medical device. In this respect the tool shares similarities with Cifter's Website for designers, in the sense that both supportive resources have been developed to inform or educate the design community. Secondly, the tool was developed so that it could be used to assess the performance against each of the issues to see how well they have been met.

On completion, Gupta validated the tool with 15 researchers with experience in product and medical product design. The researchers were asked to use the Spidergram using a product, preferably medically related, to identify any issues and challenges with its use. The tool was reported to be well received by the research community with participants finding it useful (Gupta, 2007). However, the tool has not been validated with actual real end users or the target population. Gupta recommended that this work should be conducted as part of some future work yet such work has not been found as part of this review.

Both the work of Cifter and Gupta represent the two main theses in the field of home use medical devices. As an output to both theses, it was concluded that supportive tools or resources (Informative Website and Spidergram tool) were necessary to aid the design and development of home use medical devices. Therefore, one could interpret that both bodies of work imply that designing home use medical devices is indeed complex by necessity and that supporting the designer in his or her role is the

best or most appropriate method to ensure the design of safer, usable and understandable home use medical devices. Without an understanding or exploration into the evaluation of these information resources from designers themselves it is very difficult to determine their practical value to industry.

In addition to this research, another theoretical framework specific to medical device design and development was found.

**Theoretical Framework for Involving Users in the Medical Device Technology Development Process (Shah, Robinson and Alshawi, 2009).**

A study conducted by Shah *et al* aimed to develop a framework for designers that would support the involvement of users within the 'Medical Device Technology Development Process' (MDTDP) (Shah, Robinson & Alshawi, 2009). The framework was developed in attempt to help manufacturers in planning and decision-making about user involvement at different stages in the design process or lifecycle. Similar to the study described in Section 2.5 conducted by Martin *et al*, the framework developed by Shah, Robinson & Alshawi posits a range of 'User Involvement Methods' that could be applied to what the authors refer to as the MDTDP (Shah, Robinson and Alshawi, 2009). By the authors own admission this process is theoretical and therefore applying such a process in practice will be influenced by external factors such time, cost and resources available for example.

Users of medical devices, particularly in the home environment, are not homogeneous which Shah *et al* suggest is often implicitly considered to be the case (Shah, Robinson & Alshawi, 2009). The users of medical devices are incredible diverse in nature including many different types and groups of users such as; healthcare professionals, carers, and end users to name but a few (Shah, Robinson and Alshawi, 2009). Satisfying the needs of users in the home environment is compounded by the fact that the end user can be one or more of a long list of potential users with different abilities and expectations. The consideration of these users within the design and development process is essential to develop an end product that satisfies a genuine need. This should include a consideration of the potential secondary and tertiary users for whom the device is not directly intended however are likely to come into contact with the device.

Shah *et al* posited that users have an expectation when devices are supplied or provided to them that the technology will fulfil their personal needs and requirements (Shah, Robinson and Alshawi, 2009). Failing to meet the user's needs has been shown to lead to device abandonment and subsequently poor adherence (Batavia & Hammer, 1990). This is particularly true for a lot of assistive technology and devices, which are increasingly used by patients in the home environment. Once users have become frustrated with a device due to the failure in meeting the patient's needs and requirements they often discard or abandon the technology. This is even the case after the user has attempted to make their own personal modifications to the device in attempt to satisfy their own needs (Batavia & Hammer, 1990).

Perhaps one reason for this, as suggested by Batavia and Hammer is that users can fail to recognise and acknowledge their own needs (Batavia & Hammer, 1990). The authors argue that through methods of trialling equipment users are then able to identify the device most suited to them. Similarly, when asking users their opinions on products and attempting to gain insight into their needs they can often find it difficult to articulate exactly what it is they require (Martin *et al*, 2008). Despite this, manufacturers should not be deterred from including users within the development process. Although user involvement may not always provide technological knowledge and understanding about complex products, it should be conducted to reveal insight into the mind of the user (Shah, Robinson and Alshawi, 2009). User research will give designers and engineers an understanding of the user's requirements and the context of use that is necessary and vital to improve device design and patient adherence.

There is a reported lack of work that has looked at patients as the end users and their involvement within the design process. The reasons for this are diverse and many, based on company size and the devices in question. Shah *et al* believe the lack of user involvement is attributable to the personal characteristics of users and the requirement to prepare, support and train users to enable their involvement initially (Shah, Robinson and Alshawi, 2009).

One must consider however that an inherent limitation of all guidance to some extent is that they are exactly that. By virtue of their nature they provide a guide that may or may not be followed in practice. Enforcing standards can only be achieved by

legislative powers through regulations and mandatory requirements. In addition it should be stated that many guidelines are subjective and therefore open to interpretation and experience would suggest that users of guidelines would typically take the process of least resistance.

Gould and Lewis posited that guidelines for design are merely general constraints and cannot deal with the choices that need to be made which are highly dependent on context (Gould, J.D. & Lewis, C, 1987).

Sharples *et al* described the difficulty in changing a manufacturer's perspective on design due an apparent lack of demonstrable 'evidence' of the benefits that can be gained through adopting an alternative, more user centred approach:

*"If we wish to persuade a device manufacturer to consider a change or enhancement to a design for example, it is useful, but often challenging, to obtain specific evidence that demonstrates the value of modifying the design, and predicting the impact of that design change on consequences of use."(Sharples et al, 2012).*

Alam and Kristensson *et al* posit that despite the existing wealth of literature on the benefits and descriptions of user involvement in medical device development, there remains a lack of research concerning the actual process of user involvement itself (Alam, 2002; Kristensson *et al*, 2003).

In the context of home use medical devices it is very apparent that design and the approaches by manufacturers are by necessity very commercially driven. When considering an output for this thesis, the research must consider and address the challenge of bridging the gap between research and practice. Addressing initially designers perspectives of guidance will determine whether developing further support for the design community is the most appropriate method to deliver 'user centred' principles for home use medical devices. Previous research on designers' perspectives towards guidance for home use medical devices was found in this review.

*"Although some of them pointed out that usability guides may be useful, most of them claimed that they would use their experience most of the time to design their devices to be user-friendly and safe." (Gupta, 2007).*

This quote suggests a potential scepticism or lack of appreciation for the value of the available usability guidance, as designers would prefer to ignore such information and use previous experience to guide their design process instead. If this is the case then it raises the question of the value in developing more guidance in the first instance that may simply be ignored. Gupta also found that:

*"The majority of designers who were involved in this study opined that they never consulted or had to consult a usability guidance to design their products for ease-of-use." (Gupta, 2007).*

This quote indicates the perceived value of usability guidance to designers. If one considers, that designers in Gupta's study preferred to use their own experience to design and develop home use medical devices; and that the majority of those designers opined that they never consulted usability guidance at all; the value of guidance for industry comes into question. This raises a serious question into the value and awareness of the design community for usability guidance for home use medical devices. It is the aim of this research to explore these issues further and by answering the three research questions of this thesis it is hoped that significant contributions to knowledge can be made in this area.

Cifter also found that designers were less likely to use available guidance resources such as information found in books, journals and industry magazines (Cifter, 2011). Rather, they would prefer to use customised information developed through interviews and observation, similar to that described by (Martin *et al*, 2008). In his research, Cifter reports that designers of home use medical devices preferred to actively take part in their data collection rather than refer to guidance (Cifter, 2011).

To summarise this section, a range of guidance documents, models and frameworks to support the design of home and professional use medical devices have been identified. Previous studies have suggested that designers fail to see the value in the

current guidance and would prefer to use their own experience and practices when developing home use medical devices. As the aim of this research is to identify how the adoption of usability principles can be incentivised for industry it is necessary to understand the application of 'user centred' principles, as outlined within the usability guidance, and how they apply to home use medical devices

## 2.9 User Centred Design

***"When the point of contact between the product and the people becomes a point of friction, then the industrial designer has failed. On the other hand if people are made safer, more comfortable, more eager to purchase, more efficient – or just plain happier – by contact with the product, the designer has succeeded."***

**(Henry Dreyfuss, 1955)**

The impact of Henry Dreyfuss on design in the 1960's was instrumental in the design for mass manufacture period. In his book '*Designing for People'*, Dreyfuss posited that the study of anthropometrics and scaling of human body measurements are integral to the role of the designer (Dreyfuss, 1955). This work provided a foundation in decision making for mass production. In many cases this movement meant significant economic and social gains for manufacturers and business holistically. The shift towards volume production at affordable prices resulted in considerable market growth and sparked the beginning of consumerism (Coleman, 2007). However, the change also meant that increasingly people who did not 'conform' in terms of physical, cognitive or mental capacity were beginning to be excluded by design.

Typically elderly and vulnerable users fell outside of the 'calculated norms' of mass production and consequently relied upon adaptive and assistive technology to use mainstream products (Coleman, 2007). Invariably, assistive technology, although well intended, lacked aesthetical value and too often shared similarities in design to that of hospital equipment (Papanek, 1984). The result of which, meant early abandonment of technology and an associated stigma towards assistive technology that in many cases is still evident today (Batavia & Hammer, 1990).

The area in which so many of these designs were deficient was the consideration of user experience and requirements within the design process. Through failing to consider the likely users of innovations and products, their needs and capabilities were overlooked. The market called for changes in the approach to design and the inclusive design movement was born. The shift in paradigm raised a widespread recognition that the user and their requirements 'should be considered and incorporated at every stage of the design process' (Coleman, 2007). The movement was compounded by the rapidly changing demographics of society that called for a change in industry's approach to design.

The impact of this change is the realisation that there will be a significant rise in users that experience age related capability loss. The reduction in capabilities such as eyesight, hearing, mobility, dexterity and cognition will come to us all at some stage in our lifetimes and it is down to the designer to accommodate for the changes in user needs (Coleman, 2007). In essence a 'user centred' approach to design is recognised as the response to changes in society and demands from the marketplace that positions the user at the core of the design process. Victor Papanek called for a social responsibility of designers in their approach to design at a time when the market place was dominated by consumerism and mass manufacture (Papanek, 1985). For the medical device industry there has been a delay in the application of truly 'user centred' designs made available for patients and professionals alike. It is the aim of this research to address this research-practice gap. This thesis sets out to understand if a 'user centred' approach to home use medical device design is realistically achievable in this technology driven and highly regulated market.

### 2.9.1 Towards User Centred Design for Medical Devices

Recent developments within research are starting to address the possible connection of 'user centred design' principles for medical device design (Vincent & Blandford, 2011). Vincent and Blandford explored how 'user centred' perspectives are built into the development process and the external forces that effect their implementation. In their study, Vincent and Blandford identified that manufacturers of medical devices were all aware of the need for 'user centred design' and 'human factors' engineering practices however they experienced difficulty in implementing them (Vincent & Blandford, 2011).

This is supported by existing research found in this review that has alluded to the challenges of delivering ‘user centred’ principles for medical device design (Gupta, 2007; Cifter, 2011; Martin *et al*, 2008; Money *et al*, 2011). In light of the increasing complexity and recognised challenges there have been significant leaps in the guidance made available to designers. Section 2.8 of this review revealed some of the specific usability guidance currently available (e.g. ANSI/AAMI HE75:2009; IEC 62366:2007). The natural progression to this work calls for the exploration of what ‘user centred design’ of medical devices and more specifically home use medical devices actually looks like in practice.

There have been previous attempts to bridge these difficulties for practitioners developing medical devices (MATCH, 2010). The Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) project in the UK has made significant steps in attempt to deliver approaches for ‘user centred design’ that provide practical value to medical device developers. The MATCH project is a research collaboration between four UK Universities: Birmingham, Brunel, Nottingham and Ulster. Founded in 2003, the Engineering and Physical Sciences Research Council (EPSRC) funded project is focused on the delivery of methods and tools that assess the value of medical devices from concept to final product (MATCH, 2003). The aim of MATCH is to deliver improved decision making for companies to bring better products to market more quickly and less expensively and enable healthcare providers to adopt products more rapidly and with confidence (MATCH, 2003).

The process shown in Figure 2.11 was developed as part of a series of design publications for the National Patient Safety Agency (NPSA) and is based on a MATCH guide to meeting user requirements in medical device development (MATCH, 2010). The process itself has been developed as part of a ‘user centred design’ process for medical devices and was the only specific example found of such a process in the literature.

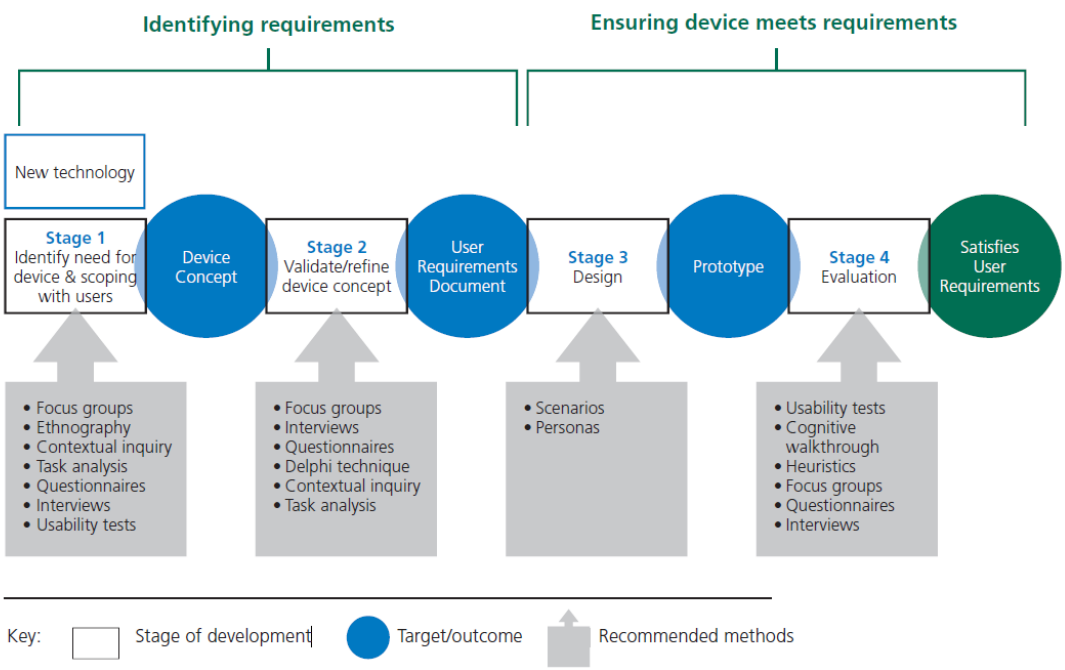



**Figure 2.11: User Centred Design Process for Medical Devices (MATCH, 2010).**

The process suggests potential stages and methods for involving users in a typical development pathway. The process is divided into two main elements, initially *'Identifying Requirements'* followed by *'Ensuring Device Meets Requirements'* (MATCH, 2010). In doing so this process refers to the principles previously described in Section 2.7 *'Design for Verification'* and *'Design for Validation'*.

The MATCH process suggests a range of methods considered suitable for the particular stage in the design process. The process evidently places an emphasis on the need for early or 'front end' user focused research, which is supported by the number and range of methods under the *'Identifying Requirements'* phase. Largely the methods suggested for the early phase of the design process are exploratory or used to define the situation or problem. In the *'Ensuring Device Meets Requirements'* the methods refer to more evaluative or validating approaches to ensure the output meets its intention. According to the NPSA guide, the entry point into this process will vary depending on the product being developed and whether the design process is an upgrading of an existing model (MATCH, 2010). Consequently this process is provided as guide for practitioners to assess their own process.

One limitation of this particular process however, is that it is yet to be validated in practice to determine whether such an approach actually leads to a better or more usable product for device users. It is not understood whether such an approach can be realistically followed and adopted by practitioners in the commercial setting.
To summarise this section it is apparent that previous attempts have been made to explore the role and benefits of a 'user centred' approach for medical devices. Much less work however has addressed the possibility of applying such an approach in practice towards home use medical devices. There has been little published research on the practicalities of delivering a 'user centred' approached to home use medical device design and designers perspectives towards such research.

## 2.10 Researcher Identity Memo

Due to the nature of research and one's personal beliefs, interests and experiences it is evident that any form of studious inquiry will bring elements of researcher bias. Robson posited that researchers have a tendency to ignore what they bring to the research process in the form of bias' and previous experiences (Robson, 2011). Thus one must challenge their own 'experiential knowledge' brought to a situation through their assumptions and values (Maxwell, 2005, Robson, 2011). The views of Hilary Putnam argue that there cannot be a single objective view and that every view is articulated through someone's perspective and is thus shaped by the eyes of the observer. (Putnam, 1990).

The values and bias that are traditionally brought to research based on the researchers own background should be removed from the study as opposed to becoming an influential part of it (Maxwell, 2005, Robson, 2011). To compensate for the researcher's bias in this field, a researcher identity memo has been developed as part of this thesis. The researcher identity memo forms part of the conceptual framework of the researchers mind set prior to embarking on this study. A copy of the identity memo can be found in Appendix 2 of this thesis.

## 2.11 Summary

There review has indicated a current gap in the literature relating to how the developed support for companies operating in the home use medical device market is

received and implemented. Currently, the lack of evidence suggests that it is not fully understood how industry are designing to meet the needs of their end users. There is insufficient evaluative research into the impact of supportive guidance and information developed to benefit designers in the design and development of home use medical devices. There is a need to understand how industry design and develop medical devices for home use and the reasons behind their chosen approach. The research questions presented in Chapter One aim to address these gaps in current knowledge and call for more research in the field.

The following chapter will now present the research methodology for the thesis. The chapter will discuss the approaches used to investigate the research aim, questions and objectives.

# Chapter 3
# Research Methodology

***"While the success of evolutionary artefacts and craft traditions suggests that many human beings are able to do a competent job of design, design failures are nevertheless common. The most common reasons include lack of method and absence of systematic and comprehensive understanding."***

**(Friedman, 2003)**

Chapter One introduced the motivations, context and research questions of this thesis. The previous chapter presented a review of existing research in the field of home use medical device design. In light of this knowledge, the following chapter will now present the relevant research methodologies to achieve the research objectives and answer the research questions. The chapter covers the reasoning behind each chosen research method and the design of the studies within the thesis.

## 3.1 Introduction

Research has previously been referred to as the systematic investigation of a topic to further knowledge and understanding. By definition the term research can have a range of meanings. In Friedman's paper, the meaning of the noun 'research' is defined as follows: '1: Careful or diligent search, 2: Studious inquiry or examination; especially: investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws, 3: The collecting of information about a particular subject.' (Friedman, 2003).

In light of this we find that research in the present day takes many forms. Research is conducted for a wide range of reasons beyond the traditional perceptions of research as merely scientific investigation within a laboratory environment.

One could be argue that all research, to an extent, is exploratory in nature as it attempts to answer the questions of the researcher(s). In some scenarios for example

research may be undertaken simply to further the understanding or explanations of a situation or phenomenon.

Robson suggests that design within research involves the conversion of research questions into projects (Robson, 2011). It is vital to consider the design and pathway of research from the outset and this next section of the thesis, as outlined by Hakim, deals with the 'purposes, intentions and plans within the practical constraints' of the researcher's study requirements (e.g. location, time and money) (Hakim, 2000).

## 3.2 Research Design

Principally, the term Research Design refers to the issues and considerations that a specific body of research should and will address. Therefore the role of design within research is critical if the ultimate goals, research objectives and questions are to be successfully met.

De Vaus states that "the function of a research design is to ensure that the evidence obtained enables us to answer the initial question as unambiguously as possible" (De Vaus, 2001). Thus, research design takes the form of a logical structure or progression towards answering or developing a solution to an inquiry (De Vaus, 2001).

According to Friedman, the most common reasons for design failure include a lack of method and absence of systematic and comprehensive understanding (Friedman, 2003). Here, Friedman refers to design failure within the process of design itself, however the quote arguably holds equally true for a research project. Without method there is no logical pathway towards progression and consequently the body of research will lack systematic or methodical rigour.

In attempt to develop a structure to this body of research a framework was considered and is described in the following section.

### 3.2.1 Research Design Framework

Robson believes it can be beneficial to construct a framework for research design (Robson, 2011). Robson posits a framework of the fundamental components required to tackle any research problem and the relationships between each component (Robson, 2011). The model shown below in Figure 3.1 provides an adaptation of

Robson's *Framework for research design*, reflecting the perspectives of this research project. The framework is divided into individual components.

The reasons for constructing the research design framework are threefold. Firstly, defining the components and their relationship to the research questions helps define a foundation from which the research can build. Secondly, the framework provides an aid to the researcher when selecting appropriate research methodologies and data analysis techniques. Finally, the framework was felt to aid the reader in his or her comprehension of the research design process undertaken in the context of this thesis. Each of the components will now be described individually to demonstrate how they apply to the research questions.

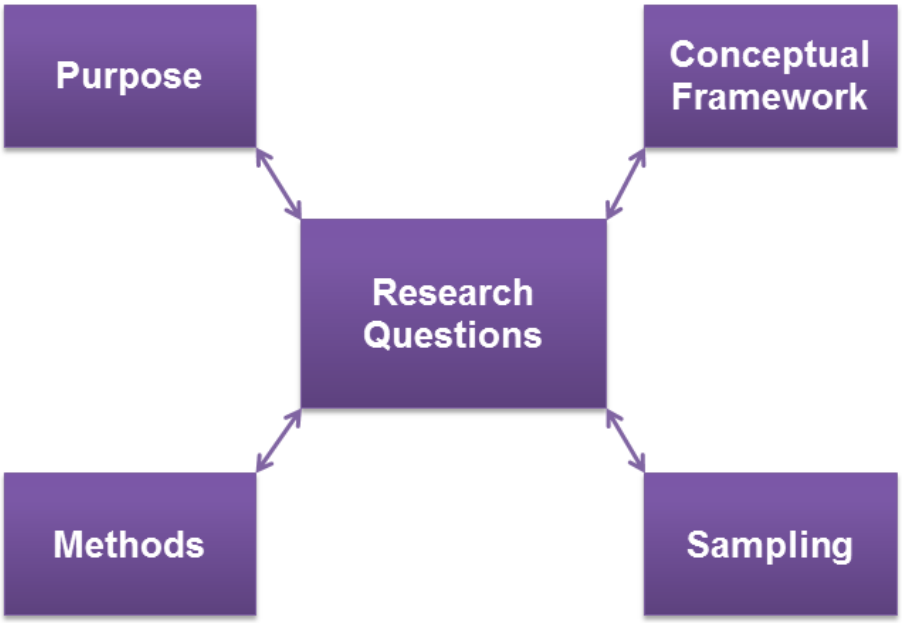



**Figure 3.1: Framework for Research Design (Robson, 2011).**

**Purpose**

The purpose of this research, as outlined in Chapter One, is to fulfil the research aim. To remind the reader of this aim it is presented here for clarity:

*To incentivise the adoption of usability principles and the practice of user involvement in home use medical device design in the United Kingdom.*

Through a systematic and methodical approach (See section 3.14 for Final Design) the research will lead to the identification of gaps in industry's approach and

potential incentives for designers to aid the development of future home use medical devices.

**Conceptual Framework**

A conceptual framework in research design refers to the theory about the current 'state of play' in the field and the interrelations between such aspects (Robson, 2011). While it may be disputed that this theory may be expressed with the bias and background of the researcher (See 'Researcher Identity Memo' in Chapter Two) the framework allows those experiences to be challenged in the approach.

It goes without saying that the conceptual understanding of the researcher has direct influence on the construction of the research questions, thus the research design framework uses directional arrows to demonstrate the processes of thought and planning in the research process. Once the purpose (Research Aim) and Conceptual Framework (Research Identity Memo) have been identified it is possible to specify realistic and quantifiable research questions that will then feed into the chosen methods and strategies to be used when sampling.

It should be noted that the framework for this research is flexible due to the nature of the chosen approach. As theory and findings emerge from the studies there will be a requirement to reflect on the aspects that make up the research framework. This may result in the refining of research questions as a result of issues arising that could not be foreseen. There may be reasoning to re-evaluate the original purpose of the research in light of new information or leads that would require answers to rather different research questions.

**Research Questions**

De Vaus states that research questions in social research are comprised of two fundamental types of question: Descriptive and Explanatory (De Vaus, 2001). However, as Saunders *et al* point out there is potential for a third type of research question, which is 'Exploratory' in nature. Saunders *et al* posit that exploratory research questions and studies are particularly useful when clarifying the understanding of a problem (Saunders *et al*, 2009). This clarification can often prove or disprove the need to research the original intended topic (Saunders *et al*, 2009)

With this in mind, the types of questions specific to this research can either be defined as 'Exploratory', 'Descriptive', 'Explanatory' or a combination of 'Descriptive and Explanatory' (Saunders *et al*, 2009). Table 3.1 presents the research questions for this research alongside the type of question they represent. With exploratory questions previously described, the descriptive and explanatory research questions will now be introduced and how they relate to one another to achieve the research aim.

**Table 3.1: Types of Research Questions.**

| Research Question | Question Type |
|---|---|
| Research Question One: How do designers consider and involve users in home use medical device development? | **Descriptive** |
| Research Question Two: What are the challenges for industry to involving users in the design process of home use medical devices? | **Explanatory** |
| Research Question Three: How can usability for home use medical devices be incentivised for industry? | **Explanatory and Descriptive** |

**Descriptive Research Questions**

Descriptive research deals with the 'real world' issues and problems of a topic or area. De Vaus interprets descriptive research in the sense of posing the question 'What is going on?' and therefore refers to the exploration of a research area in attempt to define the current state of play (De Vaus, 2001).

Descriptive research has come under some scrutiny, as it is perceived by some as mere 'fact finding'. Critics argue that descriptive research can lack focus and that it fails to add new information to a field. Others argue that descriptive research is essential in developing a greater understanding and knowledge of any field (De Vaus, 2011). With reference to the medical device arena this is fundamental as the topic is so vast in its complexity and the networks from which innovations, new

research, funding and regulations arise. Providing clarity to this field will provide real benefit to industry and an understanding of the relationships between end users and designers. It is worth noting that these challenges are not only unique to home use and professional use medical device design and subsequently could have applications in other fields such as consumer products for example.

Good descriptive research should provoke the 'why' questions that form explanatory research (De Vaus, 2001). As such, descriptive research is fundamental and has added immeasurably to our knowledge of the shape and nature of our society today (De Vaus, 2001).

**Explanatory Research Questions**

The explanatory questions help define the 'Why' questions of research (De Vaus, 2001). These questions help develop explanations for why a particular theory or phenomenon is occurring. In the context of this research these questions deal with reasons and theories behind industry's current approach to design.

Table 3.1 presents the different types of research questions for this research. Research question one is descriptive in nature as it aims to identify facts about current design practice towards user involvement in home use medical device design. Prior to understanding and exploring the explanatory research, it is necessary to clarify the current situation in the field. Only then can theories be built from the research, which will lead to the development of future studies.

Research question two is explanatory in nature and thus requires a change in approach to come to a solution. Preliminary answers to explanatory research questions may be identified through conducting descriptive research. That is, in identifying current practice towards home use medical device users, information on the challenges towards their involvement may be revealed. Understanding the challenges towards adopting usability principles and involving users in the design process of a home use medical devices will reveal suitable incentives to change current practice.

Research question three is both explanatory and descriptive in nature. This question combines the approaches and knowledge of research questions one and two to

develop a deliverable or incentive to designers and developers of home use medical devices to adopt the principles and practices of usability.

**Methods**

Deciding upon a method is generally regarded as the critical element to achieve any target or goal. From a research perspective, the chosen methodology will define whether the project will end in success or failure. Applying method to design research however is particularly difficult. Methodology as a concept in design research is relatively new to the field when compared with the more established fields such as the social sciences and psychology. Furthermore, it is often argued that design or designing in its practical sense is by necessity an inherently creative process and as such the application of method and rigour is received with some scepticism by some researchers and designers. Despite this, there is now a growing body of literature addressing the issues of applying research methodologies specific to conducting research in the design field (Blessing & Chakrabarti, 2009).

The following section describes the theoretical perspective of the researcher and the approaches taken for this research. Prior to the selection of any methods or strategies it was deemed necessary to explore the topics of theory, epistemology, and research philosophy to draw upon existing research and identify the most suitable method for the context of this research.

## 3.3 Research Philosophy and Approach

Saunders *et al* define research philosophy as the development of knowledge and the nature of that knowledge (Saunders *et al*, 2009). According to Saunders *et al*, the research philosophy that one adopts in researching a subject will contain 'important assumptions' based on the perspective of the researcher and the way in which one views the world (Saunders *et al*, 2009). Without due consideration these views or bias' may well be overlooked. The researcher identity memo described in Chapter Two of this thesis provides one of the attempts to deal with this potential bias.

Perhaps what is most crucial with regards to research philosophy, as argued by Johnson and Clark, is not whether the research concerned is 'philosophically informed', but rather how well the researcher is able to reflect upon the philosophical

choices made and the ability to defend them with respect to the numerous alternatives that could have been adopted (Johnson & Clark, 2006).

The relationship between research philosophies and approaches is clearly presented in 'The Research Onion' developed by Saunders *et al* (2009), shown below in Figure 3.2. This image was sourced online at http://noormanmasrek.blogspot.co.uk, however can be found in Chapter 5, page 138 of (Saunders *et al*, 2009).

The model is comprised of different 'layers' that essentially refer to the different choices that the researcher must consider and make to solve the research problem. The following chapter addresses much of these topics presented here and therefore the model is provided for clarity to show the associated relationship between what Saunders *et al* define as: Philosophies, Approaches, Strategies, Choices, Time Horizons, Techniques and Procedures (Saunders *et al*, 2009).

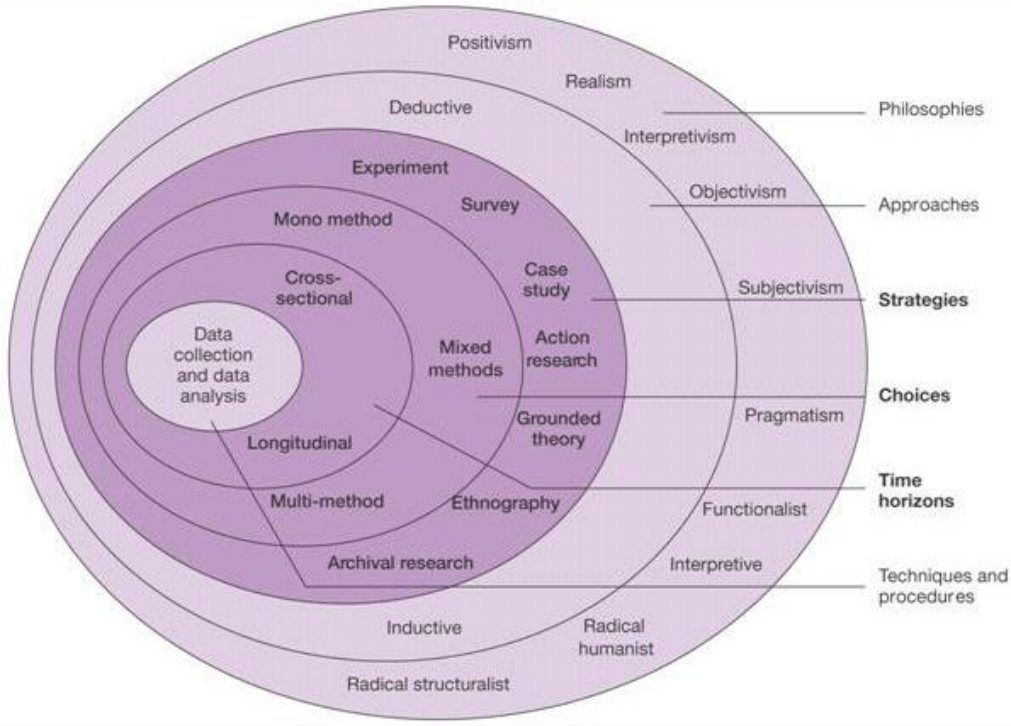



**Figure 3.2: The Research 'Onion' (Saunders *et al*, 2009).**

Saunders *et al* state that prior to any consideration for data collection and analysis techniques, something that Robson described is often the first consideration in a

research project, it is necessary to address the outer layers of the 'onion' first (Robson, 2011; Saunders *et al*, 2009). This is primarily because the philosophy of the researcher and the associated assumptions will 'underpin' the research strategy and selected methods (Saunders *et al*, 2009).

To have an understanding of research philosophy it is necessary to examine the topics of Epistemology and Ontology and how they relate to one another. The following section addresses these topics and explores in more detail the approaches for this research.

## 3.4 Epistemology and Ontology

One aim that arguably all forms of research share is the acquisition of new knowledge, to further the current level of human understanding in a particular domain or field. As previously described the aspect that makes each study unique is the philosophical perspective of the researcher. The researcher's definition of knowledge dictates not only the application of the knowledge acquired but also the way in which others perceive that knowledge.

Epistemology refers to the philosophical understanding of knowledge and is therefore determined by the researcher. Gray describes epistemology as the philosophical background for deciding what kinds of knowledge are legitimate and adequate (Gray, 2009).

As shown in Figure 3.3, Crotty believes there is a relationship between epistemology and methods chosen by researchers (Crotty, 1998).

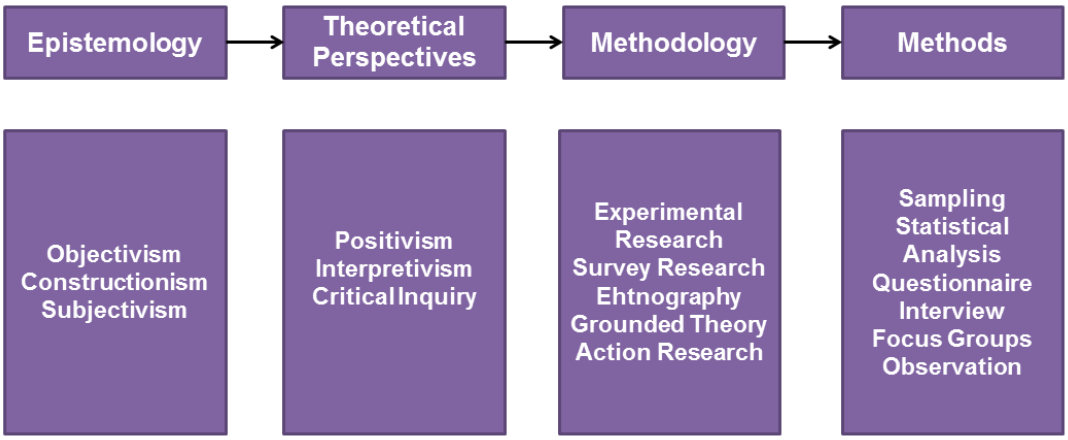



**Figure 3.3: The Relationship between Epistemology, Theoretical Perspectives, Methodology and Methods (Adapted from Crotty, 1998).**

Ontology refers to the study of being, the very nature of existence (Gray, 2009). Saunders *et al* describe ontology as being concerned with the nature of reality (Saunders *et al*, 2009). Therefore, ontological issues raise questions of the assumptions made by the researcher about the way in which the world operates and the commitments held to particular views (Saunders *et al*, 2009).

In contrast, epistemology tries to understand what it means to know (Gray, 2009). Epistemology is concerned with the understanding and interpretation of knowledge specifically. Using Figure 3.3 as an example would suggest that at the very least there are three epistemological stances, however Saunders *et al* in the research 'Onion' refer to up to 10 different philosophies (Saunders *et al*, 2009). For the context of this research it was not considered necessary to explore every research philosophy available. Rather, it was deemed more suitable to address the commonly recognised stances and determine the nature of the researchers own viewpoint and how it relates to the intended research strategy.

An objectivist epistemology holds that reality exists independently of consciousness thus there is an object reality (Gray, 2009). Therefore, research of this stance is about discovering this objective truth and could perhaps more commonly be associated with, but not limited to, quantitative research. The theoretical perspective most linked or closely related to objectivism is positivism.

In contrast to this epistemological stance, constructionism rejects this view of human knowledge. Rather, truth and meaning do not exist in an external world but are created by the subjects interactions with the world (Gray, 2009). Hence in constructionism, meaning is not discovered but constructed by the individual even where research may be concerned with the same phenomenon. This form of epistemology is most closely linked to Interpretivism (Gray, 2009).

It is believed that the researcher's theoretical perspective sits somewhere between these two concepts of knowledge and theory: Positivism and Interpretivism. The following section will now explore the two philosophies more specifically to provide more clarity and to ascertain the implications of theoretical perspectives on research designs.

### 3.4.1 Positivist Paradigm

Positivism was regarded as the dominant form of epistemology in social science between the 1930's and 60's. The core argument, as defined by Gray, being that the social world exists external to the researcher and that the aspects or properties can be measured directly through observation (Gray, 2009).

Typically, science does not begin from observation, but from theory, to make observations intelligible (Gray, 2009). It is inevitably necessary to grasp an understanding of the 'research arena', which may include underlying theory that drives the need for investigation or observation. A concept that Williams and May refer to as observations that are 'theory-laden' (Williams & May, 1996).

One argument against the positivist philosophy is the belief that no theory can be proved through observations alone. Popper suggests that it only takes one instance or case that refutes that theory to demonstrate that the theory is false and as such believes theories in this sense can only be proved to be false (Popper, 1968).

A positivist research strategy is likely to use an existing theory and will therefore be hypothesis based. The existing theory will then be tested, as part of that research to confirm or refute the hypothesis hence this type of research is commonly known as 'Theory Testing'.

The topic of home use medical device design for research is very much in its early stages. The use of medical devices in the home environment has only seen a particular rise in the last 15 years (National Research Council, 2011). Therefore, it is understandable that there is a lack of existing theories in the literature associated with design practice for their development.

Chapter Two of this thesis described the works of Gupta and Cifter and how both research projects concluded, at least in laymen's terms, that designers need support in the development of home use medical device design. It is widely understood that the design and development of home use medical devices is a challenging process (Gutpa, 2007; Cifter, 2011; Martin *et al*, 2008). Thus, it could be argued that the existing knowledge of the field and current understanding would suggest that supporting the designer in this process is the 'best' approach to delivering improved

home use medical devices for the end user. These ideas and knowledge represent a form of theory for developing ‘user centred’ home use medical devices.

With this is mind, one of the objectives of this research is to test this theory or perhaps more accurately research recommendation, in practice. A fundamental component of this research is to establish the extent to which supportive guidance and information relating to usability is followed and adopted by practicing designers and developers of home use medical devices. By applying the methodology described throughout this chapter, this research will ascertain whether supporting the designer in the process of home use medical device design is the best approach to delivering improved devices for end users.

### 3.4.2 Interpretivist Paradigm

An Interpretivist approach asserts that the natural reality including the laws of science and the social reality are intrinsically different and therefore require different kinds of method (Gray, 2009). Gray explains that while the natural sciences look for any consistencies in the data to deduce laws (nomothetic), the social sciences often deal with the actions and behaviours of individuals (ideographic) hence the requirements for alternate methods.

An interpretivist would argue that a positivist’s view of the world fails to allow for the complexity of the social reality itself (Saunders *et al*, 2009). They add that the origins of interpretivism come from two intellectual traditions, namely: Phenomenology and Symbolic Interactionism (Saunders *et al*, 2009). Whereby Phenomenology refers to the way in which humans make sense of the world around them and; Symbolic Interactionism places humans in a ‘continual process of interpreting the social world around us’ (Saunders *et al*, 2009). These two paradigms are compared in Table 3.2.

**Table 3.2: Positivist Paradigm Vs. Interpretivist Paradigm (Adapted from Easterby-Smith *et al*, 2002).**

| | Positivist Paradigm | Interpretivist Paradigm |
|---|---|---|
| **Basic Beliefs:** | The world is external and objective.<br>The observer is independent.<br>Science is value-free. | The world is socially constructed and subjective.<br>The observer is a party to what is being observed.<br>Science is driven by human interests. |
| **The Researcher Should:** | Focus on facts<br>Locate causality between variables.<br>Formulate and test hypothesises (deductive approach) | Focus on meanings<br>Try to understand what is happening<br>Construct theories and models from the data (inductive approach). |
| **Methods Include:** | Operationalising concepts so that they can be measured.<br>Using large samples from which to generalise to the population.<br>Quantitative methods. | Using multiple methods to establish different views of a phenomenon<br>Using small samples researched in depth or over time.<br>Qualitative methods. |

While the researcher can relate to both sets of arguments for Positivist and Interpretivist research, it is believed that the philosophy of the researcher and context of this research is placed within Interpretivism.

This research is specifically focused on the observation and understanding of current practice for home use medical device design. In particular interest of this research is the involvement of users within the design and development process and the meaning or reasoning behind the methods chosen by practicing designers. The combination of an interpretivist stance and the nature of the research questions previously described calls for a mixed method approach. The following sections of this review will continue to address the 'layers' defined by Saunders *et al* in the 'research onion' (Saunders *et al*, 2009).

Conducting this review on research philosophies has revealed that is it necessary to establish the nature of the research approach, in particular the type of reasoning that

in turn will establish the use of theory throughout the thesis. As such the following section will begin with Inductive and Deductive reasoning.

## 3.5 Inductive vs. Deductive Reasoning

The use of theory in research raises an important question for research design. The key question as described by Saunders *et al* is that whether the research will take a deductive or inductive approach (Saunders *et al*, 2000). In a deductive approach, the researcher develops a theory or hypothesis and consequently designs a research strategy to test that hypothesis (Saunders *et al*, 2006). In contrast an inductive approach involves collecting data and developing a theory based on the analysis of the results.

Gray states that deduction in research begins with a 'universal view of a situation' and therefore is based on an initial theory (Gray, 2009). In contrast, Induction moves from 'fragmentary details' that in turn develop into a connected view of a situation through induced theory (Gray, 2009).

An alternative way of thinking about induction and deduction in research is that of theory testing and theory building. These terms largely refer to the same principles as previously described, however for clarity are discussed here.

### 3.5.1 Theory Testing vs. Theory Building Research

According to De Vaus, research can be classified as either one of two styles: Theory Testing or Theory Building (De Vaus, 2001). Theory testing refers to research that begins with a theory and then uses that theory to shape the research process. The perceived theory is used to direct the observations to be made and through deductive reasoning these observations should test the theory. This deduction enables the research to derive propositions about the theory to assess whether the theory is true against real world issues (De Vaus, 2001).

The literature review in Chapter Two discussed the lack of research that has been previously conducted in this field. Presently there is very little theory available regarding current practice for the design of home use medical devices. In the review only two existing theses were found to explore this area of medical device

development: Gupta (2007) and Cifter (2011). Thus this type of research is not hypothesis based.

The research will therefore begin with observations and exploratory research sometimes referred to as descriptive based research to establish theories from the field.

Typically theory-testing research is associated with quantitative or clinical research such as Random Controlled Trials (RCTs) where established theories already exist. The nature of this research is very much concerned with the exploration and explanation behind current design practice to deliver improvements as far as is reasonably practicable. Thus, this research can more suitably be considered as Theory Building.

Theory building is a process by which research begins with observations and uses inductive reasoning to derive a theory from these observations. Previously this type of research has been referred to as 'Post-Factum' theory whereby the researcher produces a theory out of the research and can therefore be considered as the antithesis of theory testing (Robson, 2011).

Through conducting studies within industry (Chapters 4, 5, 6, 7 and 8), theory will be established about current home use medical device design and subsequently lead to recommendations that are hoped to provide practical value to the field.

In light of this, an inductive and theory building approach to the studies presented in this thesis is employed. The following section will now discuss the concepts of quantitative and qualitative research.

## 3.6 Quantitative Research

The overarching aim of experimental research is the production of credible results that are objective, valid and replicable either by the lead researcher or by others (Gray, 2009). This form of research is often associated with objectivism and is historically determined by a positivistic theoretical stance to research.

Typically, quantitative research is guided by specific research questions. These questions are investigated through the relevant literature, which guides the development of formulated research hypotheses. The research is then about studying

and analysing the dependent and independent variables to determine whether those hypotheses can be accepted or rejected (Gray, 2009). Quantitative research is therefore considered by many to be more rigorous and scientific in its application than qualitative research.

There are however criticisms of quantitative research and this approach is not always the most suited method to all disciplines for undertaking research. Gray posits that quantitative research can often be removed or 'disengaged' from people and the field of study (Gray, 2009). For some disciplines this may be necessary or considered a positive aspect of the research methodology due to the objective nature of the work. For fields such as design research, interaction with target populations and the social and cultural aspects of research are very much a critical part of the methodology. In such instances a qualitative or mixed methods (i.e. combination of quantitative and qualitative) approach can be more practical and fruitful in ascertaining theories and insights to support design improvements.

## 3.7 Qualitative Research

Qualitative research is sometimes criticised for an apparent lack of rigour in its methods or approach. Some argue that there is little difference between case study-based research and qualitative research. Hakim argues that there are however fundamental differences between these bodies of work, particularly from a research design perspective (Hakim, 2000). Qualitative research is concerned with obtaining personal accounts of a situation or event while case study research is concerned with obtaining the 'rounded picture of a person's life, a situation or event' using a variety of methods or information sources (Hakim, 2000).

In contrast to much of quantitative research, qualitative research is not built upon a unified theory or methodological approach (Flick, 2006; Gray, 2009). As such qualitative research adopts various forms of theoretical stances and applies a range of methods to develop theories and increase the knowledge of a particular phenomenon.

Essentially, qualitative research involves a number of characteristics that are presented in Table 3.3 below (Gray, 2009).

**Table 3.3: Characteristics of Qualitative Research (Gray, 2009).**

| |
|---|
| It is conducted through intense contact within a 'field' or real life setting. |
| The researcher's role is to gain a 'holistic' or integrated overview of the study, including the perceptions of participants. |
| Themes that emerge from the data are often reviewed with informants for verification. |
| The main focus of research is to understand the ways in which people act and account for their actions. |

Qualitative research can be particularly useful in fields or circumstances where relatively little is known about the phenomenon, or to gain new perspectives on issues where there is already existing knowledge (Strauss & Corbin, 1998; Gray, 2009).

Quantitative and qualitative research are two established and widely recognised types of research. It is unsurprising therefore that the recent (mixed methods), regarded by some as the third, 'paradigm' for research is met with some scepticism. The following section explores mixed methods research before outlining the relevant research strategies for this thesis.

## 3.8 Mixed Methods Research

Mixed methods research is a combination of the principles and philosophies applied in quantitative and qualitative research. As Johnson *et al* explain the approach adopts a 'pragmatic method and system', which is based on a view that knowledge is socially constructed (e.g. constructionism) (Johnson *et al*, 2007). As such a mixed methods approach to research makes use of induction, deduction and abduction (Gray, 2009). Johnson and Onweugbuzie describe these terms for theory as follows (Johnson & Onweungbuzie, 2004):

- Induction – To identify Patterns
- Deduction – Testing Theories and Hypotheses
- Abduction – Uncovering and relying on the best explanations for understanding one's results.

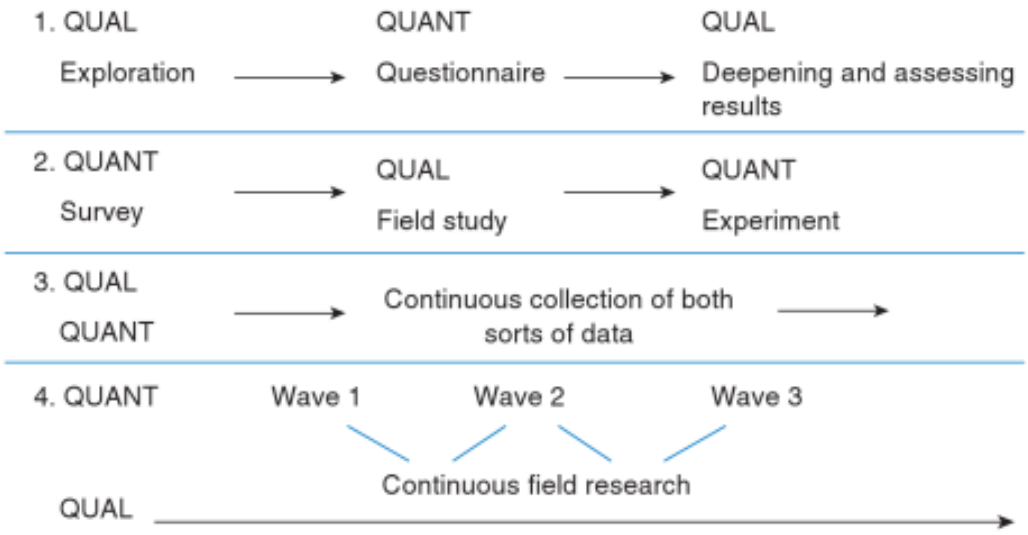



**Figure 3.4: Four Mixed Methods Models (Gray, 2009).**

As Gray explains, these methods can be used interdependently and in a range of different sequences to answer the same research question or different questions (Gray, 2009). In his book, *Doing Research in the Real World*, Gray presents four different types of mixed method design, which are shown above in Figure 3.4. The image above is sourced online from Google Books and can be found in Chapter 8, page 206 in Gray (2009).

Model One, or Design One as Gray describes, presents an approach utilising a qualitative strategy followed by a quantitative strategy and finally a qualitative study at the end. In his example, the process begins with an exploratory, qualitative framework, which informs the classification of themes and concepts under study (Gray, 2009). The importance of the exploratory study at the beginning of the research process is to support and aid the development of the quantitative questionnaire as shown in Figure 3.4. The findings of the questionnaire and quantitative data are then tested and deepened by the next qualitative study (Gray, 2009).

Design Two begins in the opposite fashion to that of Design One. Here, an initial quantitative survey is conducted to determine the importance of issues under research. This is followed by a qualitative study that provides the researcher with a deeper understanding of the phenomenon. To conclude this model, an experiment is designed to test some of the results, findings or theories established through conducting the earlier studies.

Design Three illustrates the integration of both qualitative and quantitative methods that may be necessary to generate an understanding of the case. Finally, Design Four presents an example of a multi-wave survey approach (Gray, 2009). According to Gray, the initial survey, wave one, indicates to the researcher what the qualitative study must look for and the findings of this will then inform and modify the next wave of quantitative research (Gray, 2009).

With these designs in mind there are primarily three types of approach for mixed methods research, which are discussed below.

**Qualitative then Quantitative**

This approach is perhaps one of the most common in mixed method designs. As shown in Design One, the qualitative study informs the quantitative study. This type of design is particularly suited to fields of study when relatively little or nothing is known about the research setting or problem (Gray, 2009). In this instance it would be inappropriate to launch into a quantitative study, such as a large survey for example, when the variables to be measured are unknown or the researcher has an insufficient understanding of the topic. Therefore the use of a preliminary or early qualitative study informs both the researcher and the research about the variables that require further investigation.

**Quantitative then Qualitative**

In contrast to qualitative then quantitative, this approach requires an understanding of the research topic to inform an initial quantitative study. This approach is reflected in Design Two of Figure 3.4 where the quantitative findings are deepened by a qualitative study that might be conducted to establish the 'why' questions of the research.

**Quantitative and Qualitative Concurrently**

Designs Three and Four combine the strategies of both quantitative and qualitative research. It is possible to pose quantitative questions within an interview for example, which can then be followed by a qualitative question as part of the same methodology. Such an approach can reveal depths and complexities within the data that might be missed within a mono-approach.

Understandably there a wide range of strategies that fall into the categories of qualitative, quantitative and mixed methods research. Some methods can be applied to all types of research paradigm and therefore categorising methods under a specific type of research presents little value in real terms. What is more pertinent in the context of research is whether the chosen method(s), or what Saunders *et al* refer to as Strategies, successfully meet the research objectives (Saunders *et al*, 2009). The following section will now address this issue.

## 3.9 Research Strategies

Deciding upon an appropriate research strategy for a particular study is no easy task. Saunders *et al* posit that the decision upon which research strategy to use must be based on whether the particular strategy will answer the intended research question and subsequently meet the objectives of the researcher (Saunders *et al*, 2009). Along with the research questions and objectives they add that the ultimate selection of the research strategy must be informed by the extent of existing knowledge, the time given to study, resources (e.g. funding etc.) and the philosophical stance of the researcher (Saunders *et al*, 2009).

Saunders *et al* describe seven different research strategies within the research onion (Saunders *et al*, 2009). Note, that these strategies for research are not necessarily exclusive and can in fact be used in combination (e.g. a survey within a case study). Each of the strategies described by Saunders *et al* can be used to conduct 'exploratory, descriptive and explanatory' research as described in Section 3.2.1 (Saunders *et al*, 2006; Yin, 2003). The strategies described by Saunders *et al* will now be introduced before the chosen research strategy is presented.

**Experiment**

An experiment within research is perhaps most commonly associated with the stereotypical and traditional understanding of research in a laboratory environment. However, as Saunders *et al* state this strategy for conducting research is used throughout social science and psychology too (Saunders *et al*, 2009). According to Hakim, the purpose of experiments are to study 'causal links' and whether a change in one independent variable leads to a change in another dependent variable (Hakim, 2000). Assessing the links between variables through controlled experimental groups

is ubiquitous throughout the commercial sector in understanding purchasing decisions for example.

This form of research strategy is typically used for exploratory and explanatory research or the 'how' and 'why' questions of a phenomenon. By their nature, experiments are typically guided by a theoretical hypothesis and could therefore classically be described as a deductive form of research. For the context of this research however, experiments are regarded as unsuitable, both in terms of the nature of the research and the ability to successfully answer the research questions of this thesis.

**Survey**

Surveys are a commonly utilised research strategy in both quantitative and qualitative research. Gray describes surveys as a systematic collection of data that whether conducted by interview, questionnaire or observation, must be focused on the 'importance of standardisation' (Gray, 2009). Here, Gray refers to the reproducibility of the survey procedure to eliminate errors in the data collection method.

Irrespective of the chosen method to conduct a survey, the researcher(s) must always ensure that the approach taken is the same with every participant to reduce the influences of bias (See section 'Dealing with Bias') and potential for errors in the data.

The popularity of the survey method is attributed to the relative ease with which large amounts of data can be collected in an economical manner (Saunders *et al*, 2009). Under the correct strategy, a survey can be used to generate findings that are representative of the whole population under study without having to invest considerable time, effort and money to access the whole population (Saunders *et al*, 2009).

Surveys are commonly administered as questionnaires. This approach allows for both quantitative and qualitative data to be collected from a sample population. Saunders *et al* state that selection of a survey questionnaire is determined on how it is to be administered, whether it is to be completed by the individuals themselves or with an interviewer posing the questions (Saunders *et al*, 2009).

In spite of this however it should be noted that one of the drawbacks in such an approach is the relationship between the length of a survey and response rate. Thus, the longer a survey takes to complete the less likely the respondent is to actually complete it. Furthermore, the survey is unlikely to be completed as intended by the researcher.

The survey strategy including all of questionnaires, interviews and observation present considerable scope for the context of this research. There are however many issues to consider when selecting this method, specifically in terms of ethics and design.

**Case Studies**

In general research terms, case studies tend to be much more focused and specific to a particular domain or phenomenon. While surveys, particularly questionnaires, can address a range of issues from a wide range of participants, case studies can focus on individuals, organisations or a specific contexts (Gray, 2009). Case studies can be invaluable when exploring areas of little or no previous experience as they are an ideal way of increasing understanding, extending experience and conviction about a subject. To refer back to Gray's Design One, a case study is a good example of a strategy that can inform future quantitative research, particularly in a field such as home use medical device design where very little theories currently exist.

Case studies however do benefit from the prior development of a theoretical position to help direct the data collection and analysis process (Gray, 2009). In this respect case study research can be deductive in nature as it looks to confirm or reject a particular theory about the phenomenon under study (Gray, 2009). Although case studies are very flexible in nature they do require the researcher to have formulated a structure and detailed research questions that they attempt to answer by doing the study. Thus, the researcher must be prepared to quickly interpret responses or react to information they receive and be informed enough to make necessary responses.

Morris and Wood posit that a case study strategy is especially useful 'to gain a rich understanding of the context of the research and the processes being enacted (Morris & Wood, 1991). This again supports the notion of an early contextual study that informs future studies as part of a mixed methods approach.

According to Gray there are four main types of case study design, which are presented in Figure 3.5.

| | **Single Case Designs** | **Multiple Case Designs** |
|---|---|---|
| **Holistic (Single Unit of Analysis)** | **Type 1** Single/Holistic | **Type 2** Multiple/Holistic |
| **Embedded (Multiple Units of Analysis)** | **Type 2** Single/Embedded | **Type 4** Multiple/Embedded |

**Figure 3.5: Main Types of Case Study Design (Adapted from Gray, 2009).**

**Single, Holistic Case Studies**

In this type of case study, one single case is examined at a holistic level (Gray, 2009). A case study at this level might explore a programme or organisation rather than individual elements within it. According to Gray, a single case study should be used when there is a requirement to test a hypothesis or theory, or where there might a 'revelatory case', which presents a unique opportunity to the researcher (Gray, 2009). Saunders *et al* state that single, holistic case studies provide the opportunity to observe and analyse a phenomenon that few have considered before (Saunders *et al*, 2009). Gray adds that this type of case study design can be used as a 'precursor' to further studies (Gray, 2009).

**Single, Embedded Case Studies**

An embedded single case study shares similarities with a single holistic design, however in this type of study there are a range of different units of analysis that need consideration. An example of such a case study might include the analysis and comparisons of a process from different employee perspectives within an organisation to gain a wider context of the case under study.

**Multiple, Holistic Case Studies**

In this type of case study a single, holistic unit of analysis is studied in multiple cases. The aim of this design is not to increase the size of a specific sample but rather

to replicate the findings of one (holistic) case across a number of cases (Gray, 2009). One of the drawbacks in such an approach however is that due to the holistic nature of the study it can be possible for the focus to shift without intention or awareness of the researcher. Rather than answering the original questions the case study can change direction and consequently answer rather different questions.

**Multiple, Embedded Case Studies**

Finally, a multiple embedded case study makes use of multiple cases and multiple units of analysis. Gray argues that embedded cases for multiple case studies are advantageous over holistic studies as they reduce the likelihood of problems occurring between the research questions and direction of the study (Gray, 2009).

**Action Research**

According to Saunders *et al* the term 'action research' was first used in 1946 and has since developed into a range of definitions used by practitioners and researchers today (Saunders *et al*, 2009). One recognised definition of action research is that the purpose and focus must be upon 'research in action rather than research about action' (Coughlan & Brannick, 2005). Here, the research may be concerned with the delivery of solutions to an organisational issue including the implications of that change on those who are affected (Saunders *et al*, 2009).

A second recognised definition of action research refers to the involvement of practitioners within the research itself. In particular, as Saunders *et al* state, its focus is upon the collaboration between practitioners and researchers to deliver a resolution that is of mutual benefit to both parties (Saunders *et al*, 2009). Another emphasis of action research is that it takes an iterative form, one that adopts a process of diagnosing, planning, taking action and evaluating (Saunders *et al*, 2009).

The aim of this research is to incentivise a change in practice amongst designers and developers of home use medical devices. Thus this research can be regarded as action research in that it attempts to facilitate change, both in terms of delivering improvements in efficiency and quality for practice (Robson, 2011).

## Grounded Theory

Grounded theory refers to one of the most influential qualitative approaches (Gray, 2009). It is defined by Strauss and Corbin as a theory that is 'discovered, developed and provisionally verified through systematic data collection and analysis of data pertaining to that phenomenon (Strauss & Corbin, 1998). Gray describes grounded theory as a process whereby the researcher works with the participants to actively construct the data from a position of static analysis to multiple layers of meaning (Gray, 2009).

In grounded theory the data collection process begins without an initial theoretical framework (Saunders *et al*, 2009). This is supported by Gray, who states that unlike deduction, grounded theory does not start with 'prior assumptions about hypotheses' or a theoretical underpinning that is guided by literature (Gray, 2009). Although Gray adds that this does not mean that practitioners of grounded theory embark on a study without a theoretical position (Gray, 2009). Rather there should be a balance of literature and theoretical understanding that does not impede on the creative nature of grounded theory as a research approach (Strauss & Corbin, 1998).

A grounded theory approach typically begins with data collection in the form of observations or a series of observations (Saunders *et al*, 2009). This data collection leads to the development of predictions which are later tested through further observations that may or may not confirm the predictions (Saunders *et al*, 2009).

## Ethnography

Ethnography as a practice is rooted firmly in the inductive approach to research (Saunders *et al*, 2009). With origins from anthropology its purpose is to describe and provide explanations within social world research. Ethnographic research therefore is predominantly associated with observation within the 'naturalistic' setting. As Saunders *et al* explain, ethnography is particularly appropriate for research that is interested in gaining insights in a specific context to provide a better understanding and interpretation from the perspectives of those under study (Saunders *et al*, 2009). Adopting this approach for research requires a level of immersion within the context of the study that will inevitably call for a level of trust amongst participants and due consideration for ethical issues along the way.

**Archival Research**

The final strategy described by Saunders *et al* refers to a type of research that makes use of administrative records and documentation as a principle source of data (Saunders *et al*, 2009). This approach allows for research questions with a focus on past information and the subsequent changes over time to be answered in an exploratory, descriptive or explanatory fashion. Understandably this process is largely guided by the availability of data both in terms of what exists and what can be legally and ethically accessed. Therefore research adopting this approach must carefully explore what data and information is available before the research proposal is clarified.

In summary, this research is considered to be a form of action research that attempts to provide recommendations and incentives leading to design improvements for home use medical devices. Having explored the strategies described by Saunders *et al*, it was concluded that the early stages of this research process will begin with case study research. Specifically two case studies will be conducted to provide a contextual background and to form the research clarification. Following these case studies will be a quantitative study as guided by Gray (2009) in Design One (See Section 3.8). This study will then inform a final qualitative study that it is hoped will provide answers to research question three of this thesis. By answering all the research questions in a systematic approach it is believe that this research will successfully meet its aim, which is to deliver recommendations and incentives for improved home use medical devices.

The following section will now discuss the topic of sampling strategies employed in this thesis.

## 3.10 Sampling Strategy and Methods

According to Gray, when conducting research to make generalisations about data, a sample must be chosen that is representative of the population as a whole (Gray, 2009). Thus, the characteristics of the chosen sample must be similar or identical to those within the population under study. In such scenarios, it is typically the case that making such generalisations to a population requires an understanding of the exact number of individuals within the population under study. This is highlighted in Gray's definition of the term population as the 'total number of possible units or elements' that are included in the study (Gray, 2009).

One example of such a sampling strategy is Random Probability Sampling. This strategy implies that each member of the population has an equal chance of being selected to take part in a study (Gray, 2009). This however is not always achievable in practical terms as access to the necessary information on the exact size of a population may not be available.

It has previously been described that the nature and scope of this research has called for a mixed methods approach. Within this approach there are to be a range of studies presented in Chapters Four, Five, Six and Seven that will form the explanatory and descriptive components of the thesis. In light of this, the sampling strategy for this research must be adaptive and reflective in accordance with the nature of this research. This does not mean however that the researcher has not defined a specific sampling strategy and this will described in the text that follows.

Section 3.9 provided a summary on the research strategies employed within this thesis. In summary, two initial case studies that are exploratory in nature are to be conducted to provide research clarification and context for the research. These studies intend to reveal insights into current practice for home use medical device design that will inform the first quantitative study of this research. For these case studies two different companies with experience in home use medical device will be chosen to take part in the research. More information on how these companies were chosen can be found in Chapters Four and Five.

The first quantitative study presented in Chapter Five of this thesis attempts to identify the current 'facts of the system' within the home use medical device

industry. Therefore the sampling strategy to be employed for this study is to access as many relevant companies as possible with experience home use medical device design.

The target population is anyone currently working or responsible for the design and development of medical devices used within the home environment. This includes any stage of the design process, as it was considered that ultimately these participants, to some extent, would have an influence on the final design. In light of this a range of sampling strategies were considered to determine how best to access this target population, including the widest range of potential participants.

Essentially there are two fundamental forms of sampling; probability and non-probability sampling. Qualitative research typically utilises purposive non-probability samples as it seeks to obtain insights into particular practices that exist within a specific location, context and time (Gray, 2009).

In non-probability sampling, participants are identified due to their characteristics or known behaviours relevant to the research area (Gray, 2009). Due to the very qualitative and mixed methods nature of this research and its intentions to access designers' perspectives towards home use medical devices and their users, it is vital that involved participants have experience in this field. Accessing this target population therefore becomes much more specific and consequently calls for a necessary consideration for appropriate sampling methods.

This approach contrasts quite markedly from quantitative approaches where samples are pre-planned. For qualitative research it is much more likely that samples develop or evolve once the research has begun. Table 3.4 presents the range of sampling methods that were considered for this research. While the list is not exhaustive (there are a wide range of methods available) it does provide an insight into some of the considerations made by the researcher for this research methodology. The rightmost column in the table briefly describes the relevance or suitability of the method for the proposed research pathway.

**Table 3.4: Sampling Methods (Adapted from Gray, 2009).**

| Sampling Method | Description | Relevance |
|---|---|---|
| **Simple Random Sampling** | Takes a completely random sample of the population. This method is used when it is believed that the population is homogenous with respect to the research context and questions. It relies on access to a complete list of the population. | Identifying the complete list of designers for home use medical devices is a very difficult task. No evidence of such figures was found therefore accurate and correct application of this method is not achievable for the context of this research. |
| **Criterion Sampling** | A sample is selected based on the focus of the study therefore all cases would be chosen to meet this criterion. | Criterion sampling would be relevant for this research as participants would be specifically home use medical device designers. Their roles within this process however will differ considerably and would therefore not necessary fit this sampling method. |
| **Theory Based Sampling** | A formal approach to Criterion sampling whereby participants are identified through theoretical constructs. | The literature revealed a lack of theory towards home use medical device design and therefore this method would not be suitable. |
| **Purposive Sampling** | Participants are deliberately selected by the researcher for a particular trait to give what is believed to be a representative sample. | Purposive sampling is very targeted and specific to the researcher and could potentially achieve a cross section of the population. |
| **Snowball Sampling** | The initial group of respondents are used to inform or nominate relevant parties or individuals for study. | Snowball sampling is a very useful method to locate additional designers in the home use market. Given the niche market, snowball sampling would be very useful for this research. |
| **Quota Sampling** | Participants are non-randomly selected from identified strata until the planned number of subjects is reached. | Accurate use of this method again requires an understanding of the size of the population. One can speculate, but exact figures are unknown. |

Based on Table 3.4 it was concluded that the sampling strategy most appropriate for this research is to adopt a combination of purposive and snowball sampling to achieve the widest sample of home use medical device designers as possible. An initial cohort of companies will be contacted to take part in the research and subsequently be asked whether they are aware of any further companies operating in the field of home use medical device design.

To achieve this, a range of different strategies will be employed to locate, contact and gain access to this population. It must be considered however that when working with modest samples it is vitally important to ensure there is a high quality of sample achieved. In order for this research to provide a meaningful contribution to knowledge it must be explicit in its involvement of participants who only have experience in home use medical device design. Further information on the access to participants under study is provided in the specific chapters.

## 3.11 Ethics for Research

Ethical considerations are fundamental within any research project. The issue of ethics presents itself as one begins to plan a research project and the necessary access to individuals, a population or organisation to collect, analyse and report data (Saunders *et al*, 2009). As such research must be planned, conducted, handled, analysed and written in a moral and responsible manner.

Saunders *et al* state that the general issue for ethics in research design is that the research design itself should not submit those under research (i.e. the population) to 'embarrassment, harm or any other material disadvantage' (Saunders *et al*, 2009). In particular one must consider the issue of informed consent and the extent to which participants are both aware and happy to be part of the research itself.

Gray provides a checklist that outlines the ethical commitments and responsibilities for qualitative research (Gray, 2009).

- Have I honoured my commitments about confidentiality and privacy?
- Have I acted in the spirit of informed consent?
- Have I used my research effectively and morally?
- Have I generalised appropriately?

- Do I have responsibility to anticipate how others might use my research and explanations?

All of these considerations cited by Gray must be taken into account when the research enters the beginning and planning of the study phase. This checklist however does not address how research should be conducted ethically across an entire project. Figure 3.6 covers this in more detail.

As Figure 3.6 shows there are a range of different ethical considerations and issues that the research must address at different stages within the process of conducting research. Saunders *et al* state that one of the key ethical issues for research is that of gaining access to participants (Saunders *et al*, 2009). Robson explains that pressure must not be put upon intended participants to grant access (Robson, 2011).

As this research project forms part of a funded body of work for Loughborough University by necessity the researcher has an obligation to act ethically in accordance with the university's code of ethics. Saunders *et al* describe a code of ethics as a statement of principles and procedures that outline the manner in which research should be conducted (Saunders *et al*, 2009).

In light of these identified ethical considerations, this research will take all necessary steps to act ethically with upmost importance placed upon the involvement of participants. Each chapter from this point forward will include the ethical principles and considerations that were specifically addressed at the time of study.

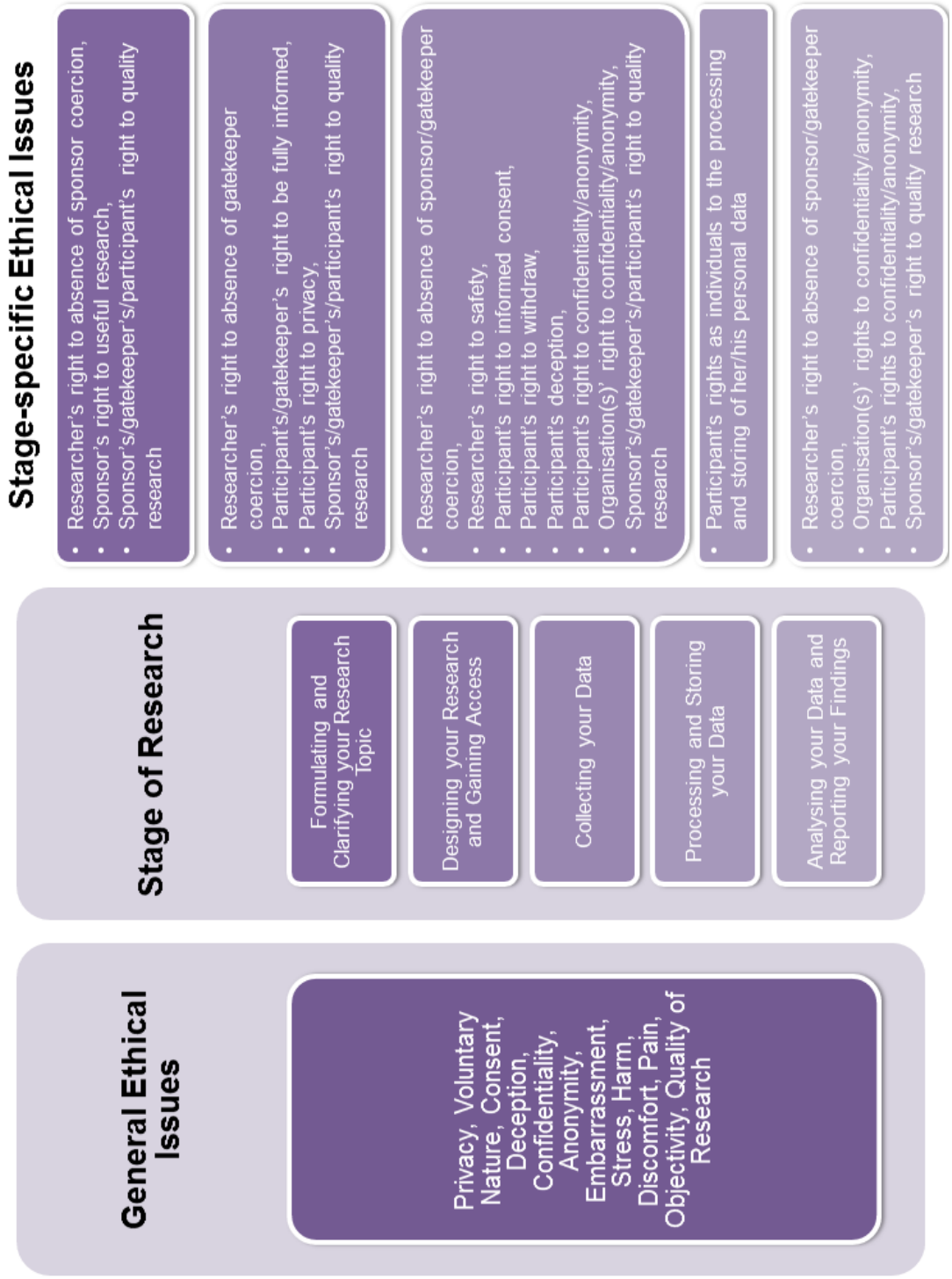



**Figure 3.6: Ethical issues at different stages of research (Adapted from Saunders *et al*, 2009).**

## 3.12 Data Analysis

There are a multitude of data analysis techniques available to researchers, many of which include specific software packages that simplify the process of analysis for large quantities of data. For this thesis the data analysis techniques used throughout this research are cited within the individual chapters. This decision was made on the basis that readers could review the analysis of the results for a particular study alongside the write up for that study. Thus, the selection of a technique for data analysis was based upon the nature of the study and the type of data collected. Refer to the necessary chapters to find further information on the analysis and handling of data within this thesis.

### 3.12.1 Triangulation

The concept of triangulation within mixed methods research refers to the combination of several qualitative or quantitative and qualitative methods to compensate for the potential weaknesses in a mono-method approach (Gray, 2009). By combining such methods it is believed that triangulation of the findings produces results that are more reliable in that they are supported by other bodies of evidence. As previously describe in Section 3.8, this research intends to adopt Design One described by Gray (2009). Through a combination of case studies, a quantitative survey and semi-structured interviews the research design of this thesis will be able to triangulate the findings based on multiple bodies of evidence, to determine whether the initial predictions were in fact correct about home use medical device design.

### 3.12.2 Validity and Reliability

Within research the terms validity and reliability refer to attempts to apply rigour to an approach. In essence these terms could be argued to have the same purpose in that the researcher attempts to demonstrate that findings are in fact replicable by others. As previously addressed, one of the criticisms often cited of qualitative research is that it is ‘unscientific, anecdotal and based upon subjective impressions’ (Gray, 2009). Therefore applying such terms to qualitative research is met with some criticism.

While the concept of validity is typically associated with quantitative research, recent times have seen the concepts of internal and external validity be adopted in qualitative research. Saunders *et al* describe validity as being concerned with whether the findings of a body of research are really about what they appear to be about (Saunders *et al*, 2009).

**Internal Validity**

According to Flick the issue of internal validity refers to the level with which the 'constructions' of the researcher are based on the constructions of those being researched (Flick, 2006). One must consider however the impact and influences of researcher bias within this process of reporting validity. Hall and Callery are critical of this issue and state that the researcher makes the assumption that the data collected is independent of their 'subjective interpretations' (Hall & Callery, 2001). Thus, Hall and Callery argue the need for what they call a 'reflexive approach' to critically reflect on the researcher's influence on the research process (Hall & Callery, 2001). This issue is addressed further in the following section on dealing with bias within research. Note that attempts to challenge the researcher's influence on the process were explored in the 'Researcher Identity Memo'.

Of course during any data collection activity it is possible for data to be 'fabricated, discounted or misinterpreted' (Gray, 2009). Being reflective in one's own approach to data collection is one way in which this can be overcome. Gray states that one approach is to involve those being researched in the checking of the data for accuracy (Gray, 2009). However this approach may not always be possible as repeated access to participants can be difficult.

Throughout this thesis the researcher must take reflective steps when progressing from one study to another. Furthermore, for the purpose of internal validity, attempts will be made to clarify details with participants, as far as is reasonably practicable, so that the data is interpreted and presented as intended by the participants.

**External Validity**

Validity that is said to be external refers to the extent by which it is possible to generalise from the data with respect to other cases or situations (Gray, 2009). As Saunders *et al* explain external validity is a term that is used interchangeably with generalisability (Saunders *et al*, 2009). Therefore external validity refers to the extent to which the findings of a study have significant implications that are applicable to other research settings.

When conducting research, the researcher must be aware of the claims they are making about the data and its application in other settings. As Saunders *et al* state, as long as the research does not claim to show results, conclusions or theory that is generalisable, without sufficient evidence then external validity is typically not an issue (Saunders *et al*, 2009).

**Reliability**

The reliability of data refers to the extent to which the collection techniques and analysis procedures have been considered by the researcher to ensure they will yield consistent findings (Saunders *et al*, 2009). According to Easterby-Smith *et al* reliability of data can be assessed by answering the following three questions (Easterby-Smith *et al*, 2008):

1. Will the measures yield the same results on other occasions?
2. Will similar observations be reached by other observers?
3. Is there transparency in how sense was made from the raw data?

For the purpose of this research, each of these questions will be answered before and during the commencement of the aforementioned research strategy. Each chapter will include a section on the reliability of the data it presents.

### 3.12.3 Dealing with Bias

Bias, it could be argued, is present within all types of research and therefore the researcher has an obligation to address the various types of bias that may be present within data.

One form of bias within research is that of 'Researcher Bias'. Saunders *et al* refer to this type of bias in an example where the researcher is also the interviewer for participants. Here, the interviewer introduces their bias to participants through the comments, tone or non-verbal behaviour (face-to-face interviews), sometimes without an awareness of doing so (Saunders *et al*, 2009). The researcher has an obligation to address this within the research design so as to not influence participants in their responses. After all it is widely understood that individuals act differently when under review or observation (Robson, 2011).

This research will take all necessary steps to ensure that any potential bias that is controllable by the researcher is removed from the data collection process. The researcher identity memo presented in Chapter Two has already discussed the perspective of the researcher before the presentation of any findings. In doing so, this memo allows readers to be aware of the researcher's position and therefore removes any potential bias in the presentation of data and information to its audience.

Another bias to consider, specifically when conducting a survey or interview based research strategy is the issue respondent or response bias. This type of bias occurs when the respondent has preconceptions about the interviewer themselves and what they are in fact researching. For example this could lead a respondent to answering questions in a manner to which they think the interviewer is looking for, rather than answering in an honest and truthful manner.

Another common issue that can lead to the introduction of respondent bias refers to leading questions or behaviour when conducting research with respondents. These specific issues for bias will be addressed in chapters presenting the studies of this thesis accordingly.

Finally, it should be stated that the use of triangulation within this research has been designed to further reduce the potential for bias. As Gray states, the use of

triangulation in mixed methods research is often used to ensure the 'inherent bias of one measure is counterbalanced' by the strengths of another method (Gray, 2009). A combination of these approaches will ensure that the results and information in this thesis in honest and credible with the least amount of bias possible.

## 3.13 Research Methodology for Design Research

Design as a practice is unavoidably humanistic and multidimensional in approach. Assigning a methodology therefore can often prove challenging. Particularly where medical device design is concerned the process of design is incredibly complex given the range of stakeholders and the regulatory requirements of the field.

Methodologies for studying design therefore have to be flexible and adaptive to be able to respond to the multiple components and stages within the design process. What is arguably integral to all permutations of design research however is the attainment and realisation of an understanding and improvement for a specific design situation. As Eckert *et al* state design research is driven by the twin goal of understanding and improving (Eckert, 2003). The methodological approach for this research is founded and adapted from the principles of Design Research Methodology (DRM) by Blessing and Chakrabarti (Blessing & Chakrabarti, 2009).

### 3.13.1 Design Research Methodology (DRM)

DRM was created to combat the challenges relating to the application of methodological issues in design research. The main aims of DRM are to help researchers in identifying research areas and projects and to aid the selection of suitable research methods to address the issues of concern (Blessing & Chakrabarti, 2009).

Blessing and Chakrabarti define design research as the integration of two main strands of research; the development of *Understanding* and the development of *Support* (Blessing & Chakrabarti, 2009). As one informs the other, an understanding of a phenomenon informing the development of support, it is apparent that the two strands are closely linked. As such when considered in combination these strands achieve the overall aim of design research that according to Blessing and Chakrabarti

is ‘to make design more effective and efficient’ and consequently enable design practice to develop more successful products (Blessing & Chakrabarti, 2009). With this in mind there are two recognised objectives of the DRM approach (Blessing & Chakrabarti, 2009):

1. The formulation and validation of models and theories about the phenomenon of design with all its facets.
2. The development and validation of support founded on these models and theories, in order to improve design practice, including education and its outcomes.

The ‘facets’ of design as defined by Blessing and Chakrabarti refer to the people, products and knowledge/methods/tools and encompass the generation of knowledge about design research that in turn through methodical study will lead to improved design (Blessing & Chakrabarti, 2009). They posit that the ‘facets’ of design are inherent parts in the process of studying design and should at the very least be taken into account in design research.

Research question three of this research sets out to define what it will take to increase the uptake of usability principles and the involvement of users in the design of home use medical devices. In order to answer this question successfully it is necessary to answer the earlier research questions first to generate a better understanding of the field and current practice towards home use medical device design. Therefore the questions and aim of this research are similar to that described by DRM and Blessing and Chakrabarti in the sense that they meet the objectives described previously and the overall goal to deliver improved medical devices for users in the home environment.

Essentially DRM consists of four main stages, which are clearly depicted, in Figure 3.7. The diagram depicts the main stages in the centre with the basic means by which each stage is explored to the left and the outcomes that are delivered on completion of each stage to the right.

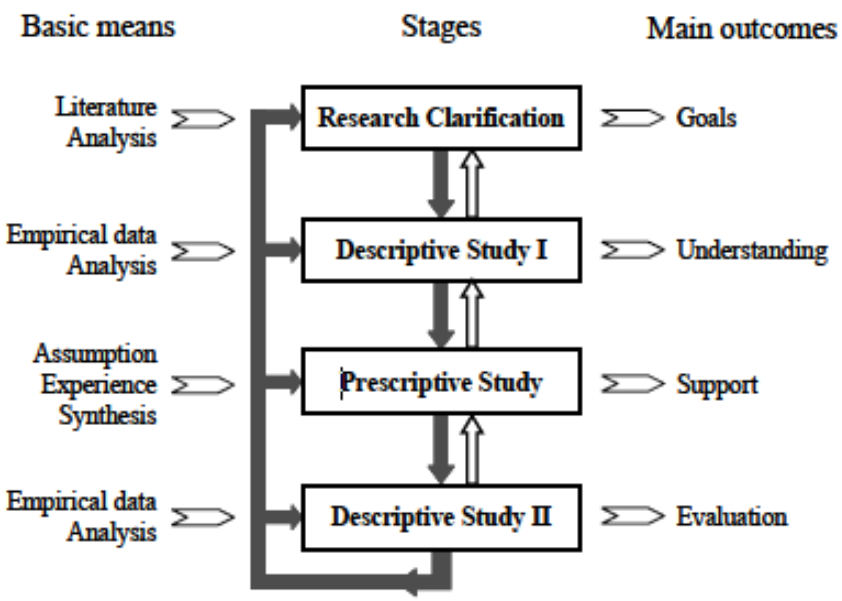



**Figure 3.7: DRM Design Research Methodology (Blessing & Chakrabarti, 2009).**

At the *Research Clarification* stage, it is typical for a literature review to be conducted although there may well be some form of initial or exploratory data analysis. This stage of the research process is about identifying evidence that supports the research intention and formulates the research goal (Blessing & Chakrabarti, 2009).

Chapter Two of this thesis very much followed this approach in its aim to identify existing research in the field of home use medical device design and gaps in current knowledge for the field.

The *Descriptive Study 1* stage refers to the detailed description of the situation under study and the factors that need to be addressed in order to improve the clarification of the research pathway. At this stage of the methodology, the research should have a clear goal and focus that gives the researcher a solid 'understanding' of the situation.

Using this understanding and the findings of *Descriptive Study 1*, the *Prescriptive Study* stage can begin. With a detailed description and understanding of the research direction, the prescriptive study represents the 'vision on how addressing one or more factors in the existing situation would lead to the realisation of the desired, improved situation' (Blessing & Chakrabarti, 2009). In Figure 3.7 this is represented

by the delivery of support to improve the effectiveness and efficiency of the specific design situation.

To achieve the aim of this thesis it is necessary to ascertain the challenges towards involving users in the design process of a home use medical device to identify how user involvement can be incentivised for industry. Using a combination of Descriptive and Prescriptive studies this approach can be tested and in doing so will ensure that this research meets its aims and objectives defined in Chapter One.

The final stage of the DRM methodology is the ***Descriptive Study 2***. This stage of the research process refers to an investigation into 'the impact of the support and its ability to realise the desired situation' (Blessing & Chakrabarti, 2009). This is where the value of output can be validated in the context of study to determine whether or not the research has in fact met its original goal. This stage of the methodology is vital to the research process as a whole and must be implemented as part of this research methodology. Only through accurate validation and reflection of one's own approach can improvements in the future be realised.

Despite the methodological approach defined in DRM, the authors state such an approach can only support the design research process. Blessing and Chakrabarti posit that a methodology should be carried out in a 'flexible and opportunistic' manner in order to adapt where necessary to any interesting findings or 'avenues' that emerge (Blessing & Chakrabarti, 2009). For example, the results of a particular empirical study may reveal a need for further, 'erstwhile unplanned, studies' that are founded on the knowledge gained from earlier findings (Blessing & Chakrabarti, 2009). At the research clarification stage it might be necessary to carry out some exploratory study (i.e. descriptive study) to clarify the research goals and to develop a research plan, when little is known about the phenomenon of interest (Blessing & Chakrabarti, 2009).

In light of this approach, the final design methodology will now be presented as a conclusion to the chapter.

## 3.14 Methodology: Final Design

Figure 3.8 presents the final design methodology for this research. The design is based upon the principles of a DRM approach and Gray's Design One which has been specifically adapted to include the research strategies for this research.

The methodology is presented with three different components that outline the research strategies, study chapters and their relationship to the research questions. Following the principles of DRM each chapter builds on the findings and knowledge of the previous chapter. Thus, the findings of the literature review inform the thesis as a whole and the case studies presented in Chapters four and five provide a foundation for study chapters six and seven. Chapter eight explores the proposed interventions of this thesis in a validation study with stakeholders from the home use medical device field. As outlined in the thesis framework in Chapter one these findings are then synthesised in an overview chapter presented in Chapter nine.

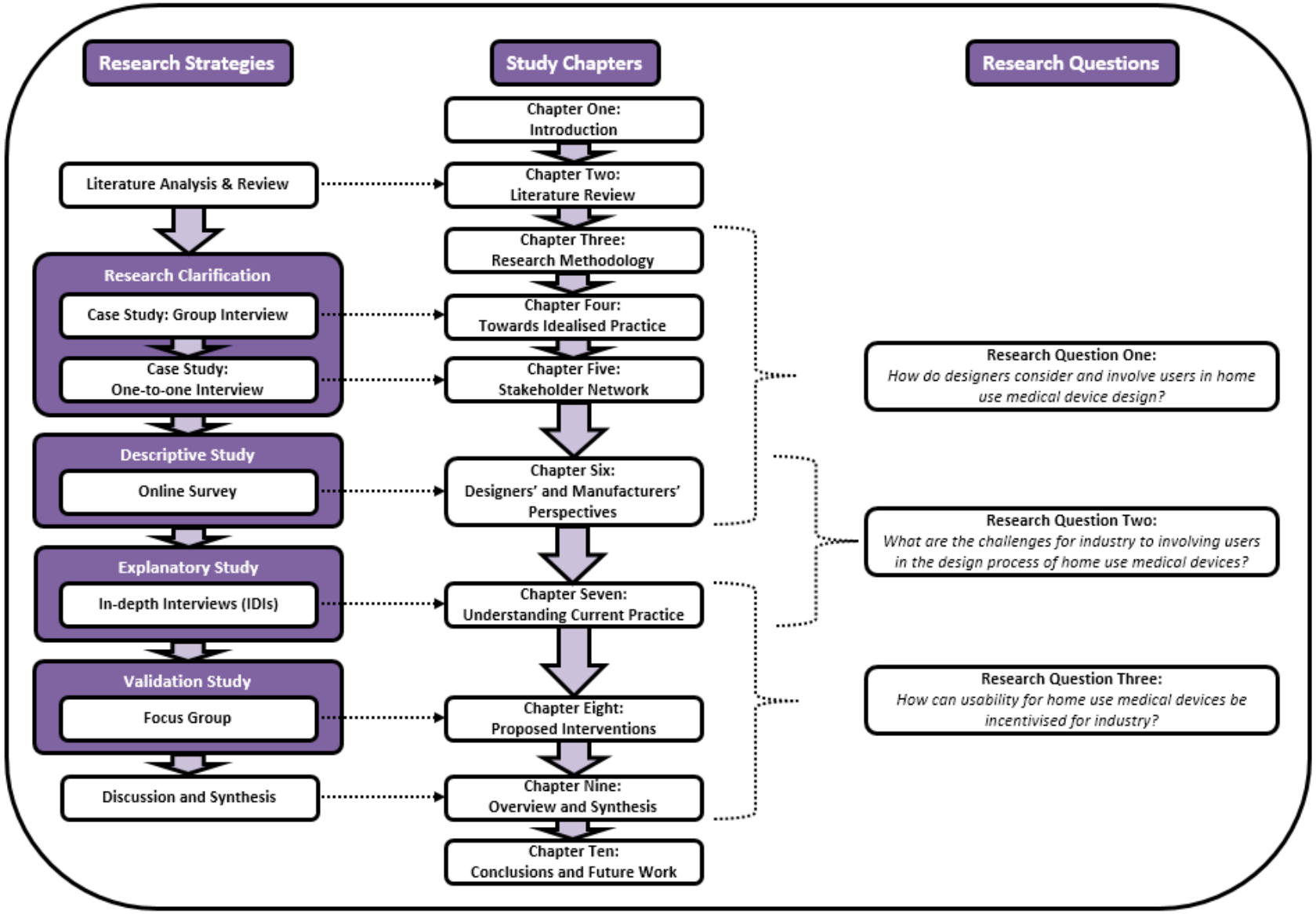



**Figure 3.8: Final Design Methodology including strategies, studies and outcomes.**

## 3.15 Summary

To summarise this chapter a final design methodology based on the DRM approach and Gray's design model one, has been adapted for the context of this research (Blessing & Chakrabarti, 2009; Gray, 2009). It has been established that the researcher's personal philosophical stance is closely linked to that of interpretivism and constructionism. The research presented in this thesis is theory building, in that there is recognised theory for home use medical device design as a practice. Rather there are ideas based on existing research, which this research aims to explore further.

The final design methodology includes two case studies that will form the research clarification (Chapters Four and Five); a descriptive study into designers and manufacturers perspectives of home use medical device users (Chapter Six); an in-depth explanatory study into current practice and challenges towards user involvement in home use medical device design (Chapter Seven) and a prescriptive validation study on the interventions and recommendations of the research (Chapter Eight).

The following chapter will now present the first case study of this research.

# Chapter 4
# Case Study One: Towards Idealised Practice

***"Most things are not designed for the needs of the people but for the needs of the manufacturers to sell to people."***

**(Victor Papanek, 1985)**

The previous chapter presented the methodology of this research. It was concluded that two case studies would be conducted with different companies currently operating in the home use medical device market. The first of these case studies, presented in the following chapter, attempts to identify a theoretical idealised practice towards home use medical device design. The identification of an idealised approach to home use medical device design will build on the knowledge acquired in the literature review and provide a basis from which future studies could be compared. Chapters Four and Five represent the research clarification of this thesis, which is recognised as a component of a Design Research Methodology (DRM) approach.

## 4.1 Introduction

Case study research is recognised to be useful in contexts of little or no previous experience (Gray, 2009). It has previously been stated that there is currently very little knowledge of design practice for home use medical devices within the literature (Cifter, 2011; Gupta, 2007). Previous research has identified that there is a lack of research specifically focused on the consideration and capturing of user issues during medical device development holistically (Martin *et al*, 2008).

To develop an understanding of the practicalities of home use medical device design, a leading design consultancy based in the United Kingdom was contacted to take part in this case study. The aim of the study was to attempt to establish a theoretical idealised approach towards involving users in the design process of a home use medical device.

The idealised approach would be established through exploration of a unique organisation in the field. This unique perspective is built upon a consultancy partnership with an academic institution, providing a theoretical core to the commercial consultancy. While the company contacted for this study represent a commercial business, they simultaneously represent an academic institution and therefore have access to the resources available to a university. This specific case is considered unique to the field as it provides the collaboration between theory and practice in the medical device sector. For the purpose of this study this organisation were considered a suitable candidate for a theoretically idealised approach due to access to resources that would not be available to a stand-alone company. Note that for reasons of confidentiality the company name is not mentioned throughout this document.

No evidence of an existing theoretical idealised approach towards home use medical device design was found within the literature review of this thesis. It is believed that through identifying an idealised approach towards user involvement in home use medical device design would provide a benchmark from which further studies could be compared. Furthermore, the researcher will gain a depth of understanding and context that cannot be established from the literature alone.

## 4.2 Background

There have been previous attempts to define a design process for home use medical devices (Cifter, 2011). The *Dual Verification Model*, identified in Chapter Two of this thesis refers to the dual verification of the regulatory essential requirements and specific user requirements, including the identification of lay users' requirements (Cifter, 2011). What cannot be inferred from this process however, are the specific details in relation to how users are or should be involved in the design process. There is no evidence within the model of the practicalities faced by designers and

developers of home use medical devices towards involving users in the design process.

The current literature on involving users in the design process in this field is much more typically focused on professional use medical device development (Bridgelal Ram, Grocott, & Weir, 2008; Craven & Martin, 2010; Martin *et al*, 2008; Money *et al*, 2012; Shah & Alshawi, 2010; Shah, Robinson, & AlShawi, 2009). Much less evidence is available however on the involvement of users in the design process of a home use medical device.

There is a need for more research into how designers tackle the practical challenges of remaining commercial whilst delivering home use medical devices that are usable and safe for their users. Buckle *et al* posit that there is a significant opportunity and need to develop a body of 'best practice' case studies and exemplars on how 'user-centred' design practice can lead to better and more competitive products for patient safety (Buckle *et al*, 2006). With the recognised use of medical devices in the home on the rise there is a need for more research to address and focus upon how designers in industry apply 'user centred design' principles.

## 4.3 Rationale

The reasons for conducting this case study were two-fold. Firstly, to gain a more detailed insight into current design practice by industry to inform and direct the research studies presented in this thesis. In doing so, this case study will provide preliminary answers to the first research question of this research and thus provide clarification for future studies.

Secondly, the case study would attempt to define a 'theoretical idealised practice' that would provide practical value to the industry. Although theoretical frameworks are available within the literature, no 'idealised practice' case studies specific to home use medical devices were found in the literature review. Literature based frameworks, such as that produced by Shah, Robinson and Alshawi provide a theoretical core towards the involvement of users in medical device development. However, it is not understood how this process is actually conducted by companies operating in the marketplace (Shah, Robinson, & AlShawi, 2009). There is a need to identify the specific steps designers take to ensure devices are as usable and safe as is

reasonably practicable for the home environment. Revealing this information will provide research clarification to this thesis and identify how designers and developers of home use medical devices are best supported in delivery of home use medical devices to patients.

## 4.4 Methodology

A leading design consultancy based in the United Kingdom with extensive experience in home use medical device design was contacted to take part in the case study. The company was purposefully chosen for this research for two reasons:

1. ***The connection to academia and resources for current research and theory in the field*** – With research ties this consultancy could be considered suitable to represent an idealised approach to design as they have access to both industry and academic resources as opposed to a solely commercial outlook. This unique perspective would provide a foundation from which other companies identified in Chapters Six and Seven could be compared.
2. ***The breadth and experience in medical device design, particularly home use medical devices*** - The consultancy have a wealth of knowledge in the home use field therefore providing the necessary insights and context required for this case study and thesis.

A scenario or 'role-play' based interview was selected to conduct the case study. Case studies designs were described in the previous chapter. The following study is an example of a single, holistic case study as it refers to specific practice of an organisation. The study presented here presents a unique perspective to home use medical device development, described by Gray as a 'revelatory' case for the context of this research (Gray, 2009).

The scenario involved two interviewers (Researchers) posing a hypothetical device to be launched onto the home use market. In total, three respondents (Industrial Designers) were present and all provided significant contributions to the discussion. Two interviewers were used as facilitators of the case study to pose the scenario to the company.

**Scenario**

The scenario involved a hypothetical device (haemodialysis equipment) currently used by trained healthcare professionals (HCPs) in the hospital environment. The interviewers posing as the manufacturer of this device were looking for opportunities to diversify into the home use market. The manufacturer was therefore contacting this organisation to understand how the device could migrate into the home environment to be used by lay users. The manufacturer was specifically concerned about the changes in design requirements for the potential end users and use environment.

**Aim**

The scenario-based interview aimed to identify and develop a theoretical idealised practice towards successfully delivering a device into the home environment, including suitable considerations for the needs of end users.

The entire interview was recorded and later fully transcribed verbatim for analysis. The key themes of the discussion were reviewed and, where appropriate, have been used in the presentation of this case study.

The analysis of the transcriptions resulted in the development of the idealised approach presented in Figure 4.3. Once an initial design was constructed Figure 4.2, based on the interpretations of the two interviewers present, the process was later iterated with the design consultancy to ensure the final model presented within the case study was accurate and verified.

The following section presents the topics and themes discussed during the interview with the design consultancy. Following the presentation of the discussion, the unverified idealised design process is presented Figure 4.2. This following section describes how the initial design process was developed.

## 4.5 Discussion

The interview began with the introduction of the scenario to the design consultancy as per the methodology (Section 4.2.2). After the introduction, a discussion commenced on which users should be involved in the design process to ensure the

device could be used safely and effectively in the home environment. One respondent suggested that potential ‘lead’ or ‘expert’ users could be used as a starting point to identifying user requirements.

Note: ‘ID’ denotes Industrial Designer and ‘RE’ Researcher. Each Industrial Designer and Researcher was assigned a number for the purpose of this study and these are used in the reporting of transcripts below.

**{RE 1}:** *“…talking about user involvement and including lead users. How typically would that be done? And who would you go and speak to?” (Case Study #1).*

**{ID 1}:** *“That depends on the product. Sometimes we say lead users we don't really mean lead users…Sometimes we just mean expert users. There is a slight difference. An expert user being somebody who has used already similar machinery [devices]. (Case Study #1).*

According to the designers in this study, it was evident that the decisions upon who to involve within the design process was project dependent. This was to be expected as it is recognised that a consultancy would work on a variety of projects for different clients. The issue of expert or lead users however raises the question of lay user involvement in the design process more specifically. If expert users are considered as someone who has used similar devices previously, they therefore have prior knowledge of device interactions. Use errors experienced by lay users without that existing knowledge or experience of use therefore might not be considered by such an approach. Using expert or lead users alone would suggest that, under specific circumstances, representatives of end users might be used in place of the intended users of home use medical devices. The interviewers therefore explored this issue further with the company.

**{RE 1}:** *“Is that a heuristics rather than a data collection process? Would you use a proxy user who embeds lots of other users, so carers are an in-hospital [experienced] user for example? Would that be a shortcut?” (Case Study #1).*

**{ID 1}:** *“That wouldn't be what we’d recommend in the first instance. That might end up being a practical thing that happens...Within the budgets of the project if somebody doesn't have the scope to get to end-users. Ideally we would get to actual end users.” (Case Study #1).*

This indicates that companies might make use of representative users in circumstances when the constraints of the project would be restrictive for real end user involvement. The company alluded that this would not be advocated in an idealised approach however; certain clients might resist involving real end users on the grounds of time and costs. This suggests that both time and financial issues are perceived as potential barriers to involving users in the design of home use medical devices. This supports previous studies that have identified 'Time' and 'Cost' to be a challenge in the involvement of users in professional and home use medical device development (Cifter, 2011; Gupta, 2007; Martin *et al*, 2008). It could be argued that these issues are more pertinent in the current economic climate where costs are even more crucial to the commercial success of a company.

On the other hand, one of the arguments to support the involvement of real end users within the design process is the potential financial and reputational damage to a company for an expensive device recall (Money *et al*, 2011). Advocacy for following usability principles with respect to involving users early and often however would appear to be ignored by some manufacturers and clients in this company's experience. In spite of a leading consultancy advocating the involvement of real end users, their clients are still keen to look for shortcuts or cheaper alternatives to designing medical devices for the home.

On this topic the interview turned towards attempting to reach a theoretical acceptable level of device usability, should such a level exist. Having identified that a manufacturer might make a commercial decision how to involve users and who to involve in the design process of a home use medical device, the researcher was interested in how such a decision is made.

**{RE 1}:** *"Do you have a process, on the one end we've got the idealised state of delivering what the user might like and the other end we've got the purely functional end of just delivering what the clinical requirement might be and somewhere in between we'll legitimise it…. Is there any specific guidance that we can use in our processes or we could use with you in our process to steer us through the right course between these two extremes and still meet this obligation?"(Case Study #1).*

**{ID 2}:** *"In terms of usability?" (Case Study #1).*

**{RE 1}:** *"Yes, because obviously it is a fairly open ended bucket that we could pour money into and make it nicer and nicer and nicer but it already does what is says on the tin. You know, why should we spend that money?" (Case Study #1)*

**{ID 2}:** *"…There's a core in the middle that is about safety and efficacy. That's the bit you have to satisfy….Outside of that core becomes a commercial decision then as to how much or how little or efficiently you apply something which allows this to commercialise [the device]". (Case Study #1)*

The interview indicated that in spite of home use medical device development representing a field of strong moral arguments for exemplar design practice, the commercial realities of operating as a business are paramount to manufacturers. Highlighted in the quote above, many of the clients this consultancy work with essentially make a 'commercial decision' on how many users to involve, furthermore who should be involved, not necessarily based on idealised practice or design principles, but on what will make a device safe enough to sell. It suggests that a manufacturer will fulfil the essential safety requirements of a medical device however the involvement of users in that process and more specifically the application of usability principles are based on the commercial nature of the company. As a practice of designing devices to be used in the home by a multitude of potential users this represents a detrimental finding for end users. It would suggest that users of devices in the home are required to 'make do' with a device that is regarded as good enough; not from an understanding of end user needs but rather a commercial decision to draw a profit.

In light of this, the case study turned towards identifying other potential barriers and or challenges to applying usability principles towards home use medical device design. In particular, the focus of the discussion addressed whether in practice the principles of usability and 'user centred design' can realistically be mapped onto the model and requirements for home use medical device development. The following section presents a list of some of the preliminary challenges identified through conducting this case study.

## 4.6 Challenges to Applying Usability Principles to Home Use Medical Devices

The literature review identified existing research that has referred to the challenges of home use medical device design (Cifter, 2011; Gupta, 2007). The context of this case study and thesis is focused primarily on the challenges to applying usability principles and involving users in the design process specifically.

The following section introduces some of the preliminary challenges towards user involvement identified in this case study that provide a foundation to research question two of this research.

Table 4.1 presents the challenges identified in collaboration with the consultancy in this study. Some of the issues identified support the previous work conducted by Abdusaleem Cifter and Suresh Gupta (Cifter, 2011; Gupta, 2007;). The table shows, each challenge cited by the company alongside a description as to how it specifically implicates or could influence a company to adopt an alternative approach to that of one advocated by usability principles in documents such as IEC BS EN 62366:2007.

It is worth noting here that the challenges identified in Table 4.1 are the perceived challenges from the point of view of the designers in this case study. The findings are based on the company's previous experiences with clients and projects. The findings are therefore enriched with the knowledge, understanding and expertise of the respondents of this study and are not based on the potential bias and subjective opinions of the researchers conducting the interview. All of the findings and views expressed in this study were verified with the consultancy prior to writing this report.

In light of this it is not appropriate for generalisations to be made on these findings from a single, holistic case study. Rather the preliminary challenges identified in Table 4.1 act as a foundation from which future studies can explore in a quantitative manner with a wider target audience. In order for this research to progress in accordance with its methodology and to answer research question two it is necessary to identify whether the wider population experiences such issues.

Future studies should explore how these challenges relate to one another in terms of weighting to see if any particular factor is more challenging to overcome than others from a commercial perspective. This could then lead to the identification of potential

routes to offer best value in supporting the involvement of users and application of ‘user centred’ principles for home use medical device design.

In total seven different challenges to applying usability principles, including the involvement of end users, were identified for home use medical devices in the case study. Table 4.1 outlines the consequences for design practice by designers and developers who avoid the advocated principles for usability.

**Table 4.1: Identified Challenges to applying a User Centred Approach to Home Use Medical Device Design.**

| Challenge | Description | Consequence |
|---|---|---|
| **Common Language** - A disparity of language exists amongst the design community with respect to usability for medical device design. | Precious time is lost during the development of a device due to a lack of common language between stakeholders in the process. | User research is often interpreted as a marketing research activity. In the medical setting, healthcare professionals avoid participation on the basis that their perceived involvement makes them liable. |
| **Ethics** - The task of gaining ethical approval for user research during development | Gaining ethical approval to conduct user studies can be a lengthy process for companies, particularly where the National Health Service (NHS) is concerned. | Companies avoid conducting studies that require stringent ethical approval and look for alternatives to user research. |
| **Finance** - The costs involved to implement a 'user centred' approach to medical device design. | There is an industry wide perception that all user research activities are hugely expensive. | Companies look for cheaper alternatives to identify the needs of end users. |
| **Recruitment** - The task of gaining participation from end users for user studies. | Considerable time and money is spent on locating and recruiting real end users for user studies. | To compensate companies look for proxies or representatives of the end user. |
| **Shared Understanding** - A lack of understanding about the methods and principles of a 'user centred' approach to medical device design due to different backgrounds and education. | Considerable time and money is spent on educating stakeholders in the design process to attain a level of shared understanding. | Designers and Consultancies have to educate companies and stakeholders on the benefits of a 'user centred' approach and the principles involved slowing the development process. |
| **Technical Difficulties** - The intrinsic difficulties of working in teams to achieve a desirable outcome. | Time is spent to achieve a common ground. Each stakeholder in the process brings his or her own perspective and bias, which creates its own challenge. | Marketing and Finance ultimately have the final say in many companies, which often results in cost driven practices taking priority. |
| **Time** - The time associated with delivering a 'user centred' approach to medical device design. | Time to conduct user research studies is perceived to be extremely resource intensive. | Companies often accept the quickest route for development to keep the cost and time to market down. |

## 4.7 Step Factors for Improved Usability of Home Use Medical Devices

Behind the rise in use of home use medical devices, the case study revealed a range of drivers, referred to by the company as step factors, increasing the demand for improved usability. Their presence within this case study was an unexpected outcome of the interview however the nature of the questioning and discussions happened to lead to their influence on design. Note the step factors raised by the company do not refer to the rise in demand for home use medical devices, as described by Gupta, but more specifically to the rise in perceptions or expectations from users of such devices (Gupta, 2007).

The case study revealed that historically home use medical devices have been a technology driven industry. This finding is supported by previous research, which has addressed the implications for design in professional and home use medical devices (Gupta, 2007; Martin *et al*, 2008; Money *et al*, 2011).

Figure 4.1 presents the existence of push and pull factors upon designers and developers of home use medical devices that have raised the demand and expectations for improved usability.

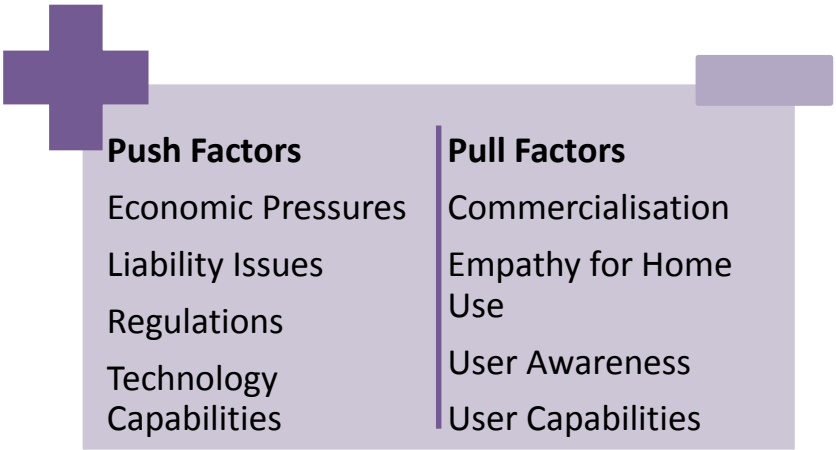



**Figure 4.1: Step Factors for Improved Usability of Home Use Medical Devices.**

A ‘Push’ factor in the context of this study refers to the forces and consequences facing devices of poor usability that ultimately may compromise patient safety. The consequences of a poorly designed medical device have been identified to compromise patient safety and lead to use errors (Ward & Clarkson, 2004; IEC 62366: 2007; ANSI/AAMI HE75: 2009). In contrast ‘Pull’ factors upon manufacturers refer to a rise in expectations by device users specifically and represent the demand for improved usability of home use medical devices.

**Push Factors**

**Economic Pressures** – This factor refers to the financial consequences to a manufacturer for placing a faulty device with the potential to cause harm onto the market. As was seen with the Exubera device described in Chapter Two the cost to medical device manufacturers can be in the £billions. The case study indicated that there is an increased emphasis in recent times upon manufacturers to consider and deliver devices of improved usability that do not compromise patient safety,

**Liability Issues** – This factor refers to liability of a manufacturer should anything go wrong with a medical device once it has been launched onto the market. Chapter Two identified that the responsibility under medical device regulation is upon the manufacturer who places a device onto the market. The manufacturer has a right to ensure that all devices placed on the market are safe and usable for the target population. This represents a considerable push upon manufacturers for improved usability of devices intended for the home environment.

**Regulations** – The governance of medical device regulation worldwide provides stringent requirements for designers and manufacturers to develop devices that are first and foremost safe and effective. With continuous updating of the requirements within the regulations in line with the rapidly changing technology capability, the push for improved device usability looks set to continue into the future. Chapter Two described how the usability engineering standard for medical devices (IEC BS EN 623366:2007) is harmonised under the current Medical Device Directive (MDD). Therefore manufacturers have a moral obligation to consider usability throughout the design and development process.

**Technology Capabilities** – Widely regarded as one of the leading factors towards medical device development in general. The sophistication, availability and capability of technology are ever increasing and consequently medical devices are more accessible and affordable today than they have ever been. The case study indicated that the capabilities of technology from competitor products, particularly for 'consumer medical devices', are raising the demand for improved devices and usability within the home environment.

**Pull Factors**

**Commercialisation** – The recognised shift towards commercially available home use medical devices (i.e. retail), referred to by the FDA as 'consumer medical devices', was indicated by the company as pull factor upon manufacturers to deliver devices of improved usability (FDA, 2013). The company opined that some manufacturers now seek to offer improved usability in home use medical devices to gain competitive advantage in the market place. This competition amongst manufacturers was identified to raise the standard of usability for home use medical devices.

**Empathy for Home Use** – The case study revealed that there is now an increasing awareness of the ageing population and requirement for home healthcare globally. In light of this the company opined that there is an empathic understanding from manufacturers to deliver devices that cater for the needs of vulnerable users within the home environment.

**User Awareness -** According to the design consultancy in this study it was indicated that participants for user research were becoming increasingly aware of the technologies and devices available to them. The company opined that as users become increasingly educated in the use of home use medical devices there is a pull upon manufacturers to deliver devices that offer greater flexibility in use. Improving the usability of devices to cater for the needs of such users was identified by the consultancy as fundamental as user groups become more experienced and diverse.

**User Capabilities** – The final pull factor identified by the company referred to the capabilities of users specifically. The company posited that, as users are becoming increasing aware and educated on the use of home use medical devices their

capabilities from interacting and using such devices improves. In light of this there is a demand for increasingly sophisticated and usable devices to be used in the home environment in the future.

Both types of factor have a varied degree of influence over the commercial decisions made by manufacturers to invest in usability for home use medical devices. While the extent to which these factors influence manufacturers cannot be drawn from this study, it was highlighted that the pull factors facing manufacturers of home use medical devices has seen a rise in recent years.

The designers interviewed for this study highlighted that user expectations with respect to not just device capability and performance but furthermore usability have seen a significant rise in demands based upon the capabilities of consumer technology devices.

One designer in the study said:

**{ID 2}:** *"…people have come to us because of expectations of android phones and apple… So there is a little bit of a pull expectation from that you could argue". (Case Study #1)*

This suggests that as users become more experienced with technology and aware of the capabilities of technology available to them, their expectations are carried through to what other devices should and must be able to do. This is not only limited to medical devices. Users of consumer products and other technologies have an expectation of technology capability including how such devices operate (e.g. affordances). These experiences are then expected in similar or related technology and consequently raise the expectations of device users.

The company opined that the commercialisation of home use medical devices with respect to the increasing number of devices that are now bought by users themselves raises the issues of desirability and aesthetics for home use medical devices. According to the company in this study, manufacturers of home use medical devices now target users to purchase their device over brands available on the shelves. A shift towards commercial home use medical devices marks significant implications for design. The company indicated that this trend looks set to continue into the future

as users will have increased choice in the selection of devices they use for treatments and diagnosis in the home environment.

The step factors identified within this case study are specific to the company and their experiences with manufacturers and clients of home use medical devices. Only through further exploration with a larger sample of practitioners could such findings be generalised to a wider population.

These challenges represent preliminary answers to research question two of this thesis. In order to successfully answer this research question the challenges towards user involvement in home use medical device design will be explored with design practitioners in more detail. For more information on the identified challenges within this thesis please refer to Chapter Seven.

Following the discussion on the challenges and step factors towards applying usability principles for home use medical devices, the interview turned towards the development of the idealised design process.

## 4.8 Theoretical Idealised Design Process

The design process shown in Figure 4.2 presents the initial design process that was developed after the interview process. Once all of the data from the interview was collected and transcribed the process was based on the transcripts, sketches and information recorded during the interview.

The initial design process was later evaluated with the consultancy to verify the model and ensure the interview data had been interpreted correctly A copy of the verified idealised design process is presented in Figure 4.3 as a conclusion to this first case study.

Chapter two described the French Model to design whereby the process begins with an identified problem or need (French, 2010). The idealised process indicated by the company in this case study shared this beginning to the design process. For medical devices a need or problem may be identified through a range of sources such as a new technology capability, a modification to an existing design or individual needs of patients.

Once a need has been identified there is an exploratory phase at the beginning of the process to understand the context of the problem. This is typically conducted concurrently with the next step in the process 'User Profiling'. According to the company these two stages at the beginning of the design process are essential in adopting a 'user centred' approach to home use medical device design. The process shown in Figure 4.2 describes the early phase of the design process as consisting of user research, feasibility studies and early stage formative testing. The evidence collected from this early feasibility research informs a fundamental step in the process of professional and home use medical device design 'Usability Goals'.

**{ID 3}:** *"At the very beginning you would set yourself some usability goals and you might set that based on benchmarking previous products, existing products or ideals of what your marketing research has indicated." (Case Study #1)*

Usability goals or 'usability objectives' as referred to in the American National Standard are defined quantitative metrics that are applied during usability testing to provide test acceptance criteria (ANSI/AAMI HE75:2009). Typical examples include task completion times, success or error rates and user satisfaction goals. These goals are often established from early stage feasibility studies that might include task analysis or dummy runs conducted by the designer themselves. The process here assists the designer in establishing at an early stage the potential for use errors to occur. One designed explained:

**{ID 3}:** *"Try to go through the steps of somebody doing it in their home… To see where users are likely to fall over, have difficultly." (Case Study #1)*

Establishing usability goals early in the design process is critical to ensuring that iteration can occur during the summative testing phase of the design process. This will assess whether the goals have in fact been met with the final design. Unsurprisingly, ANSI/AAMI HE74 and HE75 by the FDA recommend that manufacturers set usability objectives as a best practice (ANSI/AAMI HE75:2009). These usability goals are then built into the design specification for the final design.

The early collation of data for user requirements and usability goals all form part of the technical file for a medical device. An integral part of this document is the

consideration and ultimately regulatory assessment of the Design Inputs and Design Outputs.

**{ID 1}:** *"The whole point is that the technical file is about Design Inputs and Design Outputs. Design Inputs are what this product needs to be, what you decide it is and the Design Outputs are the all the things that deliver those Inputs if you like and it is basically just to check them through. So you've got a PDS, you would typically conduct a risk analysis." (Case Study #1)*

During this pre-concept phase and once a product specification has been clarified there is then a need to consider the issue of risk. According to the company in this study, many companies fulfil this requirement in the form of a Failure Modes and Effects Analysis (FMEA).

**{ID 1}:** *"That FMEA allows you to go from the top down and look at it as a big system and also break it down by component, sub-assembly by the journey maps if you are a doing a user FMEA but it basically allows you to break down these things, identify all the possible risks that you can potentially think of…" (Case Study #1)*

In an idealised approach this would typically be conducted with three different FMEA's.

**{ID 1}:** *"My recommendation to you is that you should be doing fundamentally three different forms that all linked up together. If you come from a design background you would intuitively do this. So there is the Design FMEA, as you design the product you are looking at the typical technical risks so component failure and what the implications of that component failure are. There is a user FMEA where you are looking at use error, because they have changed the law now where it has gone from user error to use error. The difference being if the user gets it wrong, it is not the users fault anymore it is your fault for not forecasting where the user will get it wrong in the first place. The final one would be a process FMEA which is just ensuring that how you make it comes out the same as your exemplar product that you have designed." (Case Study #1)*

The culmination of these early stages defines the design inputs that ultimately form an essential part of the verification and validation stages in medical device development. As was described in chapter two of this thesis, verification is about

asking the question "Are we building the right thing?" through the comparison of design inputs and design outputs (Alexander & Clarkson, 2000). In comparison, validation refers to the wider process of design and user needs, asking the question "Have we built the right thing?" (Alexander & Clarkson, 2000). According to the findings of this study however, the consideration of the user within this process is where many companies fall short. The company in this study advocate the involvement of users within the design process to gain insights into actual device use.

**{ID 1}:** *"Verification is that it does what it says it does and validation is that it needs to run through the requirements basically. But if you apply that back across to users you can start identifying user errors as well and this is where a lot of people get missed out. So with user error there could be a real problem with this, if you have come from a non-medical background as well. Home use it could be anyone of us. How does the user know how to use it? There are a number of ways you can approach that. The way I would recommend is that you actually get some users involved in this process somewhere." (Case Study #1)*

At this stage in the process concepts start to be explored based on the early requirements capture in the design process. Informing the creation of these concepts however requires due consideration for how the insights gained from users are translated into design requirements.

**{ID 3}:** *"So it's not sitting down with users and saying what would you like us to create. It is sitting down with the user to understand; what's going on, what the user environment is like, what their daily routine is like, how do they interact with the technology that existed, and trying to use that information to develop enough empathy and understanding of the situation to come up with a solution." (Case Study #1)*

Using the information gathered through early studies and FMEA type analysis, prototypes or simulations of concepts are then created and tested with real end users. This stage will often call for repeated iteration of conceptualisation based on testing with the identified user population until a detailed design is selected for the evaluation phase. This is typically where the regulatory ramp up for approval is conducted and validation in the form of summative testing would occur. This stage in

the process is about the company ensuring that the resultant device of the process successfully meets its aims. As stated in chapter two, this forms the critical component of the regulatory approval process. Ultimately the MHRA in the United Kingdom will base the decision on whether a device is suitable to launch on the validation of a medical device.

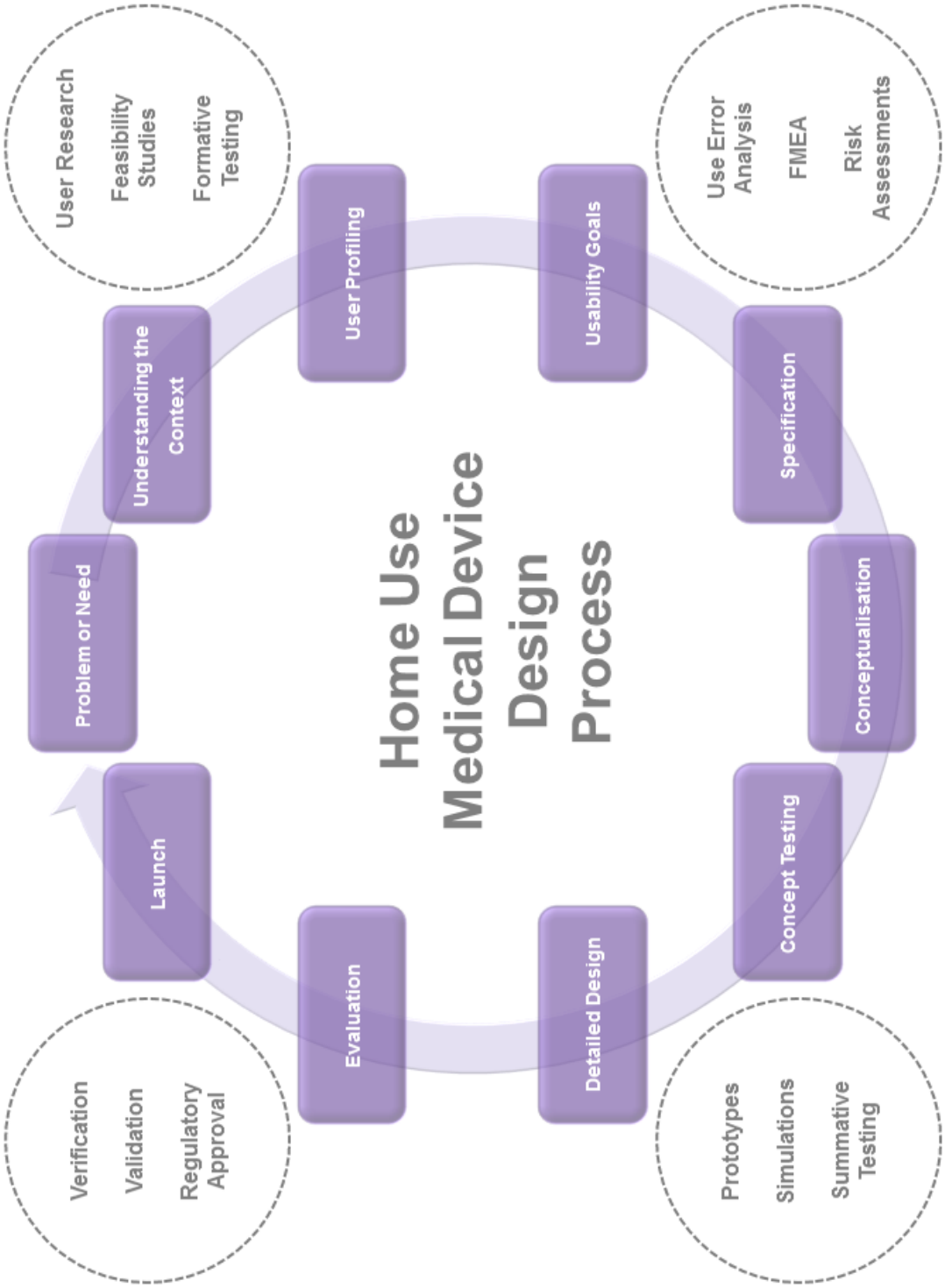



**Figure 4.2: Theoretical Idealised Design Process for a Home Use Medical Device. (Non-verified Model).**

## 4.9 Verified Idealised Design Process

Following the development of the initial design process the model was referred back to the design consultancy to verify the stages and components. A copy of the verified idealised design process for a home use medical device is presented in Figure 4.3. Evidently, the process itself changed quite markedly from the initial design process shown in Figure 4.2. The following section outlines the amendments proposed by the company during verification.

**Features of the Verified Idealised Design Process**

**Formative Testing -** The first change made on verifying the process concerned the timing of formative and summative testing within the design process of a home use medical device. In the initial design it was stated that formative testing would begin in the early stages of the design process, however the company opined that this is typically not the case. Figure 4.3 demonstrates that formative testing would occur during the verification process or 'Verify' stage. According to the company, this process would typically involve 5-8 users from each homogenous user group that the device itself would be targeting. The earlier profiling stage outlined in the 'Identify' phase of the process is where the range of potential users would be established and defined for future formative studies. The figure of 5-8 users per homogenous user group is based on the guidance of both IEC BS EN 62366:2007 and ANSI/AAMI HE75: 2009 that states testing with such numbers will see patterns emerge. For an idealised approach however the company within this study suggested a more comfortable range of users for a formative study would involve 10-12 users per each homogenous user group.

**Summative Testing –** According to the company the summative testing phase was located in the correct stage of the design process presented in Figure 4.2, however verification of the process revealed more detail here too. Summative testing relies upon sample size based error rate and specific acceptance criteria that again are set early in the design process with usability goals and specifications. According to the consultancy, this phase of testing would typically see 16-20 users from each homogenous user group. For instances of high risk devices, such as infusion devices

for example, the company opined that samples of over 24 users per homogenous user group would be involved in summative testing.

**ISO 14971:2007 Medical Devices: Application of Risk Management to Medical Devices –** On presenting the initial design process to the consultancy it was expressed that the key element of risk should be more explicit within the idealised design process. The company highlighted that the application of risk management throughout the design process of any medical devices is an essential requirement for regulatory approval. One respondent explained how the design process itself is largely based on the principles and stages involve in the risk assessment process for medical devices. Thus, Figure 4.3 demonstrates this mapping of the risk assessment procedure onto the idealised practice design process itself. According to the company an idealised process has to take into account the requirements of ISO 14971:2007 and therefore each stage within the design process supports for the risk management process of a medical device. The stages in the design process use two-way arrows to demonstrate the iterative nature required in this process. The company indicated that the identification of one risk may reveal new risks to device users therefore an idealised approach must account for design iterations with device users.

**Identify, Specify, Verify, Validate –** Finally, using all the information collated in the final design it was decided that the process would be broken down into four stages, namely: Identify, Specify, Verify and Validate. The decision to classify the process into four specific stages was largely to simplify the process itself. Evidently there are a number of key decisions that need to be made within the design process of a home use medical device. The four stages in the verified model simplify the legibility of the key concepts within the design process. The choice of terms is based on the importance and significance of end users and their requirements within the design process.

The early stage calls for the identification of the users themselves through profiling and feasibility studies. With an understanding of the problem and potential users one can then begin to develop usability goals and the necessary Product Requirement Specification (PRS) and User Requirements Specification (URS) that form the 'Specify' stage of the process. Conceptualisation can then begin which leads into the verification stage of the process. This is where the process calls for formative testing

with users to ‘verify’ that the design outputs meet the design inputs. Finally the process moves into the validation stage with the final design ready to conduct summative testing with real end users and the attainment of regulatory approval.

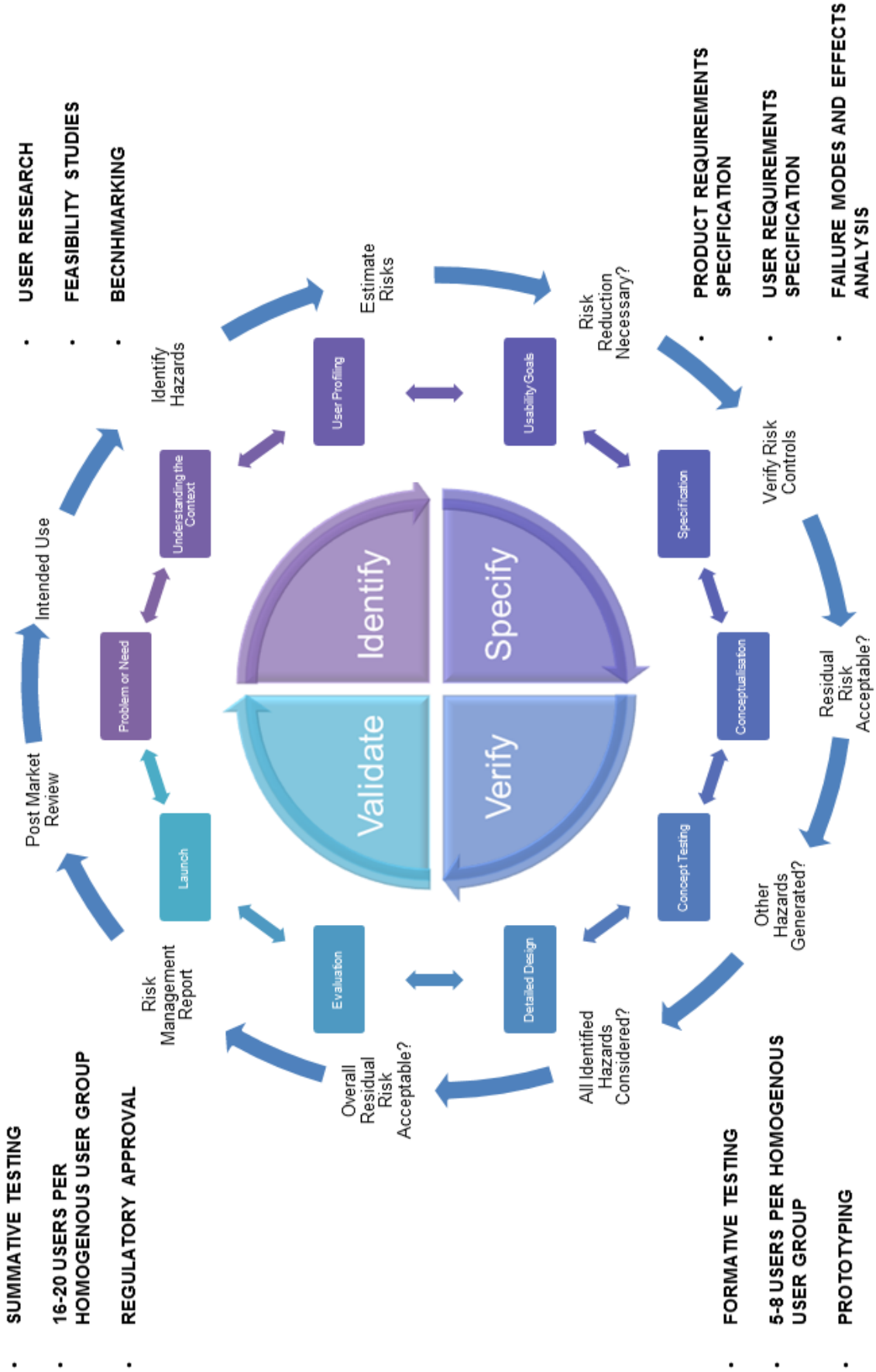



**Figure 4.3: Theoretical Idealised Design Process for a Home Use Medical Device (Verified Model).**

## 4.10 Conclusion

This chapter has revealed a significant amount of information about the design of home use medical devices. The study indicated some of the preliminary challenges faced by manufacturers towards adopting usability principles in the design of home use medical devices. Early answers to research questions one and two have been identified and now require further study with a wider population to ascertain whether such issues are industry wide.

The study developed a theoretical idealised design process towards home use medical devices in collaboration with a leading UK based design consultancy. The verified design process includes information relating to the involvement of users within the design process and management of risk throughout.

To summarise this chapter a number of conclusion are presented below:

- Seven Preliminary challenges to designing usable home use medical devices were identified and discussed. The challenges include: Common Language, Ethics, Finance, Recruitment, Shared Understanding, Technical Difficulties, and Time.
- A series of step factors driving the rise for improved usability of home use medical devices were identified. These step factors were identified as either: Push Factors or Pull Factors.
- Push Factors included - Economic Pressures, Liability Issues, Regulations and Technology Capabilities.
- Pull Factors included – Commercialisation, Empathy for Home Use, User Awareness and User Capabilities.
- A theoretical idealised design process for home use medical devices was developed and verified in collaboration with a leading UK Design Consultancy.

Chapter Five presents the second case study of this research that combined with this chapter forms the research clarification of the thesis. Following the research clarification, Chapter Six will present the first descriptive study of this research.

# Chapter 5
# Case Study Two: A Stakeholder Network

The previous chapter revealed seven preliminary challenges to the adoption of usability principles in the design of home use medical devices. The company in the case study indicated that the involvement of end users (e.g. patients) in the design process is, to some extent, defined by the various stakeholders. Chapter Four revealed that a lack of common language and shared understanding amongst individuals within the design and development process were a challenge to implementing usability principles. The following chapter explores this issue further with a home use medical device manufacturer to establish the range of individuals involved in the process of delivering a home use medical device to market.

## 5.1 Introduction

It is recognised that there are myriad people with different requirements involved in the delivery of home use medical devices (Gupta, 2007). In 2002 the head of the medical department at PDD, a product innovation consultancy based in London, described the importance to understand the needs and requirements of all the stakeholders within the process in order to design a successful medical product (EMDT, 2002). From an end user perspective the final product will ultimately be defined by the requirements of the stakeholders within the design process. Therefore, the potential for 'contradictions' between stakeholders is recognised to seriously add to the complexity of successfully delivering a medical device to market (EMDT, 2002). Cynically, it could be argued that any product whether medical device or otherwise is the result of compromises made throughout the design process. The real challenge for development is delivering a device that will ultimately benefit the end user whist satisfying the requirements of all necessary stakeholders.

The following chapter presents a case study from the perspective of a buyer of technologies for the home use medical device market. The company in this case study act as a distributor and supplier of home use medical devices to the National Health Service (NHS) in the United Kingdom (UK).

## 5.2 Rationale

The purpose of this case study is to build upon the researcher's understanding of the home use medical device industry and to ascertain a context for the thesis as a whole. The chapter forms the second component of the research clarification as part of a design research methodology (DRM) approach.

The study is focused upon the development of an exemplar stakeholder network for a supplier and distributor of home use medical devices in the UK. Understanding the potential stakeholders of a home use medical device company will reveal insights into the relationships and networks between the different parties involved in delivering of a device to the patient. This case study aims to ascertain the compromises or challenges that exist between stakeholder relationships in attempting to deliver usable and understandable home use medical devices.

This chapter builds on the findings of the previous chapter by reviewing the design and development process more abstractly from the perspective of different stakeholders. The stakeholder network developed within this chapter will provide further insight into the individuals involved in the delivery of a home use medical device to patients.

In doing so the following case study will provide answers to the following questions:

- How do different stakeholders interact with one another?
- What influence, if any, do these stakeholders have on the design process?
- Where does the patient sit in this process and how are their needs considered?

## 5.3 Methodology

A semi-structured interview was conducted with a home use medical device distributor and supplier based in the United Kingdom. The purpose of the study was to identify an example of a stakeholder network for home use medical devices

including the influencing bodies or individuals that affect the selection, design and delivery process.

The company in this study was identified and recruited through a medical device conference in the United Kingdom. As a distributor and supplier of home use medical devices to the diabetes market, the company were considered suitable representatives of the target population of this research. The profile of the company is presented below. For reasons of confidentiality, the name of this company will remain anonymous.

| | |
|---|---|
| **Number of Employees:** | 35 |
| **Annual Turnover:** | £5 Million |
| **Devices Developed:** | Drug Delivery and Monitoring |
| **Context of Use:** | Home and Professional Use |

For the purpose of this case study the company were asked to refer to their home use medical devices specifically. As the aim of the study was to ascertain the various stakeholders that interact with an exemplar home use medical device company, a semi-structured interview protocol was developed. The questions were structured to identify the various stakeholders involved and the nature of their relationships. The interview was approximately one hour in duration and covered a range of issues.

The interview was recorded using an audio-recorder and later fully transcribed verbatim. Analysis of the recorded data resulted in the development of the stakeholder network in collaboration with the company. Two interviewees were present from the company at interview and the researcher acted as the sole interviewer. Each interviewee (supplier) was assigned a number and these are used in the reportage of the interview transcripts.

During the interview notes, diagrams and sketches were made in discussion with the interviews and where appropriate these are used throughout the presentation of this case study.

## 5.4 Discussion

It is recognised that stakeholder requirements and relationships add to the complexity of delivering medical devices to market (EMDT, 2002). The company in this case study indicated that a hierarchy amongst their stakeholders influenced the consideration and capturing of patient user needs. A copy of the stakeholder network from the perspective of the company in this case study is presented in Figure 5.1.

The network developed applies to devices used for drug delivery and disease management for diabetes care in the United Kingdom. The company in this study predominantly operate in this market and therefore the process does not relate to other devices or stakeholders.

According to the company, stakeholder relationships can be interpreted from a top-down or bottom-up approach. The nature of this approach is defined by the specific device or innovation and how the concept is conceived. The company described that a bottom-up approach refers to a concept or idea that is specifically identified from a patient need and subsequently filtered upwards towards a manufacturer. This could be through a simple request to a healthcare professional at primary care or practice level that then might filter up to a manufacturer.

Alternatively, and in the experience of the interviewees' for this case study, this process would more typically be technology driven and therefore 'sold-down' to the patients. The adoption of usability principles including the involvement of users for the participants in this case study it was indicated that user engagement would typical stop at the nurse level within the stakeholder network.

**{S1}:** *"The bottom-up approach is effectively where you would go to the nurse stakeholders and drive change at the very local level". (Case Study #2)*

In light of this the interviewees expressed that they would not typically attempt to drive change from the patient level upwards. Much more likely would be the involvement at the primary care level, which was considered less time intensive. The company indicated that involvement of healthcare professionals (HCPs) provided access to specialist knowledge about patients and their needs. This was highlighted in

the quote above whereby a bottom-up approach to user involvement was considered to begin with the nurse stakeholders as opposed to the patient themselves.

This approach would suggest that there is a hierarchy amongst the stakeholders in home use medical device development. This finding supports the work of Money *et al*, who also found that a hierarchy exists amongst the medical device design field (Money *et al*, 2011). Money *et al*, in their study on manufacturers' perspectives towards involving users in the design process, found that some manufacturers believe the needs of patients do not originate from the patient themselves (Money *et al*, 2011). They found that manufacturers perceived the needs of patients to be better articulated through a 'hierarchy' of health professionals including surgeons and clinical champions (Money *et al*, 2011).

The stakeholder network in Figure 5.1 demonstrates the nature of this hierarchy for a drug delivery or diagnostic device used in the home environment. Evidently, the patient in this particular network has little influence on the device design and ultimately choice in the device they use. This is primarily the result of the hierarchy in place for such devices. According to the company in this case study diabetes devices (e.g. insulin pens) used by patients in the home are 'sold down' to patients.

The interview protocol explored why involving patients was not considered as valuable as the involvement of healthcare professionals in the selection and delivery of home use medical devices. According to the company it was felt that working from the patient need upwards was deemed a much harder sell to investors and subsequently much more difficult to implement change when selling a medical device into the NHS in England.

**{S2}:** *"The problem with that is it becomes hugely time intensive, because you are literally, you know, granulation is massive. The number of people you have got to try and talk to." (Case Study #2)*

The company felt it was too time intensive to talk with what was considered large numbers of patients to have an impact on the use, uptake and design of a device.

**{S1}:** *"If we do it on the…patient level we have a limited number of patients that will potentially change from product X to product Y and that takes a long time." (Case Study #2)*

In light of this, the company often preferred to approach the launch of a new device through avenues with much wider populations of potential users rather than identify specific needs or requirements.

**{S1}:** *"We like to work in population units of 5 million…Its just literally there are 5 million people that live in West Yorkshire for example and out of that population there are 200,000 diabetics or whatever it may be. So if we can influence on that level then we can potentially capture 20-30% of the business. That is the easiest way for us [to drive change]." (Case Study #2)*

The company indicated that influencing patient selection and use of their devices required a different approach of delivery. According to the company a top-down approach involving influential or 'key stakeholders' is more powerful in changing the devices that patients use. It was expressed that such an approach would provide more 'clout' to driving change in the NHS and consequently was the approach to medical device delivery that was more typically adopted by buyers and suppliers in the home use market.

Interestingly, the involvement of users in the design process for this company referred much more specifically to marketing research as opposed to user needs research. The case study indicated that the company were driven by financial and commercial decisions as opposed to identifying and understanding the needs of device users specifically. This consequently influenced the practices and stakeholders that were involved throughout the delivery of a device to patients.

The company explained how more typically their business, including the design and selection of devices they provide, was driven by a 'top-down' approach. In the context of this study, the top-down approach would typically begin with the Clinical Commissioning Groups (CCG's) formerly known as Primary Care Trusts (PCT's) in the UK until April 2012.

According to the company, the stakeholders represented at this level would typically include Chief Financial Officers (CFO's) and Chief Executive Officers (CEO's). The case study indicated that the company in the delivery process of a medical device would occasionally consult these stakeholders. More typically the company would

consult the head of medicines management at this level within the stakeholder network shown in Figure 5.1.

**{S2}:** *"If you are talking about stakeholders in there your sort of 'go to' person would be the head of medicines management…and if you like at the senior level here [CCG level] you would have people like chief financial officers, these are obviously hierarchically above them…and also occasionally we would engage with chief executive officers (CEO's)."(Case Study #2)*

The company revealed that they would engage with CEO's if they encountered any resistance at the medicines management level and would therefore approach individuals higher within the hierarchical process of medical device delivery to overcome such resistance (See Figure 5.1).

**{S2}:** *"And that is normally if we have got a resistance here [medicines management level]…We would go and talk to these guys [CEO's] because they are more interested in the money…at the PCT level these are normally the 'go-to' gatekeepers." (Case Study #2)*

At the most senior level of the hierarchy, the CEO's and financial officers were very much considered the 'gatekeepers' to the marketplace for the company. By consulting these stakeholders, manufacturers were much more likely to receive the backing by medicines management which would filter down to the acute hospital trusts and primary care.

**{S2}:** *"Some PCT's will then drive that change…That message will then go out to practices and that can be directly from the PCT, which will be a letter. Sometimes it can be just a website…." (Case Study #2)*

The company explained that manufacturers have a responsibility to establish relationships with the stakeholders shown in the stakeholder network. According to the company this is fundamental if a manufacturer wishes to have an impact on the uptake of a medical device. This refers not just to the patients themselves but also by the sector as a whole, including healthcare professionals for example. In the context of this case study, the company explained that prescribers of their devices were the gateway to patients.

This case study indicates that the delivery of home use medical devices to patients is a hierarchical process. The company in this study opined that senior stakeholders (e.g. Financial and Executive Officers) are the most influential stakeholders in driving changes in devices used by patients in the home. It was not considered part of the scope of this research to address the requirements of each of the stakeholders identified in this study. The study suggests however that there could be value as part of further research to promote advocacy of usability research to senior executives and board members. According to the company in this case study these individuals represent the key influencers in the device design and delivery process. If ‘user centred’ principles are addressed at a senior level, the findings of this study would suggest that such practices could be filtered down the hierarchy to offer benefits to the end users.

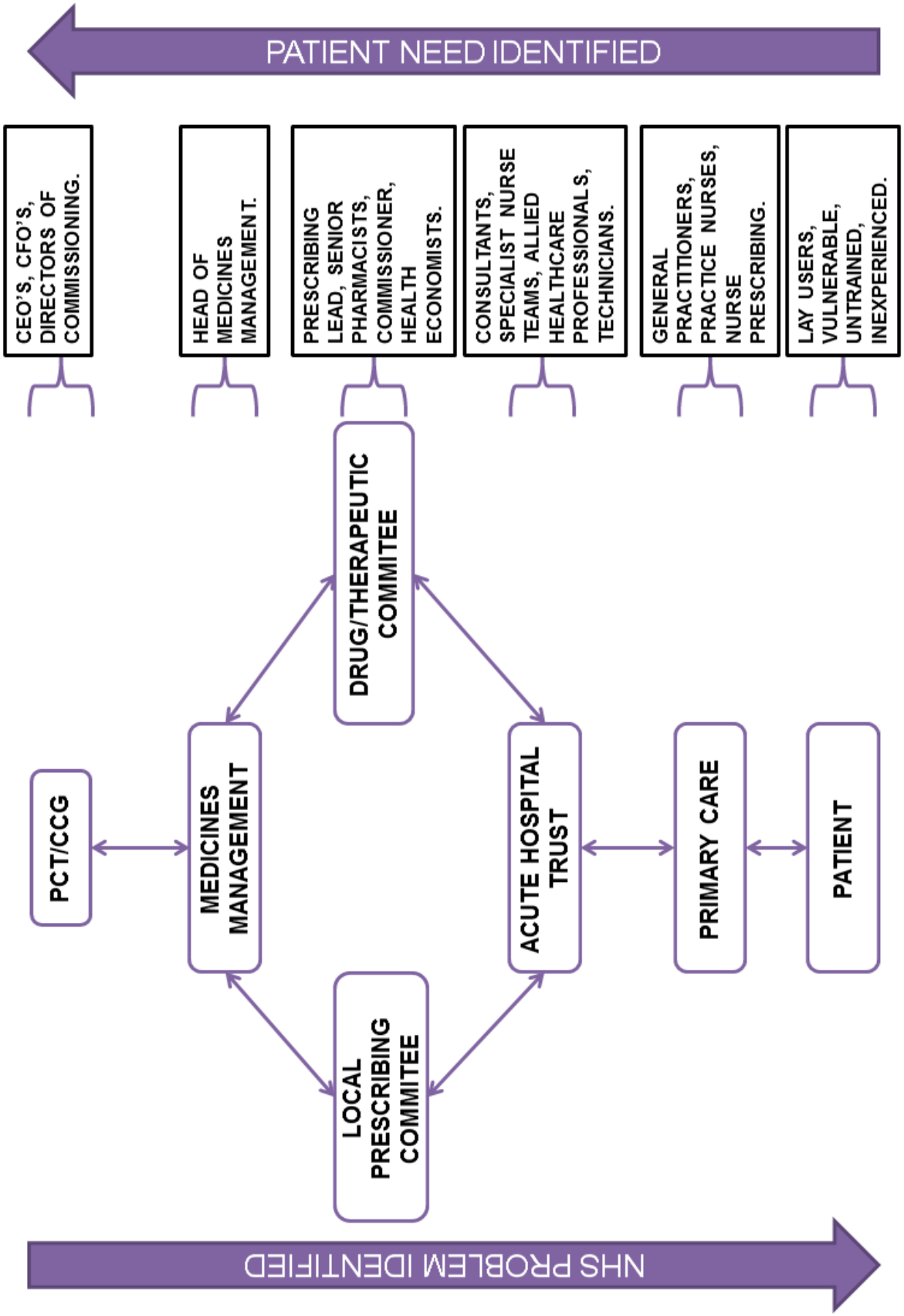



**Figure 5.1: An Example of a Home Use Medical Device Stakeholder Network.**

## 5.5 Conclusion

This chapter has revealed an example of a stakeholder network for a distributor and supplier of home use medical devices in the UK. The company's perspective provides a unique insight into the different stakeholders in the delivery process of a device for diabetes management in the home. The findings of the study support the work of Money *et al*, in that the study revealed an emphasis towards consulting senior healthcare professionals rather than addressing the preferences of patients specifically. As with the previous chapter, the case study presented here has revealed that the home use medical market is largely commercially driven. The company in this study indicated that devices are more often 'sold down' to patients as opposed to identifying the needs of users and iterating such information with designers and developers.

To conclude the main findings of the case study are summarised below.

**Main Findings:**

1. The case study has highlighted the power of a top-down approach whereby the use of a particular device is 'sold down' to the patient. Where real patient needs are concerned, the 'bottom-up' approach was considered much less likely to have an impact on the uptake of a device by patients due to their lack of influence in the process as a whole.
2. A bottom-up approach to delivering a home use medical device in this case study was seen to stop at the nurse stakeholders. The company in this case study indicated that healthcare professional feedback was more valuable and influential than that of patients.
3. Patient involvement in the process of selection and delivery was considered to be too time consuming and had little effect on uptake by users. The company in this case study opined that they would typically operate in large populations where the influence on the market has a greater influence on sales.

Chapters four and five represent the research clarification of this thesis. The following chapter will now present the first descriptive study of this research as part of a DRM approach.

# Chapter 6 Designers' and Manufacturers' Perspectives

***"If the full benefits of involving users are to be realised, more primary research is needed to better understand manufacturers' perspectives and motivations and also how the results of user research can be effectively incorporated into the product development process."***

**(Martin & Barnett, 2012)**

Chapters four and five presented two case studies that provide a context and clarification for the research presented in this thesis. The chapters highlighted the commerciality of the home use medical device industry. Chapter four of this research revealed seven preliminary challenges faced by designers and developers of home use medical devices. As part of a Design Research Methodology (DRM) the following presents descriptive study one of this research. The chapter presents an insight into current designer and manufacturer perspectives towards home use medical device users.

## 6.1 Introduction

The aim of this study is to answer research question one of this research.

***Research Question One: How do designers consider and involve users in home use medical device development?***

According to Martin and Barnett, to increase industry's uptake of 'user centred design' practice for medical devices requires a better foundation and understanding of manufacturers' perspectives towards user involvement (Martin & Barnett, 2012). The purpose of this study is to ascertain current designer perspectives towards user

involvement in home use medical device design through a descriptive with practicing designers.

## 6.2 Rationale

Previous research has conducted surveys amongst the design community in an attempt to ascertain perspectives on medical device design. Abdusaleem Cifter conducted a survey with designers to explore their perspectives, requirements and expectations for a suitable method to support them in the designing of home use medical devices (Cifter, 2011). The study formed the major component of his thesis *'An inclusive approach towards designing medical devices for use in the home environment'*. The survey was completed by 43 designers.

The primary focus of Cifter's study was to identify a method to support designers in the development of home use medical devices. The main findings of Cifter's study with industry can be condensed into the following points:

- Cifter found that 76% of respondents believed there is a difference between designing home use medical devices and everyday consumer products (Cifter, 2011). This finding contrasted the work of Gupta as previously described in Chapter 2 (Gupta, 2007).
- The most reported reasons for differences in the approach were cited as the **'Safety and Risks of the Device'**, **'User Related Issues'**, **'Regulations and Legislation'** and **'Function and Usability'** (Cifter, 2011).
- Cifter found that the majority of designers in his study consulted a specialist when collecting user information to support the design of home use medical devices. This was closely followed by observation techniques or simply using the Internet to find information on their users. Interestingly, only 3.8% of respondents stated that they would refer to a toolkit to collect information (Cifter, 2011).
- Cifter found three main areas where designers may require assistance when designing home use medical devices: **'Regulatory Information'**, **'Specific Information regarding the design process of home use medical devices'** and **'Other sources where designers may find information relevant to the design process'** (Cifter, 2011).

In light of this knowledge the following study aims to build on this understanding of design practice towards home use medical devices. The study will therefore address the following two questions, which have been developed on the basis of existing research:

1. If designers consider the involvement of users in the design process to be a unique challenge to the design of home use medical devices then how are users incorporated into the design process?
2. What types of process are designers of home use medical devices following and at what stages are users involved?

The following study will address these questions to ascertain designers' perspectives of users in home use medical device design. Aside from the work of Cifter and Gupta, previous research has addressed the design approaches taken by the medical device industry.

Eatock *et al* conducted an exploratory survey with the medical device industry to identify the tools and strategies used by varying company sizes (Eatock *et al*, 2009). The survey addressed the manufacturing practices and techniques adopted by 38 companies across 68 products. Table 6.1 below presents some interesting conclusions from the study.

**Table 6.1: Conclusions from Eatock *et al* (Eatock *et al*, 2009).**

| **Expected and Supported:** |
|---|
| • Large companies use a wider range of methods.<br>• Small companies have a very low uptake of Lean, Six Sigma, Stage Gates and Total Quality Management (TQM). |
| **Not Unexpected and Supported:** |
| • Large companies like to stick with known technologies.<br>• The survey findings proved consistent with the innovation model where large companies buy up the new technology they need.<br>• Large companies use a number of different methods possibly in parallel.<br>• Small companies prefer new-to-the-world technologies. |
| **Surprising Findings:** |
| • Major upgrades versus minor upgrades are favoured by the large companies even though the success rate of major upgrades is lower than that of minor upgrades.<br>• High success rates reported by those with new-to-the world technologies. |

Using these findings by Eatock *et al*, it was deemed necessary for this study to consider the impact of company size on the findings for this research. Martin *et al* posit that the size of a company will have a direct influence on the resources available to conduct user research (Martin *et al*, 2008).

The principle aim of the research conducted by Gupta and Cifter was to develop support for designers and developers of home use medical devices. However, as previously stated, it is not currently known the extent to which practicing designers make use of such support. There is a need to explore how designers perceive user involvement in the design process of a home use medical device. Cifter identified that only 3.8% of respondents in his survey would refer to a toolkit for information therefore raising the question for this research on the value that current design guidance has in practice (Cifter, 2011).

In exploring these issues, this descriptive study will answer the first research question and reveal current industrial perceptions towards the involvement of users

in the design process of a home use medical device. It is believed that this knowledge will identify avenues for further research that will provide the most value to industry.

## 6.3 Methodology

Designing a survey must address a range of core issues in the planning stage to ensure that resulting data is reliable, concise and unbiased.

The previous section described previous research conducted by Cifter, Gupta and Eatock *et al*, which indicated that conducting surveys in the medical device sector can be met with difficulty (Cifter, 2011; Eatock *et al*, 2009; Gupta, 2007).

Accessing currently practicing designers for research that is focused on their methods and processes will always be met with some difficulty given the priorities, workload and confidentiality of individuals and organisations. In Cifter's study with designers, 400 different individuals were contacted to take part in his study, however a response rate of 13.25% was received (Cifter, 2011). This clearly highlights the issue of non-response and the difficulty to access participants for research. Despite this, the findings are no less powerful or potent for their audience if the correct sampling frame has been chosen. Cifter adopted a purposive sample of a target population which was successfully reached thus the responses are regarded as indicative of current practice, even though wide assertions of the findings cannot be explicitly expressed.

The design of this survey must therefore take into consideration the lack of time designers can spare to take part in this research. The survey must be designed in such a way that respondents are willing and focused to complete the survey honestly and truthfully in its entirety.

Chapter three of this research introduced that a survey-based approach to descriptive study one would be adopted. This strategy was selected as part of a Design Research Methodology (DRM) approach to develop greater insights into current designers' perspectives towards user involvement in home use medical device design.

Surveys are recognised as one of the most common methods to collect significant amounts of information from large populations (Gray, 2009).

The initial draft of the survey aimed to provide answers to the first research question. With this in mind, a series of key themes were identified that the survey should probe from respondents. These themes would collectively provide answers to the first research question and in doing so reveal current designer perspectives towards user involvement in home use medical device design.

The initial themes of the study that the survey would attempt to address were as follows:

- The types of medical devices designed.
- The drivers for selecting a project.
- The challenges to involving users in the design process.
- Who industry considers to be their users.
- How designers prioritise the needs of users.
- The processes designers follow for home use medical device development.
- How success is measured.
- The stages of user involvement in the design process.

Identifying and answering the questions of the researcher often requires a separate and different question to be posed to the respondent. This makes the process of designing questionnaires particularly difficult. Gray described a series of steps that are important considerations when drafting questions for questionnaires (Gray, 2009).

- The researcher has to be clear about the information required.
- The respondent must interpret the question in a way that the researcher intended.
- The respondent must construct an answer that contains information that the researcher has requested.
- The researcher must interpret the answer as the respondent had intended it to be interpreted.

It is therefore critical to ensure that the presentation of the questionnaire and accompanying information facilitates an ease of understanding for the participant. This can be achieved through clearly worded, unambiguous questions that are concise on the issues they address.

Following these principles, a series of questions were developed that attempted to address these issues. At this stage, consideration for the presentation and delivery of the questionnaire were considered. In order to ensure the methods employed in the study were suitable for the target population a range of methods were considered prior to selection.

### 6.3.1 Paper-based Questionnaires

Sometimes referred to as Postal questionnaires, paper-based methods for collecting information from participants are suited to populations that are distributed widely geographically and where the target population have a high level of interest in the subject matter (Gray, 2009). The design of such questionnaires must be short and straightforward to complete as to not have a negative impact on the response rate from participants. Paper-based questionnaires are also particularly suited to situations where the content may be personal to provide an anonymous medium for participants to respond.

One of the drawbacks to this method of data collection however is the relatively low return rate. According to Gray, response rates of 40-50% are common therefore strong generalisations about the data to a wider population can be difficult (Gray, 2009). There is also the opportunity for response bias within the data as respondents with low levels of literacy may not understand or be able to complete the questionnaires.

This method of data collection does offer advantages for the target population of this study however. As the study targets designers of home use medical devices, the population will conceivably have a high level of interest and knowledge in the context of this research. The drawback however being that the time and effort to complete and return the questionnaire may result in a low response rate. Therefore a more rapid method of distribution and completion needs to be considered to ensure the best response rate possible.

### 6.3.2 Internet and Web-based Questionnaires

Online questionnaires can be administered in two forms, either by email or via the World Wide Web (WWW). One of the advantages to using email questionnaires is the relative ease to access a respondent’s email address and consequently distribution

of the questionnaire amongst a target population. It is possible to create mail merge templates that enable large numbers of participants to be contacted at one time. This form of distribution however could potentially be received by some participants as a form of 'spamming' or 'cold-calling' and it is widely understood that people do not appreciate receiving unsolicited messages (Gray, 2009).

Despite this, distributing questionnaires via email can be very effective at increasing response rates and allows questions to be either included within the message itself or in a separate attachment. Difficulties can be experienced in evoking visual stimulation or interactivity however (Gray, 2009). This can be achieved much more effectively with web-based questionnaires that provide a formal platform from which the questionnaire can be presented. Some argue that many of the limitations of paper-based questionnaires also apply for email questionnaires, as participants are unable to make use of the available skip patterns and drop down menus for example (Gray, 2009).

The advantage of web-based methods over paper-based questionnaires however is the rapid return of data from participants. Once the questionnaire has been completed online the data is instantly available to download in a format ready for analysis. For this study such an approach would be particularly suited to the busy schedules of designers operating in the field.

### 6.3.3 Chosen Method

On reflection of the methods presented above the questionnaire for this study was conducted online through a survey-based website. This method of questionnaire distribution was chosen for a number of reasons:

- The ease for respondents to answer the questionnaire without requirement to send any paper based forms via post saving both time and money on behalf of both the researcher and the respondent.
- The interactive nature provided by the web-based platform with drop down boxes and scales.
- The simplicity and readiness to access the results online.
- No requirement to enter the answers to the questionnaire into a software package ready to be analysed.

- The ease of accessing data in a format suitable to data analysis. (E.g. SPSS or Microsoft Excel).

Once the selected method for administering the survey was identified, the issues of design were considered. Using a preliminary design for the questionnaire based on the themes described earlier in this chapter, pre-testing was necessary. The following section describes the pre-testing process used to assess the ambiguity of the questions and whether they were perceived in the manner the researcher intended.

## 6.4 Pre-testing

Pre-testing a questionnaire is fundamental to assess the form, structure and wording of questions prior to any piloting. Questionnaires are recognised as a one shot opportunity for data capture and therefore any ambiguity or misleading questions cannot be modified or re-worded as would be the case in an interview scenario for example. It is therefore of paramount importance that the respondent understands what the survey is asking of them in order to provide a response that is both relevant and meaningful.

Robson suggests pre-testing can be carried out informally among colleagues, friends and family to provide constructive comments to ensure the questions are clear, simple and unambiguous (Robson, 2011). Gillham advises trialling the initial questions with two or more people from outside the target population to answer the questionnaire and point out any questions that are unclear (Gillham, 2000).

For the purpose of pre-testing in this research the initial survey was presented to academics with experience in questionnaire design and conducting design research. As a follow up to pre-testing, a formal pilot would then be conducted with representatives of the target population to finalise any modifications to the questionnaire. If the results from the piloting were as intended then the questionnaire could be sent out formally as part of the first descriptive study.

The pre-testing process raised a number of issues and identified problems with both the wording and structuring of questions in the initial survey.

One of the issues raised by respondents to pre-testing concerned the appearance and usability of the survey system. While some of the issues raised were restricted by the

limitations of the software used to develop the online questionnaire (Survey Monkey), some respondents opined that a survey website with the questionnaire embedded within it may improve the aesthetics of the survey and allow for more information about the research as a whole.

One respondent to pre-testing questioned the use of rating scales within the survey design. The respondent argued that the options of 'Not Applicable' and 'Don't know' were unnecessary responses questions within the survey, as they perceived people for whom the questionnaire was intended would only answer the questionnaire.

Whilst the survey was intended for designers and developers with experience in home use medical device design, it was considered unsuitable to remove these options from the question design. Distributing a survey online via email does not guarantee that only the target population will only answer the questionnaire, despite every effort being made to ensure they are the respondents. It is possible that a company may be very busy and thus feel they have no time to fill in the questionnaire, even though it has been designed to take the shortest amount of time possible to complete. In such cases the questionnaire may be handed to someone else within the company that does not fall into the target population.

Furthermore, it was reasonably foreseeable that certain questions within the questionnaire may not be relevant or applicable to every company or individual completing the questionnaire. For this reason the option to include the responses 'Don't know' and 'Not applicable' were kept in the questionnaire to give respondents the choice. It was felt that providing these options to respondents would possibly result in higher user satisfaction when completing the survey and thus lead to a better response rate and more meaningful results.

The pre-testing of the questionnaire proved to be extremely valuable prior to any formal piloting amongst the target population. A number of iterations were made to the question lengths and number of questions. The feedback from respondents to develop a website and embed the survey within it was chosen as the preferred method to submit the questionnaire to the pilot audience. The following section describes the design of the survey website

## 6.5 Design

The survey was designed and developed using the online survey and questionnaire tool Survey Monkey. The service allows users to create questions, distribute surveys and analyse results online. Survey Monkey was selected as the most appropriate method to develop the survey due to the ability to edit, preview and analyse the survey and results online. Furthermore the data collected from participants remains safe and secure under recognised online trust seals including Norton, TRUSTe and McAfee (Survey Monkey, 2013).

The design of the survey included a progress bar to provide a reference for respondents of much of the survey they had left to complete. The length of the survey was identified as a critical issue for response rate as it is widely understood that long questionnaires result in respondents losing interest or simply not completing the survey (Robson, 2011).

Once the survey has been completed by participants the results are instantly available to download in a format ready for analysis in software packages such as SPSS. SPSS is an advanced Statistical Package for the Social Sciences (SPSS) that provides modelling techniques for accurate analysis and handling of statistical data. A copy of the survey final design is presented in Appendix 3 of this thesis.

The survey website was developed through the use of the online website developer, Wix. The service enables users to develop their own website with interactive content that is viewable to anybody with access to the Internet. The screenshots shown in Appendix 4 present the look and design of the survey website. The design makes use of bold colours with black font on either yellow or white background to ensure the best possible legibility for the reader. All of the important information in relation to the research and study was presented on the website. A contact page was provided on the website to allow users with questions or difficulties to quickly send an email or provide feedback to the lead researcher.

## 6.6 Piloting

Following the completion of pre-testing, the website design was distributed in a pilot to three contacts representative of the target population. The email briefly introduced the research to give context to the message and then included the following link: www.wix.com/tgrantmail/medicaldevicedesign to allow respondents to access the website and questionnaire in their own time. The survey was open between November 2011 and February 2012.

The first participant to complete the pilot represented a home use medical diagnostic device company. The company was identified and selected at a medical device networking event within the United Kingdom. The company were considered suitable respondents to the survey based on their experience of designing and developing home use medical devices for patient use.

The second of the pilot contacts was a global pharmaceutical company. As part of their research and development, the company specialise in diabetes management devices for use in the home. Diabetes represents a rapidly increasing problem in this country and worldwide and an area of disease management that is commonly treated in the home environment. This company was the largest of the companies contacted and as part of the pilot survey the questionnaire was submitted to the UK head of Diabetes and the Diabetes head of Japan, Australia, Canada, and Europe (JACE).

The final of the three pilot questionnaires was sent to a diabetes specialist company that develop a wide range of injection devices available on the market today.

Each of the pilot contacts was selected on their representation of the target population for the research. While only three contacts were chosen for the original pilot, the questionnaire was forwarded onto the head of diabetes for the UK and JACE and subsequently submitted worldwide. The spread of contacts based on the markets in which they operate and size of the company in terms of turnover/number of employees allowed the results of the pilot to identify any possible early themes that could be explored further in the real study.

## 6.7 Distribution and Sampling

A purposive strategy towards distributing the survey amongst the target population was developed. The plan was supported by previous studies from the literature that attempted to evaluate design practice by medical device companies. In his thesis, Gupta used www.designdirectory.co.uk, a database of design companies and consultancies to identify medical device manufacturers (Gupta, 2007). Using this service enables bespoke searches to be conducted for companies specialising in 'Industrial Design – Medical and Equipment Design'. Conducting this search at the time of this study (November 2011-February 2012) provided an initial list of 54 companies registered in the UK.

This cohort of contacts provided a foundation from which other companies would then be identified. Purposively contacting design consultancies operating in the field of home use medical devices would hope to reveal other companies that were suitable for this study. In light of this, as described in Chapter three of this research, a combination of purposive and snowball sampling methods were adopted to gain participants for the first descriptive study.

Purposive sampling is a recognised method used by researchers to define a population for study. A sample is built using the researcher's judgement to satisfy their specific needs in the area of study (Robson, 2011). As the research methodology chapter described, the nature of the first study uses a flexible design or mixed method approach which Robson describes as appropriate for purposive sampling (Robson, 2011). Once the initial sampling has been carried out, results of the study may be analysed and further explored using alternate methods of sampling. Follow up sampling methods might include methods guided by emerging theories developed within the data such as theoretical sampling, as described in Chapter three (Robson, 2011).

Due to the nature of the target population for the survey, locating a wide range of home use medical device companies is a particularly difficult task. This meant that once a company was identified they would be asked if they were aware of any further companies operating in the field. In this respect a snowball sampling approach to

participant recruitment was appropriate to establish as many practicing designers, with the relevant experience, as possible.

According to Robson, snowball sampling is particularly useful when there is difficultly to identify members of a population (Robson, 2011). Once a participant has been identified from the target population they are used as informants to identify other members of the population who again will be used as informants to identify other participants and so on (Robson, 2011) Hence the analogy of a snowball, participant recruitment should continue to grow significantly. Using a snowball method enables the researcher to identify networks for a particular area of study. Through acquiring participation, the study will also determine the connections that occur between companies, consultancies and organisations such as Medilink UK. Medilink UK is a not-for-profit organisation that aims to bring together the NHS, academia and industry to 'stimulate innovation and support the of the healthcare technologies sector' (Medilink Website, Date viewed: July 2012).

To access further participants for this research, the regional Medilink bodies were contacted to identify industry partners involved in home use medical device design. Medilink is comprised of eight bodies that make up the UK network and are spread across different regions.

Initial contact with Medilink was made to the East Midlands (EM) organisation as they were identified at a medical device conference in 2011. Medilink EM suggested that the research was particularly relevant to many of the members registered under the West Midlands (WM) region. In light of this both regions were contacted regarding the nature of the research and study. While Medilink EM and WM were contacted for this study it was believed that should any alternative Medilink body, or external company, be recommended by these organisations as suitable to provide further assistance with the research they too would be contacted. Each Medilink body consists of a wide range of members that operate in the healthcare sector. Members of the Medilink network include organisations such as; medical device companies, suppliers, pharmaceutical companies, contractors and many more.

On contacting the Medilink bodies it was indicated that contacting the home use medical device companies directly was not possible or appropriate due to the agreements held with their members. Alternatively, using the Medilink webpages

each member was reviewed and then the relevant companies were explored further using their official websites to determine who was relevant and suitable to contact. As the intended respondents were designers and developers with experience in the home use medical devices, the websites were reviewed for any content relating to this nature. If a company was deemed suitable as a potential respondent, they were initially contacted via email to introduce the research and the online survey.

Further contacts were established through exhibitions and conferences attended throughout the first year and second year of this thesis (2011/2012). Attendance to events such as the Medilink Innovation Day, Design 4 Health Conference in Sheffield and the Medtech UK exhibition in Birmingham were all used as opportunities to identify participants.

This approach to recruiting participants was considered appropriate due to the limited existing knowledge of home use medical device companies based within the United Kingdom. The following section covers the recruitment of participants in more detail.

## 6.8 Recruitment

All of the participants identified through the distribution strategy described in the previous section were collated into a spreadsheet. Initial contact with participants for the study was made via email. The developed spreadsheet included contact details and specialisms of each company in Microsoft Excel software for clarity and project management purposes.

Using this spreadsheet as a foundation of potential participants, a mail merge template was developed to assist in the distribution of a large number of emails to participants. The advantages of using such an approach to contact participants are summarised below:

- **Rapid Email Distribution** - Once the template and contact information is in place, large numbers of participants can be contacted with a single button. Due to the number of participants contacted in this study, speed of contact was vital to the strategy selection.
- **Consistency** – Using a template will ensure that each participant receives the same structured and formatted information.

- **Time Saving** – Mail merging enables the researcher to type the necessary message only once thus saving a considerable amount of time when contacting each participant individually and consequently allowing numbers of participants to be contacted within a finite time frame.
- **Record keeping** – Having every contacted participant in a spreadsheet improves project management by keeping a record of when initial messages were sent thus providing a reference for when follow up contact is necessary.

The recruiting email introduced the researcher and the nature of the research in the opening paragraph. A copy of the initial contact email can be found in Appendix 5 of this thesis. To support the recruitment email participants were provided with an information sheet that outlined further information about the study (Appendix 6).

The website was designed to provide participants with much more detailed information about the research and study so the email could be kept suitably brief (www.wix.com/tgrantmail/medicaldevicedesign). Providing further information this way meant that participants could conduct the survey and have access to further information at their leisure. Participants would also be able to refer back to the website at any time to read further information or to get in contact with the researcher through the 'contact' page.

It has been reported that there are approximately 11,000 Medical Device companies in Europe, 80% of which are small and Medium Enterprises (EC, 2013; Quotec, 2010). Over 2000 of these companies are registered in the UK (Quotec, 2010). Of those 2000 small and medium companies operating in the United Kingdom, no evidence for the breakdown of the companies into Micro, Small, and Medium enterprises was found.

In light of this, a population of specialist home use medical device companies cannot be established for the purpose of this research. With that in mind, the study aimed to contact as many home use medical device companies as practicable within the UK. To establish a wider audience of home use medical device companies, the professional network 'Linked In' was explored. Linked In is an online networking platform for professionals in all fields and sectors to contact and share content with one another.

For the context of this study the head of the largest online Medical Devices Group was contacted with reference to the possibility of contacting participants through the group and online forum. The request was successful and an advert for participation for the research was submitted online and can be seen in Appendix 7 of this thesis. The recruiting advert included; a brief introduction to the research and researcher, the intended respondent profile and a link to the online survey.

This advert was purposively targeted at the Medical Devices Group on Linked In and was specifically focused upon home use medical device designers. According to the group leader the members were indicative of Small and Medium Enterprises in the medical device industry, which as previously described represent approximately 80% of the marketplace (EC, 2013).

With the recruitment of participants and survey design presented the following section introduces the results of the survey from current designer perspectives towards user involvement in home use medical device design. The section includes the presentation of qualitative and quantitative data, statistical analysis where appropriate and a discussion of the main findings to the survey.

## 6.9 Results

The following section presents the results to the survey in the order in which the questions were presented to respondents. Each question is provided with the number of respondents that answered each specific question. A total of 42 respondents completed the survey. The section begins with the presentation of all of the data from the study before the analysis performed on the results. Following the presentation of the data and analysis the interpretation and discussion of the results is presented.

**Questions One, Two and Three:**

The survey opened with simple profiling questions designed to ease respondents into the survey and to ascertain the profile of respondents. The questions included: Company Details, Approximate Number of Employees and Approximate Turnover/Annum (£). A copy of the respondent profiles is presented in Appendix 8 of this thesis.

The company size for each participant was calculated using the reported company headcount and turnover in conformance with the definition provided by the European Commission (EC, 2003). According to the recommendation by the European Commission 2003/361/EC enterprises qualify as micro, small and medium-sized enterprises (SMEs) if they fulfil the criteria summarised in Table 6.2.

**Table 6.2: Defining Small and Medium Enterprises (Adapted from EC 2003/361/EC).**

| Enterprise category | Headcount | Turnover | or | Balance sheet total |
|---|---|---|---|---|
| Medium-sized | < 250 | ≤ € 50 million | | ≤ € 43 million |
| Small | < 50 | ≤ € 10 million | | ≤ € 10 million |
| Micro | < 10 | ≤ € 2 million | | ≤ € 2 million |

A total of 35 respondents answered question three with seven respondents not providing an answer. Twelve participants expressed that certain information pertaining to company turnover was confidential and therefore no figures were disclosed. Table 6.3 provides a summary of company size for the different respondents in the study.

**Table 6.3: Company Sizes Represented in the Study.**

| Company Size | Number of Respondents |
|---|---|
| Micro | 19 |
| Small | 10 |
| Medium | 4 |
| Large | 2 |

Micro companies represent companies with fewer than ten employees and consequently have less-resources available to conduct user research with end users. These companies represent a unique perspective for this study in reference to how they overcome the preliminary challenges to user involvement highlighted in the idealised practice case study (See Chapter Four). In contrast Small companies

represent a workforce of less than 50 employees and Medium and Large organisations represent companies with upwards of 250 employees.

One participant in the study represented a company that conflicted with the values provided by the EC towards defining the size of the company. While this company had fewer than ten employees (Micro company), the turnover of the company was greater than £2M, which would technically define them as a small company. For the purpose of this study it was decided that employee headcount would take priority in this scenario as respondents were found to be more likely to answer question two in relation to headcount as opposed to question three which referred to annual turnover. This could be attributable to some respondents perceiving such information to be confidential.

**Question Four: Which of the following best describes the area(s) of medical devices you have worked on?**

A total of 29 respondents answered this question with 13 respondents skipping the question. The results to this question are presented in Figure 6.1, which presents the different types of medical devices developed by respondents. Note the results to this question are not exclusive. It was highly foreseeable that respondents would have experience in more than one domain of medical device development and as such could potentially be involved in all domains shown in Figure 6.1.

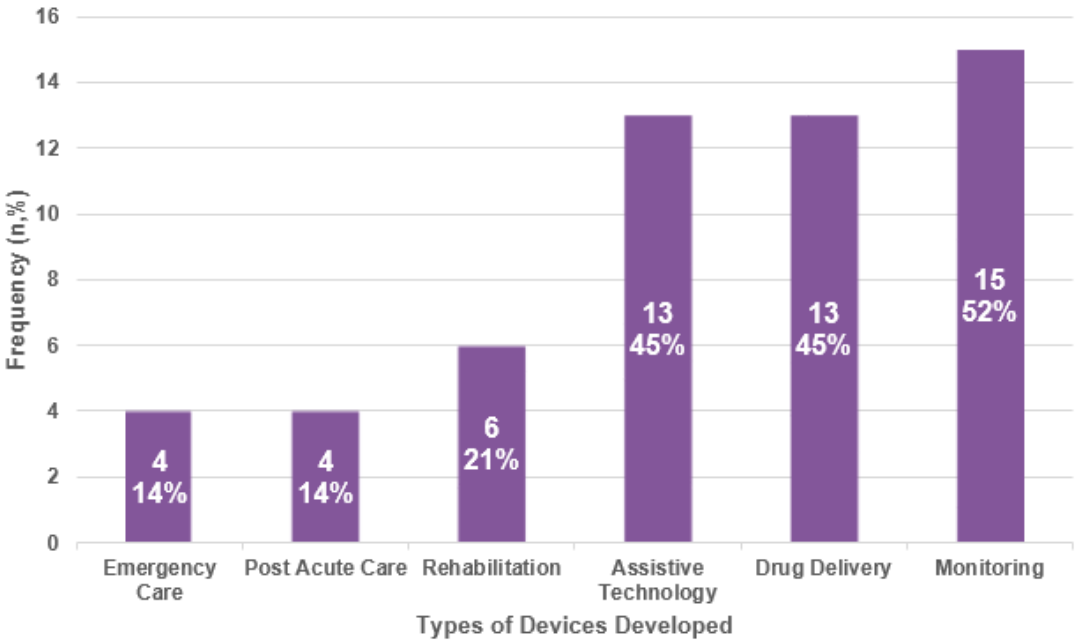



**Figure 6.1: Types of Devices Designed by Respondents.**

**Question Five: If you were designing a medical for the home environment, what would be the prime drivers for development?**

A total of 36 respondents answered this question with six respondents skipping the question. The results to question five are presented in Figure 6.2 concerning how designers and developers of home use medical devices identify and select a project to take forward for development. The maximum value of importance that could be assigned to any one driver was seven. The mean ranks expressed in Figure 6.2 present the mean scores from all respondents to question five. To compare the differences between the identified drivers for development the Freidman Test and

Pairwise Comparisons were performed on the results. Please refer to the analysis section for information on the statistical tests performed in this study.

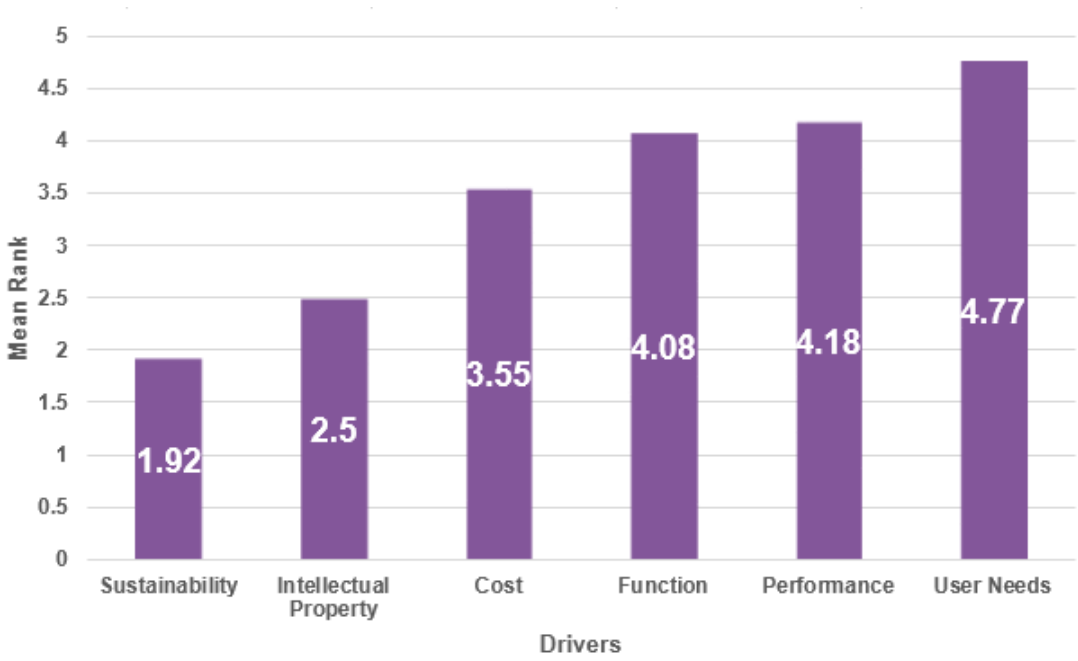



**Figure 6.2: Perceived Importance of Selected Drivers for Home Use Medical Device development.**

**Question Six: What do you consider to be the barriers and or challenges to user involvement in your design process?**

A total of 36 respondents answered question six of the survey with six respondents skipping the question. The results to question six are presented in Figure 6.3 concerning the challenges towards involving users in the design process of a home use medical device. The results to this question are not exclusive.

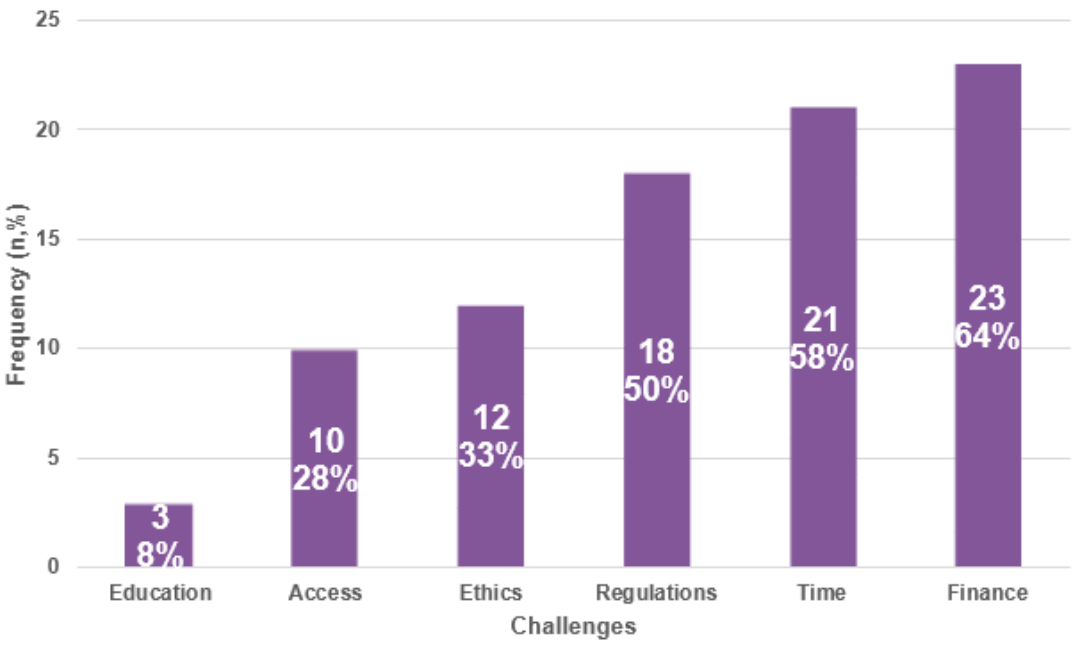



**Figure 6.3: Perceived Challenges Towards Involving Users in the Design Process of a Home Use Medical Device.**

**Question Seven: When designing a medical device for your core business, who from the following list do you consider to be your users?**

A total of 35 respondents answered question seven with seven respondents skipping the question. The results to question seven are presented in Figure 6.4. A range of potential home use medical device users was developed based upon the case studies (Chapters 4 and 5) and existing research (Cifter, 2011; Shah & Robinson, 2008). Respondents were also given the option to provide additional users to the list through the use of the 'Other' category. The results to question seven are not exclusive, as it is foreseeable that any one device could potentially have a multitude of users (Martin *et al*, 2008). The option of 'All of the above' was provided to participants if they considered every user mentioned on the list to be a potential user for a home use medical device.

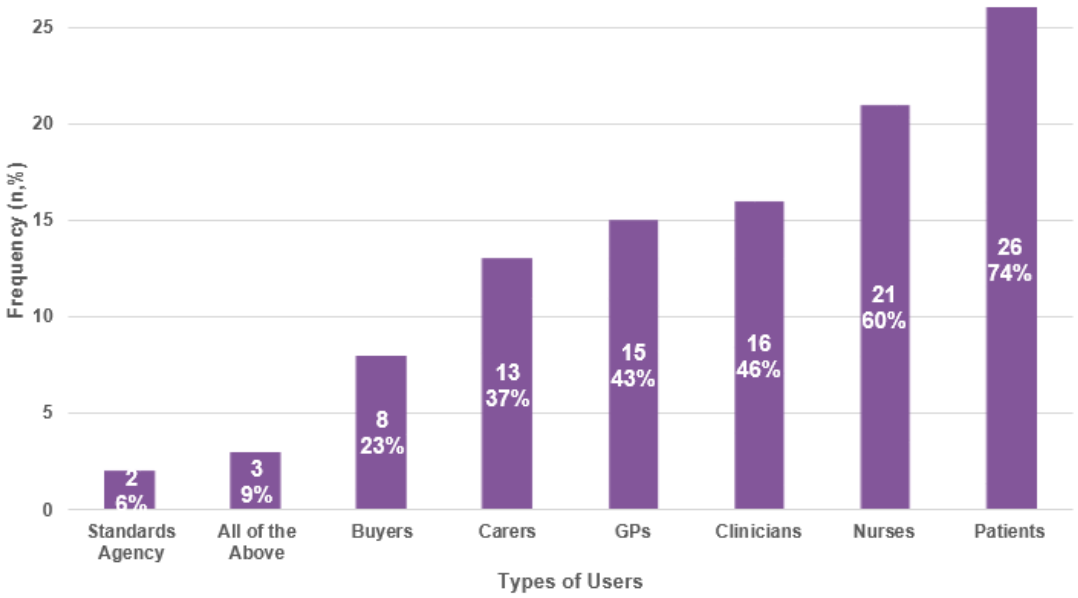



**Figure 6.4: Designers' Perspectives of Perceived Users for Home Use Medical Devices.**

**Question Eight: Of the user groups mentioned in the previous question, who needs do you consider to be the most important?**

A total of 38 respondents answered this question with four respondents skipping the question. The responses to question eight are presented in Figure 6.5. The responses to this question are exclusive as respondents were asked to provide a single answer.

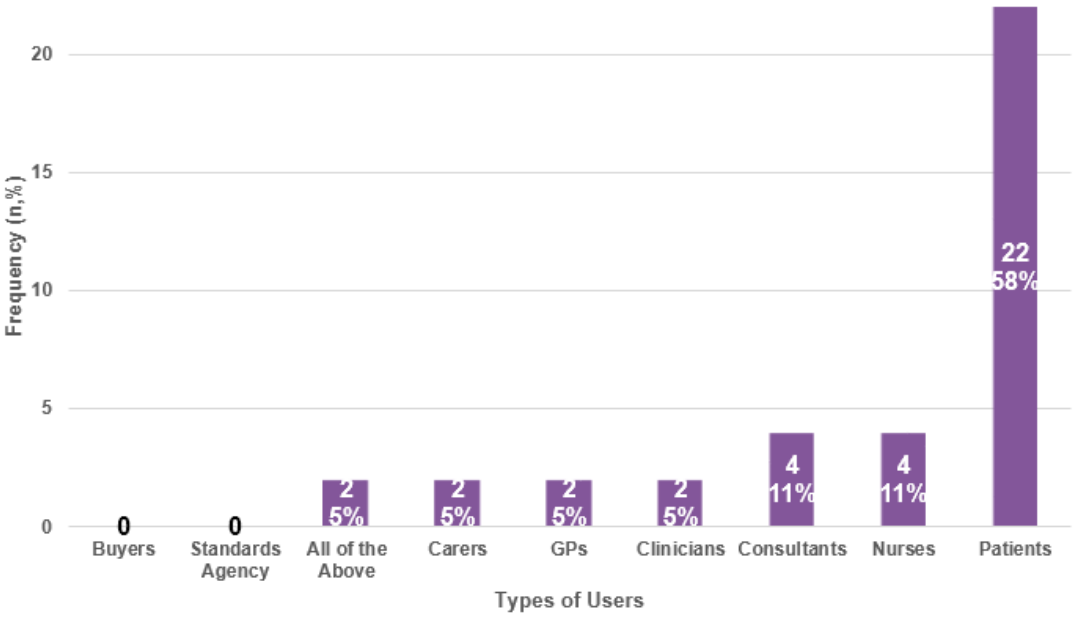



**Figure 6.5: Designers' Perspectives on Priority Users of Home Use Medical Devices.**

**Question Nine: What are your reasons for choosing this user group? (Open-ended question).**

A total of 42 respondents answered this question. Question nine required participants to provide an answer in order to continue with the survey. Eighteen respondents provided random alpha-numerical responses that were not considered coherent answers to the question. The 24 genuine responses provided for question nine are presented in Table 6.4:

**Table 6.4: Descriptive responses provided for Question Nine.**

| User Group Selected | Participant Response |
|---|---|
| ALL OF THE ABOVE | All are involved in product use and have important roles. Chain of involvement means if one member of the chain fails the product will be ineffective. |
| PATIENTS | They are the end user and therefore the most important. Everyone else is just helping them use [the device]. |
| PATIENTS | [We] design devices for intended users |
| CONSULTANTS | For theatre lighting: Tend to be the front line user and have significant influence on purchase decision. For kitchen design would choose consumers/buyers. |
| PATIENTS | They are ultimately the user (recipient) of the medical effect or treatment. |
| NOT ANSWERED | Because we design and develop a broad range of devices all for different segments and markets each will have a different set of user group priorities, for example a home health care advisory product for detecting breast abnormalities is completely different to a clinical device for measuring retinal function. |
| PATIENTS | They are the least ""expert"", but again it depends... if it is a piece of specialist equipment used by the clinicians or nurses only and safety is critical then the focus would be on making is easy (and error free) for the professionals to use. |
| PATIENTS | I am a design researcher and my job is mainly to examine the design of the product from a user's perspective, through research and evaluation. The product user will ultimately use the product and it is extremely important that the device is free from misuse, but also accepted by the user (patient compliance is a really important issue often ignored by designers). |
| PATIENTS | Assisting them is the whole point of the exercise! |
| ALL OF THE ABOVE | Not a straightforward question. As we design many products, there are many answers. |
| PATIENTS | The end user will determine whether the product meets the specific need in an adequate way - i.e., cost effective, easy to use, accurate and reliable, etc., |

| User Group Selected | Participant Response |
|---|---|
| GENERAL PRACTITIONERS | GPs are the gateway |
| CONSULTANTS | They're our end-user |
| PATIENTS | They use the product |
| NURSES | The nurse has to meet her user needs (i.e. the patient has to be confident in the nurse's choice of dressing). But the Nurse also has to satisfy the clinical need as well. Gets both bits and generally has to apply the dressing to the patient and will receive the complaints if performance is unsatisfactory |
| CARERS | It's the group we address |
| PATIENTS | Products largely used in the home care setting by the end user. |
| PATIENTS | Depends on the product type, but the patients' needs tends to be considered most important, particularly in home use medical devices. With this type of device, it is often the case that the patient will also be the main end user and the one directly interacting with the product. Therefore it is important that their experience of that product and its usability is well considered, especially during the design and development stages. |
| GENERAL PRACTITIONERS | I'm answering as though I were still at Cardiac Science where most of our products were sold through distribution to general practitioners. |
| PATIENTS | Technology needs to support patients first. Reducing the cost of health care - and enabling better patient support is something long overdue |
| PATIENTS | Scope of survey is home care and therefore end user is the patient and design considerations would be focused on the end user in this case, the patient. |
| NOT ANSWERED | That definition seems to be the most logical. |
| CARERS | Closest to the end user |
| PATIENTS | None is happy if the patient is not happy. |

**Question Ten: What best describes the process you follow when designing or developing a new device for the market?**

A total of 31 respondents answered question ten with eleven respondents skipping the question. For the purpose of question ten a range of commonly recognised design processes were presented to participants. Respondents were provided with an 'Other' category should they have followed an alternate process to the examples presented in the list. The results to question ten are presented in Figure 6.6.

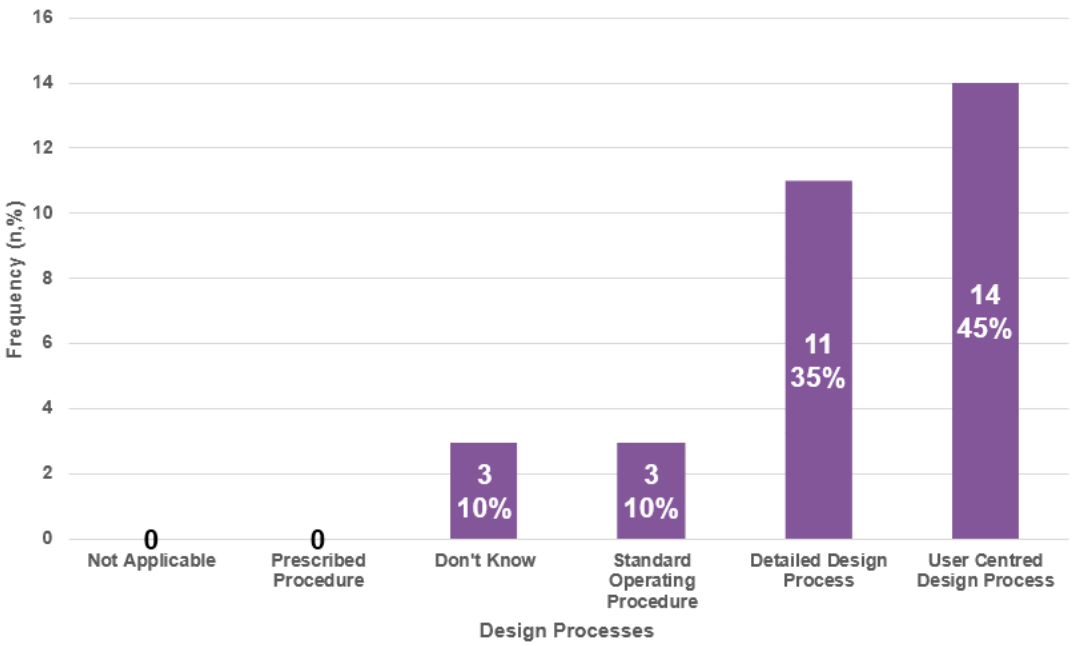



**Figure 6.6: Different Design Processes Followed by Respondents.**

**Question Eleven: Do you actively collect design feedback from your end users once a product has been launched onto the market?**

A total of 35 respondents answered question eleven with seven respondents skipping the question. The results to question eleven are presented in Figure 6.7.

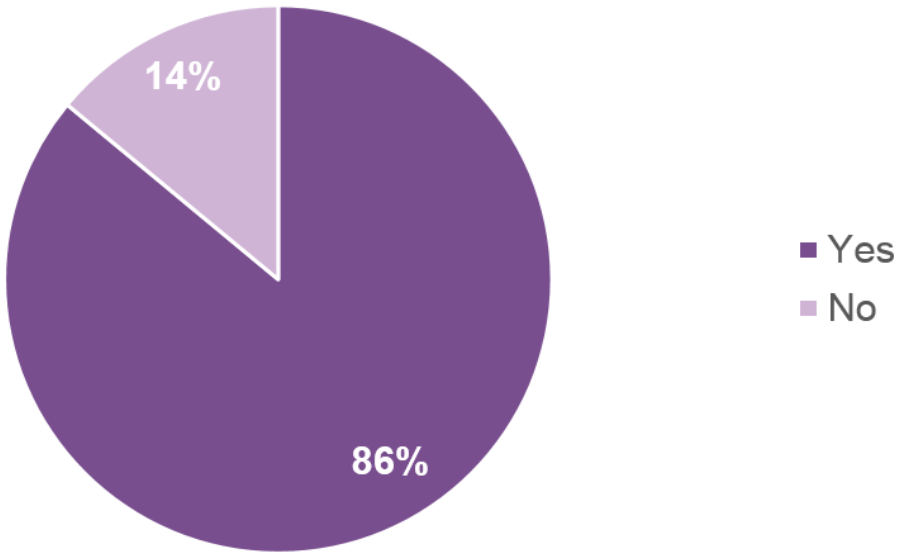



**Figure 6.7: Is Design Feedback from End Users Actively Collected by Designers.**

**Question Twelve: How do you measure the success of a new device once it has been launched onto the market?**

A total of 34 respondents answered question twelve with eight respondents skipping the question. The results to question twelve are presented in Figure 6.8. For the purpose of question twelve respondents were provided with different criteria relating to the launch of a medical device onto the market. As with question five, the maximum value of importance that could be assigned to any one measure of success was seven. The mean ranks expressed in Figure 6.8 present the mean scores from all respondents to question twelve.

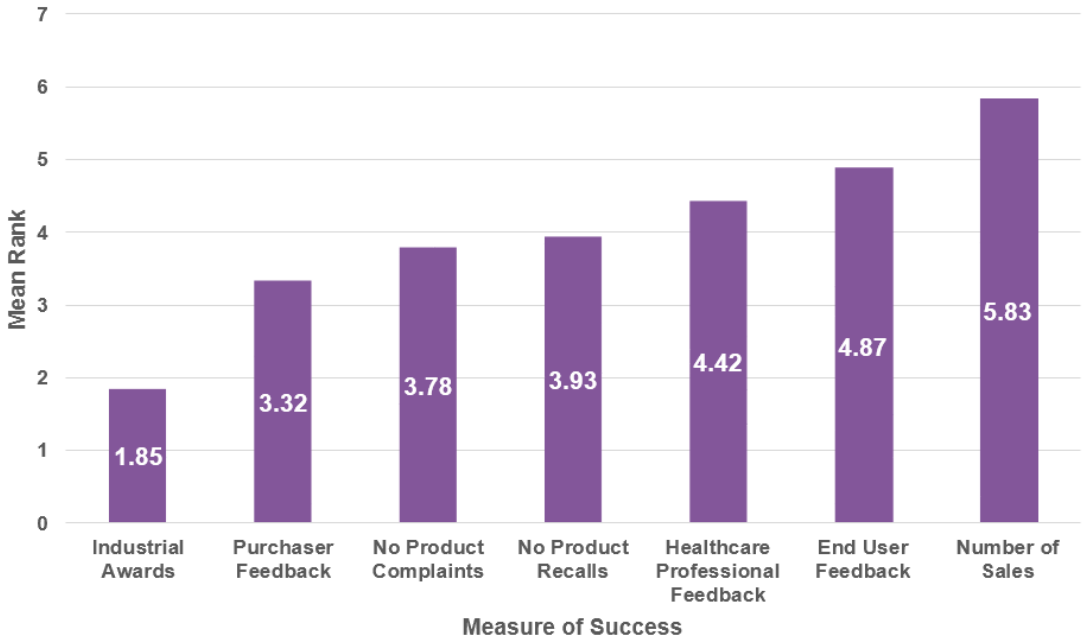



**Figure 6.8: Designers' Measures of Success for Home Use Medical Devices.**

**Question Thirteen: At what stage(s) and to what extent during your design process do users become involved?**

A total of 34 respondents answered question thirteen with eight respondents skipping the question. Using a Likert Scale, question thirteen asked respondents to rate the level of user involvement for six different stages of a typical or generic design process: Initial Concept, Design Stage, Product Design Specification, Product Development, Product Testing and Post Launch. The rating scale ranged from 1 = 'Not Involved', 2 = 'Rarely Involved', 3 = 'Sometimes Involved', 4 = 'Often Involved' and 5 = 'Highly Involved'. Figure 6.9 presents the results to question thirteen.

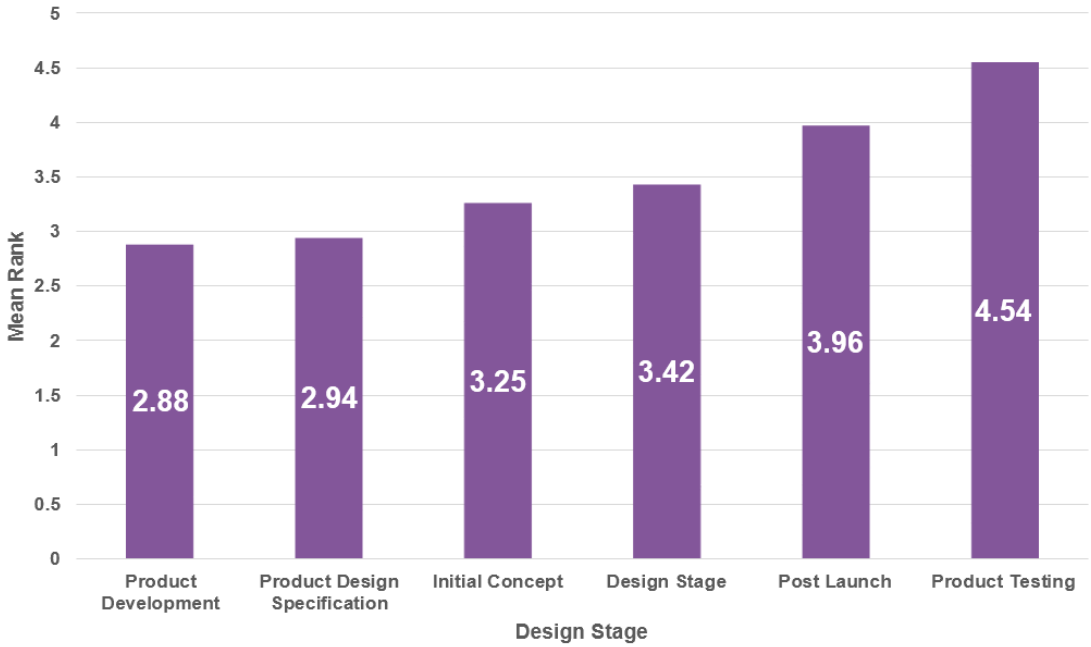



**Figure 6.9: The Level of User Involvement at Different Stages within the Design Process of a Home Use Medical Device.**

The following section will now present the descriptive results of the study.

## Dealing with Descriptive Data

A number of responses from respondents in the study fell under the ‘Other’ category. On exploring the responses provided by respondents it became apparent that only five participants used the ‘Other’ category in question five. The descriptive insights provided by respondents were considered more appropriate to reflect on qualitatively and to support future work with designers in the field.

The qualitative nature of the open-ended questions in the study was considered for grouping into themes that could subsequently be added to the original data set. This was however considered unacceptable for the reliability of the study and the opportunity to introduce potential researcher bias.

While respondents were openly allowed to provide their own responses for ‘Drivers for Development’ it was deemed inappropriate for these responses to be regrouped based on the researcher’s subjective interpretation of the responses. The responses are limited in context due to the data being collected from an online survey. If the survey was conducted as part of an interview there could have been more detailed insight and discussions into the interpretation and understanding of respondents. Using this methodology would have the added benefit to the researcher of exactly what the respondent meant by their answer.

The data however did provide interesting insights for future probing as part of some further research to explore what respondents understood by each term and whether recurring themes emerged.

Table 6.5 presents examples of the ‘Other’ responses provided by participants for question five.

**Table 6.5: 'Other' Responses for Question Five.**

| Responses | Potential Theme |
|---|---|
| Profitability | Cost |
| Ease of use | Performance/User Needs |
| Business case | Cost |
| Profit | Cost |
| Safety | Performance/User Needs |

Three of the responses (‘Profitability’, ‘Business Case’ and ‘Profit’) it could be argued refer to the commercial drivers behind home use medical device development, which are closely related to the implications of ‘Cost’. The ‘Safety’ and ‘Ease of Use’ of a device potentially fall into two categories, namely ‘Performance’ and ‘User Needs’ dependent on the interpretation of the respondent. The results shown in Table 6.5 therefore can be considered indicative of the whole population of respondents as no new themes for possible ‘Drivers for Development’ were identified. It would be reasonable to assume that the respondents to this study deemed the options presented in question five covered their desired responses to the question of project selection.

With all of the results recorded in the study now presented the following section will describe the analysis performed on the results to explore the data and its implications further.

## 6.10 Analysis

To understand the differences and significance of the results in this study it was necessary to perform statistical comparisons of the data. The following section describes the analysis conducted on specific questions within the survey.

Question Five (5) of the survey addressed designers’ perspective of the drivers behind the development of home use medical devices. To ascertain whether any significant differences exist between the drivers cited by respondents a Freidman Test followed by a Pairwise Comparison was performed on the data for question five.

The Freidman test is the non-parametric equivalent of the one-way within-subjects analysis of variance (Brace, Kemp & Snelgar, 2012). The test is sometimes referred to as the Freidman two-way ANOVA because in a within-subject analysis of variance participants are considered to be a factor (Brace, Kemp & Snelgar, 2012). A copy of the Freidman Test results is presented in Equation 6.1.

The test revealed that respondent's perception of drivers for the development of home use medical devices varied significantly:

**Equation 6.1: Freidman Test**

$$\mathbf{X^2\ (5, N=31) = 56.838,\ p < 0.05}$$

Where;

- $X^2$ is the calculated value for the Freidman test, which is assessed for significance using $X^2$ distribution.
- The degrees of freedom = k – 1, where k is the number of levels of the factor. Hence, the value of 5 for this question (Six Drivers).
- P is the p value.

The results of the Freidman test alone however do not determine where the significant differences exist. This non-parametric test demonstrates that a significant difference is present in the data set as a whole. To determine which drivers are significantly different from one another requires a Pairwise Comparison to be performed on the mean ranks for the perceived drivers.

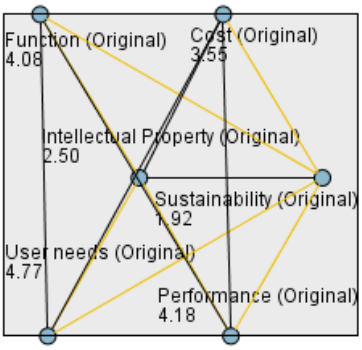
A pairwise comparison of a data set determines the relationship between the variables and reveals which results are significantly different from one another. The simple null hypothesis test summary shown in Figure 6.10 demonstrates that one or more of the drivers when compared with each other produced a result that was statistically significant. A full breakdown of the Pairwise Comparison results can be found in Appendix 9 of this thesis.

**Hypothesis Test Summary**

| | Null Hypothesis | Test | Sig. | Decision |
|---|---|---|---|---|
| 1 | The distributions of Sustainability (Original), Intellectual Property (Original), Cost (Original), Performance (Original), Function (Original) and User needs (Original) are the same. | Related-Samples Friedman's Two-Way Analysis of Variance by Ranks | .000 | Reject the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

**Pairwise Comparisons**




Each node shows the sample average rank.

**Figure 6.10: Pairwise Comparison Test Results for Question Five.**

The Pairwise Comparison shown in Figure 6.10 compared each variable with one another to determine any significant differences in the data. The significance level for the test was 0.05. Any p value less than 0.05 was recognised as statistically significantly. A Bonferroni correction was conducted on the data set.

Figure 6.10 revealed seven significant differences in the results received for question five. The differences in order of significance are shown below:

1. **'Performance' (Rank = 4.18)** significantly differed from **'Sustainability' (Rank = 1.92).**
2. **'User Needs' (Rank = 4.77)** significantly differed from **'Sustainability' (Rank = 1.92).**
3. **'Function' (Rank = 4.08)** significantly differed from **'Sustainability' (Rank = 1.92).**
4. **'User Needs' (Rank = 4.77)** significantly differed from **'Intellectual Property' (Rank = 2.50).**
5. **'Performance' (Rank = 4.18)** significantly differed from **'Intellectual Property' (Rank = 2.50)**

6. **‘Cost’ (Rank = 3.55)** significantly differed from **‘Sustainability’ (Rank = 1.92).**
7. **‘Function’ (Rank = 4.08)** significantly differed from **‘Intellectual Property’ (Rank = 2.50).**

**Analysis of Results to Question Twelve:**

In order to understand the significance of the differences in the results for question twelve, the Freidman Test followed by a Pairwise Comparisons was performed. As before, the significance level for the test was 0.05. Any p value less than 0.05 was recognised as statistically significantly. A Bonferroni correction was conducted on the data set. A full breakdown of the results can be found in Appendix 10 to this thesis.

The tests revealed eight significant differences between the measures of success for home use medical devices:

1. **‘Number of Sales’ (Rank = 5.83)** significantly differed from **‘Industrial Awards’ (Rank = 1.85).**
2. **‘End User Feedback’ (Rank = 4.87)** significantly differed from **‘Industrial Awards’ (Rank = 1.85).**
3. **‘Number of Sales’ (Rank = 5.83)** significantly differed from **‘Purchaser Feedback’ (Rank = 3.32).**
4. **‘Healthcare Professional Feedback’ (Rank = 4.42)** significantly differed from **‘Industrial Awards’ (Rank = 1.85).**
5. **‘No Product Recalls’ (Rank = 3.93)** significantly differed from **‘Industrial Awards’ (Rank = 1.85).**
6. **‘Number of Sales’ (Rank = 5.83)** significantly differed from **‘No Product Complaints’ (Rank = 3.78)**
7. **‘No Product Complaints’ (Rank = 3.78)** significantly differed from **‘Industrial Awards’ (Rank = 1.85)**
8. **‘Number of Sales’ (Rank = 5.83)** significantly differed from **‘No Product Recalls’ (Rank = 3.93).**

**Analysis of Results to Question Thirteen:**

As before, a pairwise comparison of the results collected for question thirteen was performed to ascertain any significant differences between the highest stages of user involvement in the design process of a home use medical device. A copy of the results can be found in Appendix 11 of this report.

The test revealed two significant differences in the data received for question thirteen in the survey.

1. **'Product Testing' (Rank = 4.54)** significantly differed from **'Product Development' (Rank = 2.88).**
2. **'Product Testing' (Rank = 4.54)** significantly differed from **'Product Design Specification' (Rank = 2.94).**

The implications of the analysis presented in this section are discussed in the following section. Section 6.11 describes the interpretations of the study results and its relation to existing research in the field.

## 6.11 Discussion

The aim of this study was to answer research question one of this research:

***Research Question One: How do designers consider and involve users in home use medical device development?***

In exploring designers' perspectives of home use medical device users and their involvement within the design process, the study has revealed information about current design practice in industry towards home use medical device design.

Respondents to this study typically represented 'Monitoring' 'Drug Delivery' and 'Assistive Technology' devices for use in the home. Figure 6.1 revealed that approximately 52% of respondents in this study had experience in designing 'Monitoring' devices for use in the home, while 45% of respondents were experienced in 'Drug Delivery' and 'Assistive Technology' devices. One could argue that this is perhaps to be expected from developers of home use medical devices as these types of devices are currently representative of the most commonly used medical devices in the home. According to the National Research Council, the

coming years will see a shift towards more sophisticated and complex medical devices migrating in to the home environment (National Research Council, 2011). Consequently, increased numbers of emergency and post-acute care devices may find their way into the home thus placing higher demand on designers to cater for these needs.

In light of the recognised trend towards consumer home use medical devices it was hypothesised that the companies participating in this study would be specifically focused on the costs associated with development (FDA, 2011). This would support the findings of Chapter Four whereby participants in the case study indicated that design decisions are often based on commercial reasoning rather than the needs of end users specifically. Question Five of the survey addressed this issue to ascertain where user needs sit alongside the commerciality of the sector. For the purpose of this study participants were provided with potential drivers identified through conducting the case studies of this research. These drivers included: Cost, Function, Intellectual Property, Performance, Sustainability, User Needs, and Other.

Figure 6.2 revealed that 'User Needs' were perceived as the most important driver behind the development of home use medical devices for designers in this study. The results suggest that the needs of users are considered more important to designers than the performance and function of the device itself at the outset of the design and development process. To ascertain whether there was any significant differences in the drivers cited by respondents in the study the data was analysed using the Freidman Test and a Pairwise Comparison.

Figure 6.10 indicated that 'Sustainability' and 'Intellectual Property' were of lesser priority to designers in the study at the outset of a project. Perhaps these issues become more important later in the development process when the device is closer to launch, however this was not explored in the survey. No evidence of a significant difference was found between 'Cost', 'Function', 'Performance' and 'User Needs' thus assertions to a wider population are not possible. This means that if this test was repeated with different participants from the home use market 'Performance', 'Function' or 'Cost' may well be perceived as the most important driving factor for the development process. To ascertain a statistically significant result for this

question would require a wider range of respondents to complete the survey. Due to time and project constraints this was not possible within the scope of this research.

It must be considered that respondents could have answered the survey in the way they would like to be perceived externally. Previous research has shown respondents can answer questionnaires and surveys in ways that are not always truthful to real life (Robson, 2012). Respondents can feel a pressure when answering questions to provide a response they think the researcher is looking for. When answering the questionnaire, which forms part of a body of research for Loughborough University, there is an inherent awareness of likely publications and the presentation of the data. As such respondents may feel obliged to answer the questionnaire in a manner that depicts their methods, processes and perspective towards design in the best light. One approach to overcome this is to conduct a secondary stage interview whereby answers to the previous questions are probed. At interview themes and previous responses can be explored in more detail with respondents to challenge the thoughts and opinions expressed in the initial questionnaire. This is explored further in following chapter, which presents an understanding of current design practice for home use medical devices.

Despite this, it may well be that user needs, including those of patients are of primary concern to designers for home use medical devices. This is of course a requirement of the harmonised standard IEC BS EN 62366 (IEC 62366, 2007). According to IEC BS EN 62366, manufacturers are required to identify and describe the intended user population, the intended user profile and the conditions of use (IEC BS EN 62366: 2007). This highlights an incentive for the design community to consider and involve the end users within the design process and thus could have driven a rise in the importance of ‘User Needs’ for the development process since its introduction in 2007. The fact that the standard is internationally recognised and harmonised under the Medical Device Directive provides a moral obligation for manufacturers to consider usability. The implications of IEC BS EN 62366: 2007 were discussed in detail in Chapter Two.

With the drivers for development in mind, the challenges towards involving users specifically were addressed in question six of the survey. For the purpose of this

question, respondents were provided with six potential challenges to involving users in the design process of a home use medical device as well an 'Other' option. For clarity purposes to designers in the study an example of each potential challenges was provided with the question. The challenges included: Access to Specialist Knowledge (e.g. In-house or Externally), Cost (e.g. The cost involved to conduct user research), Education or Training (e.g. The training of research methods), Ethics (e.g. Gaining ethical approval to conduct user research), Regulations (e.g. Compliance with the Medical Device Directive) and Time (e.g. The time involved to conduct user research). All of the challenges cited in this question were based on existing research found within the literature review. Participants were also provided with 'Don't Know' and 'Not Applicable' options.

Figure 6.3 revealed that 'Cost' in the context of involving users in the design process of a home use medical device was identified as the leading challenge cited by respondents (64%). This supports previous research that has indicated the cost of involving users as a challenge to medical device development. In a study by Money *et al* it was found that product developers perceived user needs research to be disproportionality costly in relation to the benefits gained from conducting such work (Money *et al*, 2011).

Perhaps designers find it difficult to see an immediate benefit from including users in the design process for home use medical devices. This is compounded by an upfront cost to involve users with no immediate monetary feedback from doing so. One must consider however that the cost of not involving users in the design process could be significantly higher in terms of implications for due diligence, legislation and also the potential for a device recall. As was described with the Exubera Inhaled Insulin device in Chapter Two of this thesis, the consequences of launching a device that fails to meet the needs of end users can be extremely costly.

Figure 6.3 supports that the challenges of 'Cost' and 'Time' are fairly fixed constraints on medical device design for manufacturers. Product development cannot continue endlessly. Similarly, the amount of money spent on developing a product must remain within a realistic budget that will potentially bring profit to a company. These factors were therefore hypothesised by the researcher to be cited as significant challenges to involving users in the design process of a home use medical device.

A reported 58% of designers in the study cited ‘Time’ as challenge towards involving users in their design process. The context in which ‘Time’ is used here refers to the actual or perceived time from the perspective of the designer to conduct user needs research. Thus, it can be said that the hypothesis of the researcher is supported by the results of this question. Consequently, the implications of ‘Cost’ and ‘Time’ are significant for the involvement of users in the design of home use medical devices.

Aside from the costs and time involved in conducting user needs research, the results revealed that ‘Regulations’ in the United Kingdom were perceived as a challenge by 50% of the designers in the study. This finding contrasts with the findings of Chapter Four whereby the current regulations were identified as a push factor towards the improved usability of home use medical devices.

The regulatory requirements for medical device development have been previously cited as a barrier to involving users in the design process of a medical device (Martin *et al*, 2008; Money *et al*, 2011). By necessity manufacturers are required to meet the relevant regulations prior to a device being tested with real end users and subsequently launched onto the market. Medical device developers therefore can be resistant to changing a device once the relevant regulation has been met (Martin *et al*, 2008). This is due to the potential requirement for re-submission once the tests have been conducted. If necessary changes to the device design are identified at a late stage in the process it can have significant implications for the cost of development. Developers should therefore have a strong incentive to involve users early and throughout the design process to ensure such an incident does not occur.

A third of designers (33%) in this study cited ethics as a challenge towards involving users in the design of home use medical devices. In the context of this study the term ethics refers to designers and developers gaining ethical approval to conduct research with potential users of home use medical devices. Thus one could infer that some of the designers in this study perceive the process of gaining ethical approval to be challenging. Perhaps the designers in the study believe the process of gaining ethical approval to be difficult or time consuming. Consequently the process of gaining approval could lead to the delays in the design and development process. Without

further insight into the reasoning behind the responses of designers it is not possible to draw a conclusion upon why ethics is perceived as a challenge. Further research must ascertain why 33% of designers in this study perceived 'Ethics' to be a challenge to involving users in the design process.

Interestingly, question six indicated that only 8% of respondents considered 'Education' as a challenge or barrier to user involvement in home use medical device design. 'Education' in the context of this survey refers to the relevant training and experience to conduct user research appropriately. This result suggests that designers consider themselves equipped to conduct user research for home use medical devices without the need of design support or training on appropriate methods for user requirements capture.

It is understood that a wide range of medical devices are currently designed with poor considerations for device users. This is supported by the recognised increase in use errors globally (IEC BS EN 62366:2007). The findings of this study therefore suggest that a range of possible scenarios exist within the field of home use medical device design in relation to understanding and capturing the needs of users.

***Scenario One: Designers are aware of the principles and methods for user needs research but do not apply them***.

Scenario one implies that designers of home use medical devices are aware of the principles and practices outlined in documents such as IEC BS EN 62366:2007 and ANSI/AAMI HE75:2009 yet fail to apply them in practice. In this scenario designers know what they should be doing in practice but either chose to ignore such guidance or are unable to apply or conduct user needs research in practice due to specific constraints on the project.

***Scenario Two: Designers are not aware of the relevant methods and so cannot apply them at all.***

Scenario Two implies that designers are not aware of the relevant principles and methods to conduct user needs research and consequently cannot adopt the approaches outlined in IEC BS EN 62366: 2007 and ANSI/AAMI HE75: 2009. In this scenario designers cannot conduct the approaches advocated by the current medical device guidance because they are either not aware of the guidance in the first instance or the available methods to conduct user research with patients.

***Scenario Three: Designers are aware of the principles and methods for user needs research but apply them sub-optimally.***

The final scenario implied by this study considers that designers are aware of the principles and methods to conduct user needs research however are unable to apply them optimally in practice. Similar to scenario one in that designers are aware of the approaches they should be taking towards identifying the needs of their users however in this instance they are unable or unwilling to adopt 'idealised' practice based on the constraints of projects.

Through questionnaire studies such as this it is not possible or appropriate to draw conclusions on which scenario is occurring and why. It is necessary to conduct further research that explores current practice in more depth to ascertain which scenario is occurring and why. Future studies in this research will reflect on these scenarios presented here to understand why home use medical devices are designed in the manner in which they are.

Previous studies have explored user requirements capture during the design process of medical devices. Martin *et al* indicated that user requirements research in medical device design appears to be considered and captured during the design and evaluation stage of the product life cycle (Martin *et al*, 2008). Martin *et al* described the process of involving users as often being an 'after-thought' in the design process (Martin *et al*, 2008). This would imply that medical devices are sometimes designed for the end users' needs or requirements retrospectively and towards the end of the design process.

In contrast, the results of this study indicate that ‘User Needs’, specifically the needs of ‘Patients’ (see Figure 6.5) are the priority consideration for designers of home use medical devices. Figure 6.4 revealed that 74% of designers in this study believed patients to be the majority users of home use medical devices, with a reported 58% of designers citing ‘Patients’ as the priority user group (see Figure 6.5).

The literature review of this research addressed the need to define the term ‘user’ in the context of home use medical device design. According to the harmonised standard, IEC BS EN 62366, a user is defined as the “person using i.e. operating or handling, the medical device.” Understandably, for home use medical devices this can cover a broad range of individuals with diverse capabilities from servicing and installers to patients and healthcare professionals (Shah & Robinson, 2008).

While Patients were identified as the leading users of home use medical devices, many respondents to survey perceived healthcare professionals to be users of home use medical devices. Figure 6.4 revealed that; nurses, clinicians and general practitioners (GPs) accounted for 60%, 46% and 43% of responses from participants respectively. This finding shares similarities with existing research on the users of medical devices.

Shah and Robinson explored the concept of the term ‘user’ in a structured review of existing literature (Shah and Robinson, 2008). The authors combined existing perspectives on the term ‘user’ resulting in a classification for users based on two classes, seven types and several types and sub-types (Shah & Robinson, 2008). Initially the users were divided into Primary and Secondary users before being classified into seven different types of user. These types included: Healthcare Professionals, Patients, Carers, People with Special Needs, Trainees & Students, Researchers and Others (Shah & Robinson, 2008).

Shah and Robinson posited that for the purpose of design, medical users are often assumed to fit in one of two generic categories ‘Clinicians’ and ‘Patients’ (Shah and Robinson, 2008). Figure 6.4 indicated that the majority of designers identified ‘Patients’ and healthcare professionals including ‘Nurses’, ‘Clinicians’ and ‘General Practitioners’ as users for home use medical devices. It could be argued that the results of this study support the work of Shah and Robinson in that the designers in

this study predominantly designed for these two ‘generic’ user groups. Shah and Robinson posited that assumptions ‘by default, if not by design’ of medical device users are that they typically fall into ‘one of two ill-defined generic categories clinicians and patients’ (Shah & Robinson, 2008). Consequently they add that such assumptions have ‘led to a narrow two-dimensional approach to users’ which has ‘belied the richness and complexity’ of the manner in which medical devices are adopted in everyday use (Shah & Robinson, 2008).

Aside from these two recognised user groups, Figure 6.4 indicated that Buyers (23%), All of the Above (9%) and Standards Agencies (6%) were the least likely of user groups to be considered by designers for their core business. This supports the findings of Figure 6.2 in the sense that the process of designing a home use medical device is perceived, as a user needs driven process by respondents to this study. This finding however contrasts with the earlier work conducted in this thesis, which indicated that, the process of designing a home use medical device is commercially driven (See Chapter Four).

In spite of this it would be inaccurate and inappropriate to assume or conclude from this study alone that such a finding implies that designers consider buyers or standards agencies of little importance or priority in the design process. It may well be that designers do in fact prioritise for such groups but do not consider them to fit under the heading of the term ‘User’. Perhaps if a separate question asked for the ‘Stakeholders’ within the process of designing a home use medical device there may have been different results to this question.

Approximately 58% of respondents perceived ‘Patients’ to be the priority users of home use medical devices. This finding contrasted with the hypothesis of the researcher. Based on existing research it was believed that designers of home use medical devices would place an emphasis upon satisfying the requirements of healthcare professionals above the needs of patients. Chapter Five of this thesis indicated that a home use medical device company based in the United Kingdom typically based decisions and their delivery process on the requirements and needs of senior level healthcare professionals with influences on procurement.

In a study conducted by Money *et al*, it was also found that designers typically valued the views, requirements and needs of healthcare professionals above that of the patients (Money *et al*, 2011). One manufacturer in their study considered surgeons to have sufficient knowledge to act as representatives of the end users for the home environment (Money *et al*, 2011). In their study, Money *et al* found that a manufacturer justified the decision to use surgeons for user needs research due to their influence upon the promotion and sales of the device to their patients. A similar finding was also found in the idealised practice case study of this research whereby the use of representative users was discussed in light of the practical constraints facing designers in the home use medical device industry.

Question nine of the survey set out to ascertain designers' perspectives and reasoning for selecting their priority user group. Table 6.5 revealed a diverse set of responses from participants that given the multiplicity of respondent backgrounds was perhaps to be expected. For clarity the list of potential users presented to respondents in the survey included: Buyers, Carers, Clinicians, Consultants, General Practitioners, Nurses, Patients, Standards Agencies and All of the Above. Respondents were also provided with the option to include any extra users they considered in the design process.

A summary of respondents reasoning behind their chosen priority user group is presented below:

**All of the Above** – 2 out of 24 responses were for All of the above (8%). One of the designers in the study opined that everyone on the list in Figure 6.5 is a potential user therefore all of the needs must be considered.

**Carers** – 2 out of 24 responses were for Carers (8%). One designer felt that carers were the closest to the end user therefore the needs of carers should take a priority when designing a home use medical device.

**Consultants** – 2 out of 24 responses were for Consultants (8%). One designer referred to the influence consultants have on the procurement process therefore designing for their needs was the priority for their company.

**General Practitioners** – 2 out of 24 responses were for General Practitioners (8%). Both responses for General Practitioners referred to them as a means of distribution for medical devices whereby meeting their requirements improved the chances of uptake in the marketplace.

**Nurses** – 1 of 24 responses was for Nurses (4%). One designer felt that the nurses have to meet the needs of their patients therefore the needs of the nurse were a priority consideration for design which would then be delivered to the patient.

**Patients** – 13 out of 24 responses were for Patients (54%). Every designer who selected patients as the priority user group alluded to the fact that for home use medical devices they are the ultimate end user in the process thus their needs are the most important for design.

To ascertain how the designers in this study considered and designed for the different user groups in this study the survey addressed the design process itself. Figure 6.6 indicated that 45% of designers in this study reportedly followed a 'user centred design' process towards home use medical devices. This result suggests that many of the respondents in this study are in fact aware of user centred design as a practice and furthermore reportedly implement such a process in the design of home use medical devices. The issue of how designers implement a 'user centred design' process however cannot be explored through a survey strategy alone. As part of further research for this thesis it is necessary to explore in greater depth the stages and methods involved in such an approach towards home use medical device design.

A reported 35% of respondents in the study indicated that they followed a Detailed Design Process towards home use medical device development. Again, further research is necessary to understand respondent's different interpretations of such a process including the involvement of users towards home use medical device development. This will be addressed later in the discussion when the results of question thirteen in the study are discussed.

Figure 6.7 revealed that 86% of respondents in the survey actively collected design feedback from their end users post launch. According to the National Research Council, there is opportunity after a product or system is marketed to 'solicit and

analyse' feedback from users to inform updates or new designs (National Research Council, 2011). Therefore by collecting feedback from end users it is possible to identify early stage problems with device use whilst also providing design insights to be iterated into future designs or upgrades. This approach is advocated by user centred principles where an iterative approach to design with involvement from end users throughout the development process reportedly leads to safer and more usable devices (IEC BS EN 62366: 2007).

One of the limitations of question eleven in the survey however is the potential for respondents to misinterpret user feedback with post market surveillance, which is a legal requirement from a regulatory perspective. One participant during piloting highlighted that they considered this question to refer to post-market surveillance and the monitoring of a device after launch. Subsequently the wording of question eleven was adapted for the final survey design. This is a recognised limitation of questionnaires as the researcher is unable to rephrase or reword a question to the respondents to draw meaningful answers as intended.

If, however, the designers in this study have interpreted this question to refer to post market surveillance it would be present a very concerning finding for the medical device field, whereby 14% of respondents (n=5) do not actively collect post market complaints.

Despite this however the findings suggest that there is proportion of the design community that do not actively collect design feedback from their users after launching a device onto the market. As previously described this is a fundamental component of a user centred approach and part of the Usability Engineering Process as outlined in the IEC BS EN 62366: 2007. It will be interesting as part of further research to explore exactly what feedback is actively collected from users post launch and how this information is used in future upgrades or new development projects.

Figure 6.8 of the results revealed that designers in the study considered the 'Number of Sales' to be the leading measure of success for home use medical device development. For clarity the measures of provided to participants included: End User Feedback, Healthcare Professional Feedback, Industrial Awards, No Product

Complaints, No Product Recalls and Number of Sales. Respondents were also provided with an 'Other' category to add any of their own success measures. The emphasis upon the number of sales highlights the significance of remaining commercial in this competitive field. Sales will ultimately make a company profitable and ensure they remain in business therefore it is understandable and perhaps expected that a company would regard this as a critical factor for success.

End user feedback was found to be the second highest measure of success for new developments onto the home use medical device market. This result suggests that the users of home use medical devices are highly valued from the perspective of designers in this study. This is despite 14% of respondents (n=5) indicating that they did not actively collect end user feedback post launch.

According to Dixon *et al* in a paper entitled, *Experiences of New Product Development in the Medical Device Industry*, product quality relative to competitors and as defined by the customer was revealed to be the most important factor in how a product performed in the market (Dixon *et al*, 2006). The authors posit that due to the highly competitive nature of the medical device industry 'product quality and increased value compared with competitors have the greatest effects on the likely success of a new product.' (Dixon *et al*, 2006). Thus the findings of this study support the findings of Dixon *et al* in that the designers in this study perceived end user feedback to be an important measure of success for a home use medical device (Dixon *et al*, 2006).

Figure 6.8 indicated that end user feedback was reportedly valued above that of the healthcare professionals. This finding contrasts with that of Money *et al* and the earlier case studies of this research whereby the views of senior healthcare professionals were held in higher esteem than that of patients (Money *et al*, 2012). It might be that although designers value the initial insight from healthcare professionals their influence is less pertinent once a device has been launched onto the market. This would require further research with designers in person to ascertain whether this is the case.

The results to question twelve also revealed a relatively low priority placed upon purchaser feedback. Chapter Five of this research identified purchasers as one of the

driving influences in decisions selected and used by patients. In contrast the results of this study suggest that purchaser feedback is of lesser significance to designers in measuring the success of a home use medical device.

Interestingly industrial awards and accolades were identified to be the lowest priority for measuring the success of a new product onto the market. The analysis of question twelve revealed that ‘Number of Sales’, ‘End User Feedback’, ‘Healthcare Professional Feedback’, ‘No Product Recalls’ and ‘No Product Complaints’ significantly differed from the attainment of ‘Industrial Awards’.

The Freidman Test and Pairwise Comparison for question twelve revealed that the ‘Number of Sales’ was significantly more important than ‘Purchaser feedback’ in measuring the success of a home use medical device. This is despite previous research recognising the need for designers address purchaser’s views in the design process (Money *et al*, 2011). It could therefore be inferred that designers might ignore a purchasers insights if they perceive an alternate approach to increase the sales of a medical device.

To understand the specific stages of user involvement within the design process of a home use medical device, participants were asked to indicate the level of user involvement throughout a generic design process. Figure 6.9 revealed that the design stage with the reported highest level of user involvement was ‘Product Testing’ with a mean rank of 4.54. The second highest recorded mean rank was ‘Post Launch’ at 3.96. This finding suggests that designers in this study typically involved users towards the end of the design process when either a prototype for testing or a final product has been realised.

In spite of the study indicating that ‘User Needs’ were the leading driver behind home use medical device development, Figure 6.9 suggests that actual involvement does not occur in a large capacity until after the design stage of a home use medical device.

Previous studies have also found that user involvement for medical device development typically doesn't occur until after a design brief has been produced (Martin *et al*, 2008). Martin *et al* posited that this may be attributable to medical

devices typically being technology driven rather than the result of identifying an existing un-met need (Martin *et al*, 2008).

Figure 6.9 suggests that users would be involved highly for the testing of a device or for post launch analysis. Involving users at this stage within the design process however provides limited scope for their involvement to have influence on the design of a device. As the National Research Council explain the 'best way to ensure a good fit with user needs, expectations and capabilities' is through 'repeated prototyping, testing and revisiting of the design' (National Research Council, 2011). Thus, advocating an iterative approach to design with users throughout the process as a whole. The National Research Council refer to iteration as follows:

*"The term "iterative" applied to the design process refers to the fact that the process should not be a one-way linear progression from concept to product." (National Research Council, 2011).*

As previously described, a user centred approach in the form of a usability engineering process as described by IEC BS EN 62366: 2007 requires an early focus upon users and throughout the design process iteratively (IEC 62366, 2007).

Question thirteen of this study suggests that the manner in which designers implement such an approach differs greatly. This again is perhaps to be expected as the practice of 'usability engineering' for medical devices is recognised to vary widely. According to IEC BS EN 62366: 2007, the variation in practice is attributed to the diversity of the practitioners themselves (IEC BS EN 62366, 2007).

Due to the diverse range of devices that fall under the 'umbrella' term of a medical device, and particularly home use medical devices (See Chapter Two for a taxonomy of home use medical devices), it is perhaps understandable that many practitioners have different backgrounds from fields such as engineering, psychology and design (IEC 62366, 2007). Consequently the practice of design for medical devices is recognised to vary quite markedly from company to company and designer to designer. The complexity of devices, users and use environments will of necessity call for slightly bespoke approaches to the design and development of home use medical devices. This was supported by the idealised practice case study presented in

Chapter Four in which the interviewees described a 'tool kit' they would bring to the process of medical device development that is typically influenced by the commercial challenges of delivering a device to market.

A pairwise comparison of the results for question thirteen indicated that there was a significant difference between the levels of user involvement during product testing and the Product Development and Product Design Specification (PDS) stages of the design process. This suggests that participants in this study were significantly more likely to involve users during the late Product Testing stage of a home use medical device rather than in the development of the PDS or during development.

## 6.12 Summary

In summary the results of this study suggest that designers of home use medical devices typically involved users towards the end of the design process of a home use medical device. In light of this, the study supports the work of Martin *et al* who reported that users were rarely involved or considered until after the design brief for a device had been developed (Martin *et al*, 2008). Failing to incorporate the users early and throughout the design and development stages of a device results in a design that is so advanced along the design process that any involvement after that stage will not be included in the final design. Despite 45% of designers in the study indicating that they follow a 'User Centred Design Process' and 'User Needs' being identified as the leading driver for development, the involvement of users within the design process was typically retrospective.

The designers' perspectives of users within this study support the findings of existing research. Money *et al* discussed the commonly held view by some designers that 'superficial' design features may be added on at the end of the development process (Money *et al*, 2011). Gulliksen *et al* refer this to as a 'cake-frosting' exercise (Gulliksen *et al*, 2006). This approach to design contradicts the principles of a user centred approach or a user needs driven development process. Further research must explore the process of design in more detail to ascertain how users are involved specifically. In order to answer research question two of this research designers of home use medical device must be consulted to understand the specific challenges towards user involvement in home use medical device design. Only then can research

question three of this research be addressed to incentivise a change in current practice towards home use medical device development.

The following sections will now discuss the reliability and validity of the data followed by the limitations of the study. The chapter will conclude with a summary of the findings and proposed future work.

## 6.13 Ethical Considerations

The ethical issues in the context of this study were considered before, during and after the collection and presentation of any data or information. The ethical principles described in Chapter Three as outlined by Saunders *et al* were employed for this study (Saunders *et al*, 2009). Every participant was made clear of his or her rights to privacy, anonymity and to withdraw at any stage in the research process. This included once participants had completed the online survey should they wish to do so. Subsequently their results would be removed from the data set without any questioning into the reasoning to withdraw. Participation in the study was voluntary and no incentives were used to force participation upon individuals or organisations.

Finally, in accordance with Loughborough University's Code of Ethics, an ethical clearance checklist was completed by the researcher in early 2011 and co-signed by the supervisors of this research.

## 6.14 Reliability and Validity

When collecting information through questionnaires there are a number of issues relating to reliability and validity that need to be considered. As with the ethical considerations of this research the issues of reliability and validity of data were explored in chapter three of this research. To address the reliability of the data in this study, the three questions identified in chapter three posed Easterby-Smith *et al* will now be addressed (Easterby-Smith *et al*, 2008).

1. **Will the measures yield the same results on other occasions?**
   All reasonable steps have been taken to conduct this study in a manner that is open and replicable. No results have been manipulated, modified or deleted in the presentation of this study. All results are indicative of the raw data

collected from participants currently operating in the home use medical device field. The presentation of the methodology, recruitment, questions and results enables any interested researcher to repeat the study if they so wish.

2. **Will similar observations be reached by other observers?**
   Due to the nature of this descriptive study it would be unrealistic for the study to be repeated by others and to draw the exact same conclusions. This is due to the nature of open-ended questions and qualitative research in general. As before all steps have been taken to make this study as reliable and valid. The study was both pre-tested and piloted with target participants before the final design was distributed.
3. **Is there transparency in how sense was made from the raw data?**
   The methods of analysis used in this study are made explicit throughout the chapter. All of the data collected for this study is presented in this chapter. Exact figures and numbers are used throughout the chapter that make all results in the study explicit.

Further to these questions, additional steps were taken to ensure the results of this study were reliable and valid. The wording and structure of questions play a key role in ensuring the information received is reliable. Ambiguity in a question's wording will lead to misinterpretation by the respondent and ultimately unreliable results. To combat this, the questionnaire was both pre-tested with a lay audience and then formally piloted with the target audience to determine any potential flaws in the questionnaires design.

Gray describes that there are two main threats to validity of questionnaires: the extent to which respondents complete the questionnaires accurately and the problem of non-response (Gray, 2009). If the response rate is particularly low then generalisations of the findings becomes limited thus affecting the validity of the data. It is therefore critical to ensure that questions are structured in such a way to cover the intended research areas and concise in its length as to ensure the best possible response rate to the survey. As far as was practicable this study was designed to have a minimal time requirement to complete the questionnaire as this has been shown to adversely affect response rate (Gray, 2009; Robson, 2011).

Finally no generalisations of the data were made. The findings of the study were compared and contrasted with the work of others in the field however for explicit generalisations to be made would require a larger sample of respondents. As part of further research posed towards the end of this chapter, the following study will explore the issues of this study with respondents in greater depth to triangulate the findings for this research. On completion of the next study the researcher will be able to reflect upon the reliability and validity of the findings and conclusions in this chapter.

## 6.15 Limitations

To evaluate any course of work requires the consideration of potential limitations in the chosen methodology and data analysis. For the purpose of this study perhaps the main limitation can be attributed to the use of a questionnaire as the study method. Prior to selecting a study method the advantages and disadvantages of potential approaches were considered. The design of the questionnaire was constructed in such a manner to attempt to combat some of the associated limitations of questionnaires. However, on reflection of the data analysis for this study, the research has established that generalisations from the data are restricted by the limitations of the methodology.

The most apparent limitation of the study is the lack of depth and insight behind the responses of participants. The survey provides a 'snapshot' of current practice for home use medical device design based on standalone responses from designers in the field. While the findings are indicative of current practice and are compared with existing research in the field it is necessary to conduct further, more in depth research with the participants of this study to gain an understanding behind their responses. Further insight into the 'why' questions of current practice could not be explored through the manner in which the survey was delivered to respondents. To explore these issues further would require an interview-based method with participants that could facilitate discussion in a two-way conversation between researcher and participant.

Another limitation to consider for the study refers to distribution of the online survey amongst participants. One must consider the fact that only individuals and organisations with access to the Internet would have been able to complete the online

survey. To accommodate for this participants were offered the option of paper-based questionnaires. However the decision to distribute the survey online was deemed suitable due to the nature of the global market in which many medical device companies operate. It was therefore considered reasonable to assume that such companies would have access to the Internet and therefore the survey. Note that no participants completed paper-based questionnaires.

Finally, it should be added that although much of the contact and access to participants was made online, the nature of the sampling strategy (i.e. purposive and snowball) for the study meant that potential participants were accessed in a number of ways and not just through a company's website online. Despite this, one must consider that this approach to sampling presents a limitation for research in that the respondents in the study are self-selecting. The context of self-selection here refers to respondents having a personal interest in the research therefore expressing a willingness to participate. Consequently one must consider that the respondents in this study come with a potential bias, background and experience in the home use medical device industry.

## 6.16 Future Work

Following the completion of the first descriptive study, a number of themes have been identified for further research within this thesis.

The limitations section highlighted that a number of the questions from the survey lacked the level of depth and insight to draw more meaningful conclusions from respondents. Therefore further research must probe on previous responses to explore the context of the findings for the descriptive study in greater detail. An interview-based approach to follow on from the descriptive study presented here has been selected as the most suitable method to generate this information from participants. The first descriptive study revealed that a number of participants have expressed a willingness to continue with the research which is particularly advantageous from a recruitment perspective.

One issue that future studies within this thesis must address is the perceived significance of the challenges towards involving users in the design of home use medical devices. It is believed that by identifying and describing the challenges

towards adopting the principles of a usability engineering process, this research will reveal potential opportunities to incentivise a change in industry's current approach towards home use medical device design.

The following chapter will address in greater detail the methods adopted by the design community to identify the needs of their end users and to overcome the issues of regulations and ethics identified as challenges within this study. This information will only be revealed through interaction between the researcher and the designers themselves to understand the 'why' questions of this research.

## 6.17 Conclusion

In summary, this chapter has presented a descriptive study on designers' perspectives towards users and their involvement in the design of home use medical devices. The discussion of this chapter has provided answers to research question one:

***Research Question One: How do designers consider and involve users in home use medical device development?***

The chapter alludes to a decision process for designers based upon the balance of meeting the needs of end users against the commerciality of the medical device industry. The study suggests that the design of home use medical devices is influenced by the incentives to involving users in the design process, as advocated by IEC BS EN 26366: 2007, against the challenges of applying such principles in practice.

This study highlights a reported user needs driven process that is ultimately dictated and measured by the commercial success of the device on the market. The study revealed that Cost, Time, Regulations and Ethics present challenges to designers in involving users in the design process of home use medical devices.

The study offers three potential scenarios to explain the reasons behind industry's current approach towards user needs research.

***Scenario One: Designers are aware of the principles and methods for user needs research but do not apply them***.

**OR**

***Scenario Two: Designers are not aware of the relevant methods and so cannot apply them at all.***

**OR**

***Scenario Three: Designers are aware of the principles and methods for user needs research but apply them sub-optimally.***

Designers in the study reported user needs as a leading driver behind the development of home use medical devices, with 45% of respondents following 'user centred design' process to home use medical device design. The results of this study imply that designers are aware of the principles of user centred design, however the approach towards user involvement in the design process of a home use medical device is 'retrospective'. Further studies as part of this research must address these three scenarios to understand current practice in industry towards user involvement in home use medical device design.

Using the findings of this study the following chapter presents the explanatory study of this research. The chapter presents the semi-structured interviews conducted with designers of this study to offer new knowledge to the field of home use medical device design.

# Chapter 7 Understanding Current Practice

**"To meet the challenges of the design process requires understanding the actions that lead from existing situations to preferred ones."**
**(Friedman, 2003)**

Descriptive study one presented in the previous chapter identified some of the current perceptions of designers towards the involvement of users within the design process of home use medical devices. The study indicated that designers of home use medical devices perceived Cost, Time, Ethics and Regulations to be challenging towards the involvement of users in the design process. As an output to the previous chapter the need to explore these issues further with the same target population was discussed. The following chapter presents the explanatory study of this research which aims to answer and develop a clearer understanding of the 'Why' questions of this research. This study is focused on unveiling the manner in which practicing designers overcome the previously identified challenges in the design of home use medical devices.

## 7.1 Introduction

Through this explanatory study as part of the Design Research Methodology (DRM) approach the following chapter aims to answer research question two:

***Research Question Two: What are the challenges for industry to involving users in the design process of home use medical devices?***

In the opening paragraph of the chapter, Professor Ken Friedman posits that in order to meet the challenges of the design process requires an understanding of the actions that take us from existing situations to preferred ones (Friedman, 2003).
Understanding the individual steps taken within a design process with respect to user

involvement will lead to the unveiling of specific challenges to the designer. With this understanding, it is believed that the challenges and constraints of the designer can be met with solutions that lead to the delivery of design improvements towards end user involvement.

The following study attempts to build a detailed understanding and explanation of current design practice towards user involvement in home use medical device design. By applying the findings of this research, this chapter will build upon existing knowledge to develop and offer recommendations as a conclusion.

## 7.2 Rationale

The previous chapter revealed that the involvement of users within the design process of home use medical devices is influenced by certain challenges within the design process. The results of the online survey presented in Chapter Six of this thesis suggested that a designers understanding of 'user centred design' principles contributed to the level of user involvement in the design process. To expand on this knowledge it is necessary to explore these challenges in more depth through consultations with practicing designers themselves. Gray argues that while the descriptions of a phenomenon can provide the basis for analysis, it is necessary to go beyond description to interpret, understand and explain the data (Gray, 2009).

To ascertain the challenges for home use medical device designers requires an understanding of the terms used (i.e. interpretations and definitions) by the design community within the context of this research. The previous study made reference to the use of the term 'user' which was identified to potentially be defined as a range different 'stakeholders' in the design of a home use medical device. Thus, the following study will utilise the advantages of an interview-based approach to reveal the understanding of designers themselves.

The reader will be aware that the term designer is used throughout this thesis, however as previous research has shown for home use medical devices this can be a variety of people within a broad team (Shah & Robinson, 2008). The background of a designer in this field therefore could potentially be one of Bioengineering, Physics or Design itself to name but a few. Clarifying the definition of 'designer' in terms of the backgrounds and experiences of individuals within this study will provide a

further insight into the practice of home use medical device design. Note that many of the key terms used throughout this thesis are defined in the Glossary section.

The previous chapter concluded that an interview based approach to data collection would be necessary for this study to gain the level of detail required from respondents. While the previous study introduced the perspectives of practicing designers towards home use medical device design there was an identified limit to the information revealed by the survey. With this in mind, this study will build on these findings using the methodology described in the following section.

## 7.3 Methodology

For the purpose of this study a data collection strategy was required to elicit practicing designers' experience, knowledge and understanding of user involvement in home use medical device design. Due to the depth and detailed responses required for the study, an interview-based method was identified as the most appropriate data collection strategy to build upon the findings of the previous chapter.

Interviews can play a central role in data collection and as such have a significant influence on the quality of the data collected from participants (Fowler, 2002). According to Fowler there are three primary roles of an interviewer:

1. To locate and enlist the cooperation of selected respondents.
2. To train and motivate respondents to do a good job of being a respondent.
3. To ask questions, record answers and probe incomplete answers to ensure that answers meet the question objectives.

**Gaining cooperation**

Enlisting participants for an interview can be difficult. Fowler describes how the interviewer often has to be flexible in their availability for when interviewees want to be interviewed (Fowler, 2002). Furthermore, where respondents are 'hard-to-reach' be it through geographical location or poor telecommunication links, the interviewer must be able or willing to go where the respondents are in order to collect data. There are however many options available to interviewers to collect data from participants and the following section will address this.

### Training and motivating respondents

The performance of respondents including the accuracy of reporting in interviews has been linked directly to the orientation and delivery of the interview itself (Fowler, 2002). A slower delivery of questions indicates to respondents to take their time in providing an answer to the question and consequently provides a more accurate and rich response (Fowler, 2002). Encouragement by the interviewer has also shown to affect the respondent's perceptions and expectations of what is required and consequently how well they report (Fowler, 2002). The interviewer, whether consciously aware or not, teaches the respondent how to behave, something Fowler describes is 'often unappreciated but critical' part of the interviewer's role.

### Being a standardized Interviewer

It is hoped that when conducting interviews the differences in responses between participants are attributable to differences in experiences and opinion and are not the result of differences in the manner in which the interview has been delivered. This includes the differences in stimulus and probes that are affected by question wording and the context and way in which questions were asked. Essentially a standardised approach by interviewers ensures that the interviewer does not affect the answers they obtain. According to Fowler, when training interviewers there are five aspects of interviewer behaviour that researchers attempt to standardise. These include: the manner in which the study and task are presented, the way in which questions are asked, the way inadequate answers (i.e. answers that do not meet the question objectives) are probed, the way in which answers are recorded, and the way that interpersonal aspects of the interview are handled (Fowler, 2002).

1. **Presenting the study:** Respondents should have a common understanding of the purposes of the study because the sense of purpose may have a bearing on the way questions are answered. It is important to clarify ethical issues at the beginning. This includes confidentiality, the voluntary nature of the interview, right to withdraw and who will use the data. These issues will all have an impact on how a respondent will answer questions at interview. Fowler recommends keeping the context of the interview constant to improve the quality and consistency of responses from participants (Fowler, 2002).

2. **Asking the questions:** Survey based interviews should be conducted in the manner they are written and intended, with no variation in wording. The smallest of changes has been shown to have significant effects on the way questions are answered by participants (Fowler, 2002). To ensure the data is consistent from designers within this study the questions must be asked in the same manner to all participants.
3. **Probing:** Asking respondents to build or add to a response that does not fulfil a question's requirement may be necessary when conducting an interview. The interviewer must therefore be ready to adapt to the responses of participants. As Fowler explains however, interviewers are supposed to probe 'incomplete answers' in non-direct ways (Fowler, 2002). Thus, in probing a response the interviewer must not influence one particular response over another, which would introduce bias into the results. Typical examples of simple non-bias probes can include "Anything else?", "Tell me more?", "How do you mean?" (Fowler, 2002). These nondirective questions ask respondents to add more detail to their previous answer without influencing the content of the next response.
4. **Recording the answers:** A standardised approach to recording must be conducted throughout all data collection so that no variation occurs. In open discussions with respondents, conversations must be recorded verbatim, word for word, without any paraphrasing or summarising at a later stage based on any subjective judgement of the interviewer.
5. **Interpersonal relations:** The personal issues of an interview can be minimised through an emphasis on the professional aspects of interactions between the interviewer and interviewee. While Fowler admits that the interviewer inevitably brings their own demographic characteristics to an interview (e.g. gender, age, education etc.) it is possible to control the interpersonal relations through due consideration (Fowler, 2002). This includes no expression of views or opinions before or during an interview. Such behaviour can again influence a respondent's answer to a particular question. As Fowler states, 'to behave as a professional, not a friend, helps to standardise the relationship across the interviewers and respondents' (Fowler, 2002).

The previous chapter described that one of the limitations in using questionnaires, as a research strategy is the inability to explore, in depth, the meaning or explanations behind the answers provided by a respondent. Gillham explains that "only limited inferences can be made because you cannot explore what lies behind the answers to the questions" (Gillham, 2005). The inferences and findings presented in the previous chapter called for the rationale to conduct interviews as the follow up study in this research.

Research of a qualitative nature that employs a survey-based strategy often reveals questions that were not anticipated by the research in the beginning. The questions however will always be more focused in scope and subsequently provide a direction to the research pathway. Thus, the knowledge acquired from Chapter Six was fundamental to the purpose of this explanatory study.

Before the selection of the interview method it is necessary to answer three specific questions, each of which has implications for the interview design. These questions are as follows:

1. **What do I expect to find?**
   The interviews expect to; identify the methods employed by industry for involving users in the design process of a home use medical device, reveal whether the available guidance and support materials for the designer are used and furthermore valued, unveil greater depth to the findings of chapter six including the challenges to applying 'user centred' design principles to home use medical device design.
2. **What would I prefer to find?**
   The study would prefer to find answers to the research questions of this thesis including the user research methods, perceptions of guidance and an indication of current design processes followed by practicing designers in industry.
3. **What would I hope not to find?**
   The study would hope to not find that the target population of the study are unwilling to participate in the interview. The study wishes not to identify reluctance from participants to answer specific questions within the interview protocol that relate to the research questions.

Addressing these questions before embarking on the selection and design of an interview method will ensure that the issues of standardisation are fully considered. The following section will now describe the different interview methods considered for this study before presenting the final design.

### 7.3.1 Structured Interviews

A structured approach to conducting interviews in many ways follows the principles of a self-completion questionnaire (Robson, 2011). Robson posits that there are a fixed set of questions, which are typically specified during pre-testing and piloting to achieve standardised wording (Robson, 2011). Thus, structured interviews typically only feature a small number of open-ended questions where respondents can provide a more detailed response to a question. This does not in itself mean that survey based questionnaires are the same as structured interviews.

The fundamental difference between the two strategies is the direct influence of the interviewer on the questioning process. Robson argues that characteristics such as the skills, experience, personality and degree of involvement within the research itself can have complex ramifications for this data collection method (Robson, 2011). To overcome these factors and remain 'standardised', Robson outlines six general advisory points presented in Table 7.1.

**Table 7.1: General advice for interviewers conducting interviews (Adapted from Robson, 2011).**

| | |
|---|---|
| 1. | **Appearance:** Dress in a similar way to those you will be interviewing. If in doubt err on the side of neatness and neutrality. |
| 2. | **Approach:** Be pleasant. Try to make the respondent comfortable. |
| 3. | **Familiarity with questionnaire/interview schedule:** View yourself as an actor, with the interview schedule as your script. Know it thoroughly. |
| 4. | **Question wording:** Use the exact wording of questions and keep to their sequence. |
| 5. | **Fixed-alternative response questions:** Only allow the standard alternatives. |
| 6. | **Open-ended response questions:** Either code immediately or record the answers exactly for later coding. Don't make cosmetic adjustments, correct or fabricate. |

### 7.3.2 Semi-structured Interviews

In contrast to a structured approach, a semi-structured interview is much more flexible in nature. Robson describes semi-structured interviewers as having a 'shopping list of topics' for discussion and consequently this approach exercises freedom in the responses from participants in the sequencing of questions and probing (Robson, 2011).

Robson argues that semi-structured interviews are "most appropriate when the interviewer is closely involved with the research process (e.g. in a small-scale project when the researcher is also the interviewer)". In this study the primary researcher is also the interviewer and as such a semi-structured approach to interviewing was considered more suitable than a structured approach. The semi-structured nature of the interview however must have a structure in place to ensure a consistent narrative as previously described (Fowler, 2002).

Robson outlines a simplified schedule for semi-structured interviews, which is presented below (Robson, 2011).

- Introductory comments
- List of topic headings and possible key questions to ask under these headings
- Set of associated prompts
- Closing comments.

The following section considers this schedule in more depth and presents how the interviews for this study will be conducted.

### 7.3.3 Face-to-Face Interviews

Interviews may be conducted in groups or individually depending on the type of information to be elicited from participants. For the aim of this study, it was necessary for the interviews to occur in real time to understand the priorities and foremost perceptions of designers in this research. Therefore the possibility of email interviews, described by Robson, were considered inappropriate for this context as they would allow participants to reflect on their answers before providing a response

to the interviewer (Robson, 2011). In light of this, Face-to-Face and Telephone strategies were considered more appropriate for this study.

Face-to-face interviews involve the interviewer travelling to the interviewees to conduct the interview. One benefit of this strategy includes the contextual information gained from observing participants as they answer questions, which is not possible in a telephone approach (Robson, 2011). Visual cues within an interview can be useful to the interviewer to identify when a topic requires further exploration or requires a change of subject to keep the interview progressing. Robson claims that face-to-face interviews can be typically longer in duration when compared with telephone interviews. According to Robson, telephone interviews are usually less than 30 minutes whereas face-to-face interviews can be up to an hour in many cases (Robson, 2011).

### 7.3.4 Telephone Interviews

In contrast, telephone interviews are typically a quicker, shorter and cheaper approach to interviewing. Robson argues that conducting an interview over the telephone reduces the potential for interviewer bias (Robson, 2011). The characteristics of the interviewer, described previously by Fowler, have less of an influence during an interview over the telephone. Robson believes that such an approach to conducting interviews are worth considering in situations where a 'lack of resources precludes carrying out an adequate sample of personal interviews' (Robson, 2011).

### 7.3.5 Interview Strategy

For the aim of this study, it was considered necessary to conduct face-to-face interviews with participants, where possible and practical. This strategy was chosen based on the potential to conduct longer interviews with participants and the potential to elicit valuable contextual data. Due to the level of detail required in the responses by participants approximately one hour would be required for the interview protocol. Robson described that telephone interviews were typically less than 30 minutes, which would be unsuitable for this study. Where possible, participants in the study would be visited at a preferred location to remove any inconvenience of travel for participants.

It was considered that should participants decline or be unable to commit to a face-to-face interview the opportunity of a telephone interview would be suggested. This was considered necessary due to the difficulty to access participants in the previous chapter and the disadvantages of a telephone strategy would have to be considered in the reporting of the data.

## 7.4 Design

With the interview strategy chosen, the design of the interview protocol itself could commence. Designing a semi-structured interview involves the consideration of core questions; potential probes and prompts to elicit information that meets the aims of the interviewer.

Table 7.2 adapted from Robson (2011) and Gillham (2005), presents two different structures to the process of conducting an interview. Both of the designs presented in the table consist of five fundamental steps to the interview process.

The strategies of Robson and Gillham both describe an interview structure than builds in depth and level of detail required from respondents as the interview progresses (Gillham, 2005; Robson, 2011). According to the works of Robson and Gillham, it is necessary to have introductory or 'warm up' questions prior to the core questions of the interview (Gillham, 2005; Robson, 2011). Robson posits that 'risky' questions that could potentially be interpreted as fractious by respondents are best left towards the end of the interview once a comfortable atmosphere has been established.

The proposed formats of Gillham and Robson both conclude with a 'closure' period where respondents are thanked for participation and given a summary of the topics covered. According to Gillham and Robson, closure at an interview helps to identify any topics potentially missed during the discussion (Gillham, 2005; Robson, 2011). The closure stage of the process also enables the interviewer to explain what happens next with the data.

**Table 7.2: Interview sequences (Adapted from Robson, 2011 and Gillham, 2005).**

| The sequence of questions (Robson, 2011) | The conduct of the interview (Gillham, 2005) |
|---|---|
| **Introduction** – Introduce oneself, the purpose of the interview, confidentiality and permission to record. | **Preparation** – Prior to the interview. Recruitment, informed consent, purpose, location and expectations |
| **Warm up** – Begin with easier questions to settle any nerves of the interviewer/interviewee. | **Initial Contact** – Primarily social and informal, Introductions and 'housekeeping' |
| **Main Body of Interview** – The main purpose of the study. Follow a logical progression of questioning. Capitalise on responses from participants and save 'risky' questions till the end. | **Orientation** – Explaining the interview, reciting information participants will have already received. 'Steer' the person into the interview covering topics such as analysis of results, confidentiality, anonymity and the interview schedule. |
| **'Cool off'** – Winding down the interview with straight forward questions to remove any potential tensions built up throughout the interview. | **Substantive** – The core of the interview and purpose of the research. |
| **Closure** – 'Thank you and goodbye' Collate or record any responses once the interview is over and be consistent with all respondents. | **Closure** – Show appreciation for what has been covered and address any details that were missed. Summarise the interview and outline what happens next with the data collected. |

Using the principles described by Gillham and Robson, an initial design of the interview protocol was developed. The principle of questions building in the level of detail required from respondents as the interview progressed was employed in the initial design.

An introductory phase given by the interviewer would initially describe the context of the research, ethical issues and purpose of the study. Informed consent, right to withdraw or refusal to answer a question would be described to the interviewees. At this time an informed consent form would be handed to the participant to authorise the use of the data collected at interview. A copy of the participant information sheets and informed consent forms are provided in the Appendix 12 and 13 respectively.

After this introductory phase, outlined by Gillham and Robson, the first stage of the interview questioning would begin (Gillham, 2005; Robson, 2011). Stage one of the

interview comprised of simple profiling questions to establish the background of the participants and to ease them into the interview.

Using the findings of the previous chapter, a range of themes was identified for exploration at interview. The seven themes included:

- Drivers for the selection and development of a home use medical device.
- Perceptions and understandings of users.
- The design process of a home use medical device.
- The importance of users within the design process.
- The challenges to involving users in the design process.
- The active collection of user feedback.
- The methods employed by designers to incorporate users in the design process.

In light of these themes a range of non-direct prompts were considered before the interview to assist the interviewer in anticipation of potential responses from participants. Table 7.3 presents examples of the probes considered suitable for each theme.

**Table 7.3: Themes and Probes for interview.**

| Key Themes | Potential Probes and Prompts |
|---|---|
| Drivers for the selection and development of a home use medical device. | • Why?<br>• How do you prioritise?<br>• Who is responsible for this decision?<br>• Can you provide more detail here? |
| Perceptions and understandings of users. | • Who?<br>• Why?<br>• How do you identify or create a profile for your users?<br>• How do you translate needs into design requirements? |
| The design process of a home use medical device. | • Why?<br>• How do you overcome them?<br>• What would make them easier?<br>• Improvements? |
| The importance of users within the design process. | • Why?<br>• Elaborate further?<br>• Can you give me more detail on how you design for them?<br>• Do you define users, user groups?<br>• Can you demonstrate this for me? |

| Key Themes | Potential Probes and Prompts |
|---|---|
| | • Can you give me a product example where you have gone through this process? |
| The challenges to involving users in the design process. | • Why?<br>• How do you decide on which approach to take?<br>• Who is responsible for design decisions?<br>• What do you think of this approach?<br>• Can you draw the process for me, in diagram form?<br>• Are there any challenges to using this approach?<br>• How could this process be improved or made easier for you? |
| Active collection of user feedback. | • Why?<br>• Assessment?<br>• What happens next?<br>• Future work? |
| The methods employed by designers to incorporate user needs. | • How are they involved?<br>• Why are they involved?<br>• Example?<br>• Recent project?<br>• Methods?<br>• Challenges? |

## 7.5 Pre-piloting

According to Gillham, the process of piloting an interview can be divided into two phases, namely the earlier pre-piloting followed by piloting itself (Gillham, 2005). Gillham describes pre-piloting as the process of gaining 'critical feedback' from the respondents, whereas piloting refers to the actual trial run of the real interview (Gillham, 2005).

Pre-piloting the interview structure is necessary to determine what information is required to successfully conduct the interview whilst also highlighting potential responses from participants. Pre-piloting allows for final changes to be made to question wording, focus, order and replacement (Gillham, 2005). This stage should be conducted with respondents of similar background to the intended respondents.

Final piloting to address the interview schedule as a whole should then follow pre-piloting. This stage is the final step prior to going out and conducting the interviews with real participants.

For the purpose of this study, three pre-pilot run through sessions were conducted with participants knowledgeable and experienced in the field of design research and interviewing. Gillham states that three such interviews of the substantive elements will allow the interviewer to ascertain whether the questions are giving the responses with the 'required focus' expected at interview (Gillham, 2005). Each participant was asked the series of questions and for their interpretation and understanding of what the question was asking, before collecting their feedback on potential improvements to be made to the interview protocol.

## 7.6 Piloting

With the pre-piloting stage complete the real pilot of the interview protocol was conducted. The final pilot of an interview allows the schedule of the protocol to be tested in practice with the target population. The timings and sequence of questions allow the interviewer to get a feel for how the interview will be conducted in practice.

For the purpose of this study two pilot interviews were conducted with participants from of the target population. The first pilot was conducted with an industrial designer with over six years of experience in home use medical device design. The second pilot was conducted with a Managing Director of a design consultancy with over 16 years' experience in medical device design including home use devices.

The pilot interviews were approximately 80 minutes and 65 minutes in duration. It was identified that with repeated execution the interview length would be reduced. This was attributable to the researcher becoming acquainted with the interview protocol. Minor changes to the protocol wording and sequence of questions were made for the final design.

## 7.7 Final Design

Following the pre-testing and piloting of the interview protocol a final design was developed. The final design consisted of four stages to the interview; Stage 1 - Interviewee Profile, Stage 2 - Survey Analysis/Questioning, Stage 3 – A discussion on the approach to design, Stage 4 - Wrap up. A copy of the interview protocol can be found in the Appendix 14 of this thesis.

## 7.8 Recruitment

Prior to participation in the study it was necessary for all participants to have completed the online survey study presented in the previous chapter. This was due to the design of the interview protocol, which expanded on the responses and themes identified in the previous chapter. At the end of the online survey all participants were asked whether they would be willing to participate in further research. Those that were interested to take part in further studies were asked to leave their contact details at the end of the online survey to allow the researcher to make contact regarding future research.

Initially, 18 participants from the initial survey expressed an interest in further research. All of these participants were contacted in the six-eight weeks that followed the completion of the online survey. Each participant was contacted via email or telephone, dependent on the details provided at the end of the survey. On contacting participants about the interview study nine expressed they would no longer wish to take part in the study. Due to the ethical considerations of the study, participants were not asked for their reasons to withdraw, as this was part of their right when consenting to the research. Despite this 50% of the participants gave reasons of time and would no longer be available for the study. One participant explained that they could not see the relevance of the research to them and would therefore like to be removed from the study. This was in spite of the participant completing the online survey and being a representative company of the target population for the research. Another participant explained that their practices for design were confidential to the company and would therefore not be willing to share such information at interview.

In light of this, it was necessary to recruit further participants for this study to achieve a significant number of participants. According to Guest *et al* in, *An*

*Experiment with Data Saturation and Variability,* 'saturation occurs within the first twelve interviews' (Guest *et al*, 2006). The study by Guest *et al* also found that 'basic elements for metathemes were present as early as six interviews' (Guest *et al*, 2006). With this in mind the study targeted the recruitment of a minimum twelve different companies for interview.

To recruit further participants for the study other companies were contacted through the methodology described in chapter six. In total four extra participants were recruited for the study. All additional participants were asked to complete the online survey prior to being interviewed, as this was an essential requirement of the study and interview protocol.

A total of thirteen interviews were conducted with designers of home use medical devices. All of the participants in the study were indicative of companies that make up 80% of the current marketplace for medical devices (i.e. Small and Medium Enterprises) (EC, 2013). All participants had experience in home use medical device design, which ranged from 2-30 years.

## 7.9 Analysis

Each interview was digitally recorded to allow for later transcription. The recordings were transcribed, verbatim, word for word, into Microsoft Word Processing software. The transcripts were then transferred into Nvivo 10 ready for content analysis. This approach to analysis was necessary to gain the depth of insights and any potential themes within the responses of participants in accordance with the objectives of this study. The responses from participants were initially grouped based on the core questions, as per the interview protocol (see Appendix 14). The questions were then further analysed and coded based on the responses of participants and the knowledge of existing research. A summary of the content analysis conducted on the transcripts is described below.

**Content Analysis**

Content analysis is a recognised approach to analysing qualitative data that involves making inferences about data (typically text) by 'systematically and objectively identifying special characteristics (classes or categories) within them' (Gray, 2009).

Achieving a level of objectivity in this process is essential. Gray posits that objectivity can be achieved through the creation of specific rules prior to the data being analysed, commonly known as 'criteria of selection' (Gray, 2009).

According to Gray there are three procedures for identifying the classes and categories before conducting content analysis. These include: Common Classes, Special Classes and Theoretical Classes. (Gray, 2009).

- **Common Classes:** These categories are comprised of 'everyday thinking' or common analysis criteria such as Age, Gender, Title etc. These classes are useful in identifying associations between specific characteristics or demographics in the data.
- **Special Classes:** This categorisation is comprised of the labels that specific communities or groups used to distinguish amongst things, persons or events (Gray, 2009). This might include professional terms given to a specific type of practice for example.
- **Theoretical Classes:** These categories arise from the process of analysing the data itself where 'key linkages and patterns' are identified. According to Flick these categories are often derived from theoretical models and not necessarily from the data itself (Flick, 2006).

Using the interview protocol and research questions, a series of classes were identified in preparation for content analysis. These primary classes are presented in Table 7.4 below.

**Table 7.4: Primary Classes for Content Analysis.**

| Common Classes | Special Classes | Theoretical Classes |
|---|---|---|
| Age<br>Gender<br>Title<br>Experience<br>Background<br>Education | Ergonomics Background<br>User Centred Process<br>Design Guidance Followed<br>Design Guidance Not Followed | Challenges to involving Users<br>Definitions of Terms<br>Method for Involving Users<br>Perceptions of Users<br>Design Feedback |

According to Gray, the key to content analysis is the reduction in volume of textual material (Gray, 2009). Due to range and depth of responses collected at interview

this process of categorisation was necessary to make sense of the rich data elicited at interview.

Flick distinguishes three types of analysis process, which are summarised below (Flick, 2006).

### I. Summarising Content Analysis

Here the material (data) is paraphrased which refers to the skipping of less relevant passages with the same meaning, a process Flick describes as the first reduction (Flick, 2006). A second reduction involves the grouping of similar paraphrases, which are 'bundled and summarised'. Summarising in content analysis therefore refers to a process of reducing the transcript data through skipping statements and 'summarising the material on a higher level of abstraction' (Flick, 2006).

### II. Explicating Content Analysis

This form of content analysis works in the opposite manner to the summarising method. Explication in content analysis refers to the clarification of ambiguity and contradictory passages by involving 'context material' in the analysis (Flick, 2006). This can include recognised definitions for terms used from dictionaries to build a context to the data. According to Flick, this can be both narrow and broad in context (Flick, 2006). Narrow context analysis refers to the selection of additional statements from the text to explicate passages to be analysed, whereas broad context analysis seeks information outside of the text thus broadening the context of the data (Flick, 2006).

### III. Structuring Content Analysis

In a structured content analysis, the text is searched for formal structures within the material (Flick, 2006). These structures may be based on formal, typified, scaling or as regards to content. In formal content analysis it is possible to filter out an internal structure from the text alone. Typifying structuring refers to the seeking of singular salient features in the text material and then attempts to describe them more exactly. Scaling in structuring is the process of rating material in accordance with predefined dimensions (e.g. Low, Medium or High Significance or Not inferable). Finally,

structuring as regards content refers to the extraction and condensing of data to certain domains of content.

For the content analysis of the data collected at interview the text was initially condensed into the classes described by Gray (2009). Using a combination of explication and structuring content analysis the data was further explored in a wider context to expand on the current state of knowledge in the field. This includes the definitions for specific terms used by designers. In the section that follows explication and structuring of the data is described where applicable.

## 7.10 Results

In total 13 participants were interviewed for the study. Due to practical constraints on the availability of participants at the time of this study, it was necessary to conduct four interviews over the telephone. A total of nine interviews were conducted face-to-face. The differences in the approaches and data received through conducting the two interview strategies are described later in the chapter.

All participants who took part in the interview had previously completed the online survey study presented in chapter six. This was a fundamental requirement of the study to expand on the previous responses of the study.

Appendix 15 presents the profiling information of the interviewed participants in the study. For reasons of confidentiality each participant is assigned a number and no names or locations are presented in this report. All participants in the study were male. This was not an intentional sample of the study, however all responses on contacting companies were from male participants.

In accordance with the predefined classes described in the analysis section Table 7.5 presents a summary of the participants profiling information. This information refers to the common classes in content analysis described by Gray (Gray, 2009). Grouping the participants in this respect enables comparisons to be made in relation to the common classes of the study. In the discussion section of this chapter these classes will be used to compare and describe the relationships between responses from participants.

**Table 7.5: Common Class Profiles.**

| Common Class | Information |
|---|---|
| **Age** | Range: 30-59<br>30-39 x 2<br>40-49 x 4<br>50-59 x 7 |
| **Gender** | 13 Males |
| **Title** | Include: Director x 5, Managing Director x 2, Industrial Designers x 2, Group Leader x 1, Big Leader x 1, President x 1, Freelance x 1 |
| **Experience:** Numbers of years' experience in medical device design | Range: 2-30 Years<br>0-5 Years x 2<br>6-10 Years x 6<br>11-15 Years x 1<br>16-20 Years x 2<br>20+ Years x 2 |
| **Background:** Educational and experience domain | Industrial Design x 3<br>Product Design x 2<br>Ergonomics x 2<br>Mechanical Engineering x 2<br>Engineering x 1<br>Biochemistry x 1<br>Sports Science x 1<br>Cognitive Psychology x 1 |
| **Education:** Highest qualification achieved | BSc or BA x 8<br>Msc or Above (e.g. PhD) x 5 |

### 7.10.1 Drivers for the Selection and Development of Home Use Medical Devices

In Chapter six participants were asked to prioritise specific drivers in terms of importance for the design of home use medical devices. At interview participants were asked to expand on their previous responses to these driving factors (priorities) for selecting a project to take forward into the design process. Participants at interview were reminded of their response to the question in the online survey. Table 7.6 presents the leading driving factors and number of responses from participants at interview. The leading factor here in the table represents the single priority factor, driving the selection and development of a home use medical device.

**Table 7.6: Responses to Drivers for Development.**

| Drivers for Development | Number of Participants |
|---|---|
| User Needs | 7 |
| Performance | 3 |
| Cost | 2 |
| Other: Business Case | 1 |
| Function | 0 |
| Intellectual Property | 0 |
| Sustainability | 0 |

User needs were considered to be the most important driving factor for the design and development of home use medical devices. One participant said:

*"User needs are paramount… involving the users and designing for the user is absolutely key to the process." Participant #8*

When probed about why the needs of users were considered crucial to the design of home use medical devices this same participant added:

*"Usability is so key because you have got the widest possible group of users" Participant #8*

One designer felt that the focus on user needs has come to fruition in the last two years in particular and added that historically the needs of users were considered a lesser priority.

*"Well it [User needs] has historically been, I would say, relatively low level of focus…I think in the last 2 years we have seen that changing and certainly from a design perspective we have been pushing for a greater focus on user needs." Participant #6*

This designer added:

*"I think there is now a recognition that the drug performance, the device performance and everything else it has also got to work for the user and certainly in the last 2 years there is a major refocusing of big brands in that area." Participant #6*

Performance was identified as the second most cited driving factor for participants in this study. One designer explained:

*"My remit is to generally come up with a delivery device that matches a brand and has to be as exactly the same as a brand in terms of performance. So they can be marginally worse or equivalent too, but they can't be better than if that makes sense." Participant #12*

This designer worked freelance assisting manufacturers in the design and development phase of medical devices for use in both the home and professional environment. This often involved working alongside or around existing patents to achieve devices at a cheaper rate to the manufacturer. He explained:

*"So there is brand device that they [the manufacturer] want to copy because they want to muscle in on the market and so they give me a patent to see if I can work around it. So in that sense I am given freedom to invent if you like." Participant #12*

He added that:

*"So my expertise is how cheap one can make it and still do the job." Participant #12*

Another designer in the study viewed performance as the leading driver in the design of home use medical devices. This designer did however feel that other factors were

close on consideration. He explained:

*"I indicated performance as a main driver but I think some were quite close to each other…We have to put a lot of effort in to make sure that our devices, that the output is consistent and that insulin must be delivered daily, so it must always be delivered. So it is a really important aspect I think." Participant #13*

Another designer concurred that certain factors were close, if not equal, when assessing the driving factors of a home use medical device. He explained:

*"I think if you were to break down, number 1, then obviously efficacy and the frequency of the performance must be paramount but we [the company] would consider usability of the device as equal priority. Performance is a must, priority one, but usability is what we would measure throughout the development." Participant #2*

Others felt that cost consideration were a significant factor in driving the design and development process of a home use medical device. One designer said:

*"The real world out there is highly commercially driven." Participant #6*

He added:

*"I have seen medical devices at a high level of development fail to reach the market because the cost of goods is too high." Participant #6*

The results of this study support the findings of Chapter six in that the needs of users were identified as the leading driver (factor) in the design of home use medical devices. Section 7.10.3 in this chapter explores who designers in this study considered to be the users of home use medical devices in more detail. The second question topic in the survey analysis phase of the interviews explored the barriers to involving users in the design process of a home use medical device.

### 7.10.2 The Challenges to Involving Users in the Design Process of a Home Use Medical Device

The previous chapter reported that Finance, Time and Regulations were the most significant barriers to involving users in the design process. At interview all participants were asked to expand on why they cited specific factors as a challenge to involving users in the design process. Participants were also asked whether there

were any other challenges, aside from those in chapter six, towards the involvement of users in the design process of a home use medical device.

To assist participants in this study they were reminded of their responses in the online survey. At interview a range of new challenges to the involvement of users in the design process of a home use medical device were revealed. Due to the range of responses from participants at interview it was necessary to analyse the data in depth. This was initially conducted through the use of word or tag clouds to identify the most frequently used terms within the transcripts.

Using Nvivo 10 software a word frequency query was performed on the data. A copy of an early stage word cloud from the analysis is shown in Figure 7.1. The size of the text in the cloud provides an indication for the number of times a specific word features in the data. The larger the text appears, the more frequently referenced the word.

**Figure 7.1: Early Tag Cloud during Content Analysis.**

The use of tag clouds in the early stage of analysis enables any possible early themes in the data to be identified. The software allows the user to click on any word in the cloud to explore the excerpts of text where the word appears. This simple process of

analysis however does not replace the systematic approach applied to the data in this study, which was outlined in Section 7.9.

All of the responses to questioning about challenges to the involvement of users were collated and analysed. In the early stages of analysis any mentioned difficulties or challenges that related to the involvement of users in the design process were coded under the heading of 'Challenges to User Involvement' in Nvivo 10. Using the principles of structured content analysis the responses were then coded again under provisional headings that summarised the nature of that challenge to designers. The headings were chosen based on the salient features of the text for each specific challenges to involving users as described by Flick (Flick, 2006). Note: Each challenge is defined explicitly in the discussion section of this chapter.

The table below presents the new range of challenges cited by respondents at interview. The in-depth responses and questioning revealed a different range of challenges that were not identified through the survey study presented in Chapter six. Each challenge in Table 7.7 is presented with the number of coded references (times cited) and range of sources (number of participants).

**Table 7.7: Responses to Challenges for Involving Users.**

| Perceived Challenges | Sources | Coded References |
|---|---|---|
| Commerciality | 12 | 58 |
| Client Relationships | 11 | 76 |
| Financial Constraints | 8 | 29 |
| Access to Participants | 7 | 24 |
| Knowledge of Usability | 6 | 44 |
| Incentives for Adoption | 6 | 21 |
| Ethical issues | 4 | 13 |
| Regulations | 4 | 8 |
| Hierarchy of Users | 3 | 7 |
| Diversity of Users | 3 | 7 |
| Intellectual Property Considerations | 2 | 6 |
| Other Issues | 2 | 6 |

The data collected at interview revealed ‘Commerciality’, with respect to being competitive in business and the ability to make profit, as the leading challenge to involving users in the design process of a home use medical device. In summarising the commercial reality of operating in the field of medical device design, one designer said:

*“I think in the perfect world we would all [involve users more] the client would like it, we would like it, everyone would like to do it but all too often the commercial pressures are such that it just doesn't take place.” Participant #3*

This designer acknowledged the need for involving users in the design process however described a lack of incentive to really conduct studies with users correctly. Under the commercial constraints experienced by his company he added that current practice restricted access to patient users of home use medical devices:

*“We never get to the end user. We will get to the clinician, we will get to the installer or we’ll get to the carer possibly but we very rarely get to speak in detail with patient.”*

To analyse these challenges further it is possible to make comparisons on the common classes and their influence on the perceived barriers to involving users. Using the common classes described in section 7.9 the perceived barriers will now be considered from the following positions: experience in years, education and whether design guidance is followed.

**Perceived challenges to involving users based on a designer’s experience**

Participants in the study had a wide range of years’ experience in the field of home use medical device design from two years to more than 20 years’ experience. To find out whether experience had an influence on the perceived challenges to involving users in the design process, participants were grouped into the following classifications: 0-5 years, 6-10 years, 11-15 years, 16-20 years and 20+ years. Using this information a matrix query was performed on the data. Table 7.8 and Table 7.9 present the number of participants represented by each experience classification and the results to the matrix query.

The colour coding in Table 7.9 provides an indication of the number of references for each specific challenge (i.e. the darker the shade of blue, the more references received).

**Table 7.8: Experience of Participants in Years.**

| Experience in Years | Number of Participants |
|---|---|
| 0-5 | 2 |
| 6-10 | 6 |
| 11-15 | 1 |
| 16-20 | 2 |
| 20+ | 2 |

**Table 7.9: Matrix Query Results to show the Effect of Experience on the Perceived Challenges towards the Involvement of Users in the Design Process of Home Use Medical Devices.**

| Challenges to User Involvement | Experience | | | | |
|---|---|---|---|---|---|
| | 0-5 Years | 6-10 Years | 11-15 Years | 16-20 Years | 20 + Years |
| Commerciality | 1 Ref, 1 Source | 24 Refs, 6 Sources | 10 Refs, 1 Source | 8 Refs, 2 Sources | 15 Refs, 2 Sources |
| Client Relationships | 0 Refs, 0 Sources | 33 Refs, 6 Sources | 16 Refs, 1 Source | 9 Refs, 2 Sources | 18 Refs, 2 Sources |
| Financial Constraints | 0 Refs, 0 Sources | 10 Refs, 4 Sources | 1 Ref, 1 Source | 9 Refs, 2 Sources | 9 Refs, 1 Source |
| Access to Participants | 1 Ref, 1 Source | 9 Refs, 2 Sources | 5 Refs, 1 Source | 5 Refs, 2 Sources | 4 Refs, 1 Source |
| Knowledge of Usability | 0 Refs, 0 Sources | 37 Refs, 3 Sources | 0 Refs, 0 Sources | 5 Refs, 1 Source | 2 Refs, 2 Sources |
| Incentives for Adoption | 0 Refs, 0 Sources | 5 Refs, 3 Sources | 2 Refs, 1 Source | 1 Ref, 1 Source | 13 Refs, 1 Source |
| Ethical Issues | 0 Refs, 0 Sources | 7 Refs, 2 Sources | 0 Refs, 0 Sources | 4 Refs, 1 Source | 2 Refs, 1 Source |
| Regulations | 0 Refs, 0 Sources | 3 Refs, 2 Sources | 0 Refs, 0 Sources | 3 Refs, 1 Source | 2 Refs, 1 Source |
| Hierarchy of Users | 0 Refs, 0 Sources | 4 Refs, 1 Source | 1 Ref, 1 Source | 2 Refs, 1 Source | 0 Refs, 0 Sources |
| Diversity of Users | 0 Refs, 0 Sources | 1 Ref, 1 Source | 0 Refs, 0 Sources | 4 Refs, 1 Source | 2 Refs, 1 Source |
| Intellectual Property Considerations | 0 Refs, 0 Sources | 5 Refs, 1 Source | 0 Refs, 0 Sources | 1 Ref, 1 Source | 0 Refs, 0 Sources |
| Other Issues | 0 Refs, 0 Sources | 6 Refs, 1 Source | 0 Refs, 0 Sources | 0 Refs, 0 Sources | 0 Refs, 0 Sources |

**Perceived challenges to user involvement based on education**

At interview participants were asked to state the highest level of qualification achieved relevant to the field of home use medical device design. All of the participants in this study were qualified to undergraduate degree level or above, including Master Degrees (MSc) or Doctor of Philosophy (PhD). In total eight participants were qualified to the level of BSc or BA and five participants had qualifications of MSc or Above (e.g. PhD). To explore the differences in perceived challenges based on educational qualifications, a matrix query was performed. Table 7.10 presents the results to the matrix query.

**Table 7.10: Matrix Query Results to show the Effect of Qualification Level on the Perceived Challenges towards the Involvement of Users in the Design Process of Home Use Medical Devices.**

| Challenges to User Involvement | Qualification | |
|---|---|---|
| | BSc/BA Level | MSc or Above |
| Commerciality | 40 Refs, 7 Sources | 18 Refs, 5 Sources |
| Client Relationships | 35 Refs, 7 Sources | 41 Refs, 4 Sources |
| Financial Constraints | 23 Refs, 5 Sources | 6 Refs, 3 Sources |
| Access to Participants | 9 Refs, 3 Sources | 15 Refs, 4 Sources |
| Knowledge of Usability | 7 Refs, 3 Sources | 37 Refs, 3 Sources |
| Incentives for Adoption | 16 Refs, 3 Sources | 5 Refs, 3 Sources |
| Ethical Issues | 8 Refs, 3 Sources | 5 Refs, 1 Source |
| Regulations | 7 Refs, 3 Sources | 1 Ref, 1 Source |
| Hierarchy of Users | 2 Refs, 1 Source | 5 Refs, 2 Sources |
| Diversity of Users | 7 Refs, 3 Sources | 0 Refs, 0 Sources |
| Intellectual Property Considerations | 6 Refs, 2 Sources | 0 Refs, 0 Sources |
| Other Issues | 6 Refs, 1 Source | 0 Refs, 0 Sources |

**Perceived challenges to involving users based on whether design guidance is followed**

Seven out of the 13 participants at interview expressed they followed the design guidance available to assist with usability issues for home use medical devices (e.g.

ANSI/AAMI HE75:2007). Six participants reported that they do not to follow specific usability guidance. On design guidance one designer said:

*"There are two or three pieces of guidance, draft guidance and proposed guidance that we use all the time…draft guidance by the FDA from June 2011 and that is freely available on the FDA website and that would basically give some guidance as to how to set up and report human factors studies. Some guidance from the American standards institute called HE75 from 2007 which again provides lots of guidance on how to set up and run usability testing and also provides quite a lot of best practice in terms of implementing human factors in to the design of your product. Then there is an ISO standard which is 62366 which is a more European focused thing but again that has got a lot of good guidance in there about how to document, how to gather the evidence that you have understood who your users are and how they are going to use the device and what they want." Participant #7*

Evidently this designer has an awareness of the available guidance on an international level that has been developed to support the design of medical devices for the needs of users. Further information on designers' perceptions of the available guidance is described later in the chapter.

The following section of the results refers to the influence of design guidance on the perceived challenges to involving users in the design process. A matrix coding query was performed on the data to understand the differences between the two groups. Table 7.11 presents the results:

**Table 7.11: Matrix Query Results to show the Effect of whether Design Guidance is followed on the Perceived Challenges towards User Involvement for Home Use Medical Devices.**

| Challenges to Involving Users | Design Guidance | |
|---|---|---|
| | Not Followed | Followed |
| Commerciality | 13 Refs, 5 Sources | 45 Refs, 7 Sources |
| Client Relationships | 12 Refs, 4 Sources | 64 Refs, 7 Sources |
| Financial Constraints | 4 Refs, 2 Sources | 25 Refs, 6 Sources |
| Access to Participants | 6 Refs, 3 Sources | 18 Refs, 4 Sources |
| Knowledge of Usability | 1 Ref, 1 Source | 43 Refs, 5 Sources |
| Incentives for Adoption | 0 Refs, 0 Sources | 21 Refs, 6 Sources |
| Ethical Issues | 4 Refs, 2 Sources | 9 Refs, 2 Sources |
| Regulations | 4 Refs, 2 Sources | 4 Refs, 2 Sources |
| Hierarchy of Users | 0 Refs, 0 Sources | 7 Refs, 3 Sources |
| Diversity of Users | 1 Ref, 1 Source | 6 Refs, 2 Sources |
| Intellectual Property Considerations | 0 Refs, 0 Sources | 6 Refs, 2 Sources |
| Other Issues | 6 Refs, 1 Source | 0 refs, 0 Sources |

### 7.10.3 The Design Process of a Home Use Medical Device

Chapter six revealed that approximately 45% of respondents to the online survey reportedly followed a ‘user centred design’ process for home use medical devices. At interview the design process itself was explored further with participants as they were asked to sketch and describe the key stages involved in the design process of a home use medical device. Due to the nature of the mixed method approach to interviewing (i.e. face-to-face and over the telephone), different strategies had to be employed for this phase of the interview.

During the face-to-face interviews participants were provided with an A3 sheet of paper and a black marker pen. They were then asked to draw out the key stages of their typical design process for a home use medical device. The process itself could be presented however the respondent felt suitable but it had to cover the key stages in the design process they perceived to be necessary to deliver a home use medical device to market. Once the design process was complete, participants were then

provided with a red marker pen to highlight on the process where users are currently involved within the process. Participants were asked to describe some of the methods used at these specific stages to identify user requirements. After these tasks participants were asked, hypothetically, to highlight on the process where and how they would involve users in the design process if there were none of the challenges previously described in section 7.10.2.

Over the telephone this approach to analysing the design process was more challenging, solely for the practical reasons of not being present with the interviewee. Therefore during the telephone interviews a different approach was employed. Participants were asked to complete the same task however the interviewer would annotate and draw out the design process as it was described. If at any stage the interviewer were unclear of a stage, process or method described, he would ask the interviewee to repeat it. Again, participants were asked to describe where users were currently involved in the design process and how they would like to involve users if there were no barriers or challenges to their involvement,

For the purpose of clarity in this report all of the design processes are presented in a linear format. This was due to legibility and the ease of making comparisons between the design processes. Note that many of the design process were originally depicted as cycles and all of the processes include iterative design stages.

**Table 7.12: Participant Design Processes.**

| Participant | Reported Process Followed | Design Process |
|---|---|---|
| #1 | User Centred Process | **Understanding the Context > Specification > Concepts > Concept Testing > Detailed Design > Evaluation** |
| #2 | User Centred Design Process | **Ideation > Concept Selection > Proof of Concept > Industrialisation > Manufacture** |
| #3 | Contingent Design Process | **User Research > Concepts > Technical Development > Prototype Development > Evaluation** |
| #4 | User Centred Design Process | **Proof of Concept > Concepts > Feasibility > Detailed Design > Manufacture** |
| #5 | Detailed Design Process | **Market Research > Concepts > Development > Prototypes > Evaluation** |
| #6 | Detailed Design Process | **Ideation > Development > Research > Refine > Implement** |
| #7 | User Centred Design Process | **User Research > Concepts > Specification > Detailed Design > Evaluation** |
| #8 | User Centred Design Process | **User Research > Concept Design > Detailed Design > Prototyping > Adapt > Implement** |
| #9 | User Centred Design Process | **Identify > Design > Build > Validate > Production** |
| #10 | User Centred Design Process | **Requirements Capture > Interaction Design > Visual Design > Specification > Construction > Evaluation** |
| #11 | User Centred Design Process | **Research > Concepts > Proof of Concept > Prototype > Detailed Design > Evaluation** |
| #12 | Prescribed Procedure | **Market Research > Concepts > Proof of Concept > Prototypes > Evaluation** |
| #13 | Detailed Design Process | **Market Research > Concept Design > Prototypes > Producability > Manufacture** |

Table 7.12 presents the design processes for all 13 participants in the study in a descriptive format. The table includes the reported design process followed alongside the specific stages taken to deliver a home use medical device to market. The stages

highlighted with Green text indicate the stages in the design process where users were involved.

Table 7.13 indicates and compares the characteristics of reported ‘user centred’ design processes against the alternative processes followed by participants (e.g. Contingent, Detailed Design or Prescribed process). In total eight participants in this study followed a ‘user centred’ approach to home use medical device design. The figures in Table 7.13 reveal that the design processes featured in the study have approximately the same number of design stages for ‘user centred’ processes as they do for alternative processes. On average the percentage of user involvement was typically higher in a ‘user centred’ design process. The proportion of designers that followed design guidance was higher for companies following a ‘user centred’ design process as opposed to an alternative process.

**Table 7.13: Comparisons of Participant Design Processes.**

| Criteria | User Centred Design Process | Alternative Processes |
|---|---|---|
| Number of Companies | 8 | 5 |
| Design Process Stages | 44 (Average 5.5 per process) | 25 (Average 5 per process) |
| Stages Involving Users | 29 | 14 |
| Average Percentage User Involvement | 66% | 56% |
| Follow Guidance | 63% | 40% |

For clarity and to gain a clearer understanding of where typically users were involved in the design process a comparison based on whether design guidance was followed is presented in Figure 7.2 and Figure 7.3. The darker shade of purple indicates a design stage where users were involved. In contrast the lighter shade of purple indicates no user involvement.

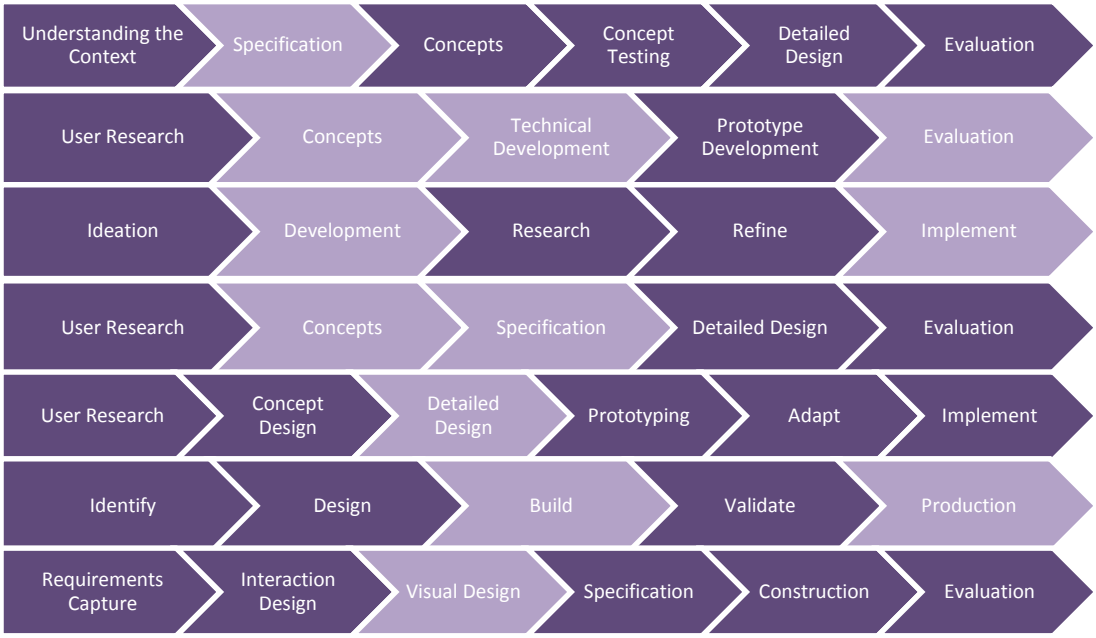



**Figure 7.2: Participant Design Processes (Guidance Followed).**

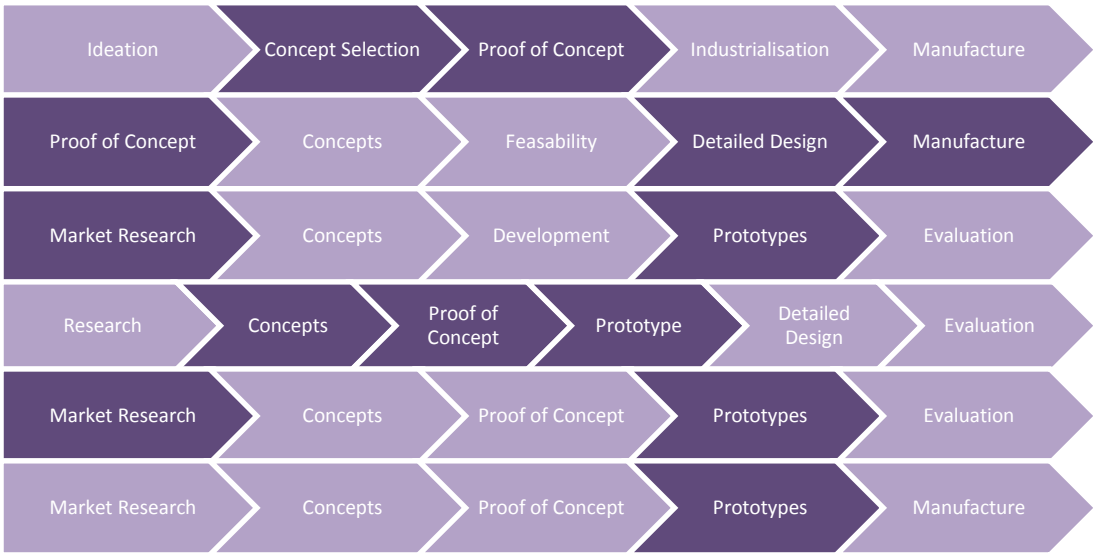



**Figure 7.3: Participant Design Processes (Guidance Not Followed).**

### 7.10.4 The Methods for Involving Users.

At interview participants were asked to describe the methods used to identify the needs of their end users. The methods cited by participants ranged from informal discussions with users themselves through to formal interviews in controlled environments. Table 7.14 presents all the methods cited by participants in the study alongside the number of participants that expressed they used that particular method when designing home use medical devices.

**Table 7.14: Responses to User Needs Identification Methods.**

| User Needs Identification Methods | Number of Participants |
|---|---|
| Observation | 19 Refs, 7 Sources |
| Interviews | 17 Refs, 7 Sources |
| Prototypes | 6 Refs, 5 Sources |
| Video Analysis | 5 Refs, 5 Sources |
| Test Rigs | 4 Refs, 4 Sources |
| Task Analysis | 7 Refs, 3 Sources |
| Focus Groups | 5 Refs, 3 Sources |
| User Studies | 11 Refs, 3 Source |
| Surveys | 4 Refs, 2 Sources |
| Usability Tests | 2 Refs, 2 Sources |
| Role Play | 2 Refs, 2 Sources |
| Informal Meetings | 4 Refs, 2 Sources |
| Anthropometry | 2 Refs, 2 Sources |
| Desk Research | 2 Refs, 2 Sources |
| Simulations | 2 Refs, 2 Sources |
| Benchmarking | 4 Refs, 2 Sources |
| Other Methods | 15 Refs, 1 Source |

In total, 26 different methods to capture the needs of users were referred to by participants in the study. All methods that were mentioned by one source only were grouped into the other methods category in the table. Observation and interviews

were identified as the most commonly adopted method for user needs capture. Observation methods here refer to a range of different techniques used to explore user interactions with a device. One participant said:

*"So usually it is a 1-to-1 interview as a design team, we usually sit behind 2-way mirrors or video it. It is really important for the designers to understand the difficulty patients are having because you wouldn't believe how difficult some patients find it to use devices." Interview Participant #2.*

Observation was considered important for the translation of user needs as opposed to asking users questions. When asked about the ability to translate user insights into specific user needs, one participant said:

*"I mean the best way to get round that is to observe what people do when they are handling devices." Interview Participant #7.*

This participant opined that observing users interact with devices revealed actual use scenarios as opposed to participants citing how they use a device based on what they believe the interviewer might be looking for. Further discussion on the methods for involving users in the design process is provided in the following section.

With the results of the interviews reported a discussion of the findings will now be presented. The following section describes the implications of the results that have been presented in this section.

## 7.11 Discussion

The aim of this study was to answer research question two of this research:

***Research Question Two: What are the challenges for industry to involving users in the design process of home use medical devices?***

The purpose of the study was to understand current design practice towards involving users in the design process of home use medical devices in the United Kingdom. The interview protocol was designed to build on the findings of Chapter six and the perspectives of practicing designers towards current usability guidance for home use medical devices. In the literature review of this thesis it was found that

previous research had alluded to industry's lack of uptake for usability guidance. In his thesis, Gupta explained:

*"The majority of designers who were involved in this study opined that they never consulted or had to consult a usability guidance to design their products for ease-of-use."* (Gupta, 2007).

Gupta's study found that the majority of designers would use their experience most of time to make their device 'user friendly and safe'. This raised the question for this research of the value of usability guidance to practicing designers, who would prefer to use their own experience. Chapter six concluded with three potential scenarios that could explain the current approaches by practicing designers towards home use medical devices. This study set out to address these scenarios specifically, in attempt to identify recommendations to incentivise the application of 'good design' principles for home use medical device design in the future.

### 7.11.1 The Challenges to Involving Users in the Design Process of a Home Use Medical Device

The idealised practice case study presented in Chapter Four identified a series of preliminary challenges to adopting user centred principles in the design of home use medical devices. These findings were explored further in Chapter six in an online survey of designers' perspectives. Content analysis of the interview data from this study revealed eleven specific challenges towards involving users in the design process of home use medical devices. These challenges will now be discussed in order of precedence based on the number of sources (participants) found in the study. Each challenge is presented with a summary of the core issues at the end of each section.

***Challenge One: Commerciality***

Commerciality in the context of this study is defined in accordance with the Oxford dictionary definition (Oxford Dictionaries, 2013). As a derivative of the adjective 'commercial', the term *commerciality* is used here to refer to the following:

I. Concerned with or engaged in commerce: a commercial agreement.

II. Making or intended to make a profit: commercial products.

The commerciality of the companies in this study was identified as the most cited challenge towards involving users in the design process of a home use medical device. One designer explained how the commercial pressures take priority over the practicing of usability principles and the studies they would like to conduct with users:

*"So, you know the whole idea that we'd go off and set up a focus group with a bunch of patients in this zone and have detailed conversations with them…long enough and with enough of them to get something that was statistically relevant is just not going to happen." Participant #3.*

In this instance this particular designer worked for a design consultancy supporting manufacturers in professional and home use medical device design. This designer described how the pressure of meeting deadlines successfully took priority over delivering a device design that was successful in their opinion and experience. This participant described a process that was based on a decision of whether to refuse work or deliver what is possible within the commercial constraints of the project. On the topic of involving users this designer said:

*"It is a major problem and maybe we [designers] are just not pushing hard enough. Maybe we should be stamping our little designer feet and making more of a fuss about it but in reality, the commercial reality is, if a client says we haven't got time, we haven't got the budget, you know, we haven't got six weeks to do studies…you've got two choices. You either refuse to do the job or you do it to the best of your ability with what you've got." Participant #3.*

This quote mirrors the findings of the idealised practice case study where the participating company opined that outside of the safety and efficacy of the device, it becomes a 'commercial decision' on the approach to usability principles and user involvement. Currently, IEC BS EN 62366: 2007 advocates the application of usability engineering principles however there is no legal obligation to satisfy these requirements in the United Kingdom. Consequently, the companies in this study opined that they or their clients, in the case of a design consultancy, would not invest heavily in usability research, as there is currently no legal obligation to do so.

Other participants in the study referred to the commercial constraints upon the industry that are influencing design practice. One participant believed that the commercial focus of the sector has been gaining momentum in recent times. This participant posited that:

*"…as well as being technically adept and maybe offering pharmaceutical performance enhancement it has got to be commercially sound otherwise it gets canned…I think there has been a commercial focus in the last 5 years, partly driven by the global market…it is a really fine line between making sure that this [the device] has the greatest success of making it through to the production." Participant #6.*

Evidently once a device has entered the development phase there is a focus upon delivering the device to market, which is driven by the investors. According to this participant, who expressed 'User needs' as a priority (i.e. driving factor), there is a point within the design process where 'commerciality' takes precedence and thus the usability of the device becomes of lesser priority.

Another designer in the study shared this opinion:

*"Once it [the device] has gone past the design team who has handed it over there is an operations team, that we can educate, but they will just ignore us because they are driven by cost and money…the trouble is that you are often faced by managing accountants or engineers and they all have great numeric answers." Participant #8.*

While there is evidence in the literature of potential benefits to both patients and manufacturers in applying usability principles, it remains difficult to demonstrate the benefits of such an approach in terms of finance and consequences of use. Sharples *et al* posited that:

*"If we wish to persuade a device manufacturer to consider a change or enhancement to a design for example, it is useful, but often challenging, to obtain specific evidence that demonstrates the value of modifying the design, and predicting the impact of that design change on consequences of use."* (Sharples *et al*, 2012).

In an industry where the commercial consequences of device failure are so great, as was identified with the Exubera device (See Section 2.2), investors are often

searching for demonstrable evidence of device success in the design process. In this respect one of the drawbacks for usability principles is that there is an upfront cost for undertaking the research that predicts potential benefits in the future. As one participant explains:

*"Your launch date is the time you start making the money and this is an expensive programme." Participant #9.*

Thus, the commerciality of home use medical device development presents a considerable challenge to the endorsement and advocacy of usability principles outlined in such documents as IEC BS EN 62366: 2007 and ANSI/AAMI HE75: 2009. This finding is supported by the work Bridgelal Ram *et al* who posited that the commercial pressures of getting a device to market as a challenge for manufacturers (Bridgelal Ram *et al*, 2008).

**Core Issues**

- Commerciality takes priority over Usability Principles.
- Tensions between insights and understanding of what is required by the Regulations and what is required from a Commercial Perspective.
- Lack of time places pressure upon design iterations and referring back to the same users in previous studies.
- Design consultancies that are paid to conduct user research on behalf of clients, typically accept projects despite an awareness that design practice is not as good as it could be.
- Internal Procurement pressures take precedent over User Research during development.
- Designers and Developers search for where the best value of end user research will come from, influencing chosen methods.

***Challenge Two: Client Relationships***

The term *'Client'* as defined by Oxford Dictionaries refers to the following:

*"A person or organisation using the services of a lawyer or other professional person or company."* (Oxford Dictionaries, 2013).

Thus in the context of this study and research, a client refers to a 'professional person or company' in collaboration with the design and development of a home use medical device. This covers the range of persons cited at interview by participants in the study. This, for example, includes manufacturers as a client of a design consultancy who might be recruited to conduct user research on behalf of an organisation. It can also refer to General Practitioners themselves who can approach a manufacturer or consultancy with an innovative concept for development. The challenge, with respect to user involvement and the application of usability principles, is therefore established between the relationships of two or more parties attempting to deliver a home use medical device to market.

'Client Relationships' were the second most cited challenge to applying usability principles in the design of home use medical devices by designers in the study. The relationships between clients revealed differences in the understanding and expectations of projects. One participant said:

*"…internally in the company they are presenting it to, perhaps the other design team get it, but the finance team don't and the marketing department don't. They don't see why they just handed over £60,000 and they got some great ideas from it, but couldn't they have got some great ideas without flying off to California and looking at somebody digging a hole or following some people in India on a motor bike for 3 months. It is that type of thing…so there is still a conflict in the merging of this." Participant #1.*

This company explained how their approach to design and specifically user testing was rejected by a past client on the grounds of having a preferred internal procedure in place. While, the manufacturer in this instance had recruited a consultancy to conduct user research the process for which they had paid for was ignored for internal reasons to the company. This participant explained:

*"It was difficult for us to apply the process that we wanted to apply...but we couldn't really get into the mapping of the use of the [device]…We got a map of the use but we couldn't get involved with the usability testing of [the device]. No, they wouldn't do the testing, they had their own testing procedure that they wanted to follow." Participant #1.*

The interviews revealed that client relationships not only inhibited the uptake of usability principles, but also affected the speed with which such an approach could be adopted. As was identified in the idealised practice case study, there is a recognised disparity of language between practitioners in the field of home use medical device design. At interview another participant opined that education on the principles and benefits of a user centred approach presented a big challenge to his company:

*"On the client side, we spend an enormous amount of time explaining the process…I am assuming nothing on that side and I really try to get them [the client] not only to buy in, of course they have to buy your services that's what I'd like to them to do obviously. But they really have to feel that this is going to be value added for them and again I think in a lot of cases it is the blindness that everybody has in their own field. We jump so quickly to just doing the thing and assuming a lot on the other side and saying 'Well you must know what I am doing and why I am doing it' 'You must know that this technique is really helping me' 'You must understand when I do an interview or when I do an observation, I am trying to do a task analysis here, instead of trying to get to high level product value goals, which is really what you do in market research." Participant #10.*

This participant then added:

*"But a task analysis is a jargon word in itself even though it is recognised by two words which are very easy to understand." Participant #10.*

For this participant it was perceived that the use of 'jargon' terms such as 'task analysis' or 'user centred design' presented a challenge when attempting to sell and deliver services (e.g. user research, user testing) to clients. Despite a manufacturer willingly investing in the guidance, service and support of a design consultancy's expertise the challenging relationships between two or more parties restricted the adoption of usability principles.

**Core Issues**

- A disparity of language and use of jargon terms amongst different communities and stakeholders restricts the uptake of usability principles.
- A shared understanding and expectation of the client's role inhibits user involvement for home use medical devices.

- Financiers and Marketing Professionals are perceived to struggle to relate to the value of a ‘user centred’ approach and therefore can be resistant to adoption.
- Internal testing procedures and practices for larger organisations were revealed to take precedent over guidance on usability from a design consultancy.
- Client relationships are motivated by financial gains
- Clients look for figurative gains or a tick box exercise - Expectations of perceived risks.
- Clients are primarily driven by technology led companies
- Time spent explaining or educating clients on justification of processes and methods
- Perceived questioning of authority
- Clients regularly look for shorter and cheaper workarounds
- Clients like to code early, sometimes prior to exploration of users and designing
- Clients often like to conduct the studies and work themselves with their own practices.
- Access to users (patients) only available through the client. In respecting the clients wishes and confidentiality one designer expressed the limited access to the actual end users.
- Hierarchical structure of clients
- Contrasting requirements between marketing and engineering
- Different clients attending each meeting making continuity and consistency difficult.
- Perceive user involvement can be conducted at the end

***Challenge Three: Financial Constraints***

The noun Financial in the context of this study and its use in the phrase ‘Financial Constraints’ is defined as follows:

*“The finances or financial situation of an organization or individual”* (Oxford Dictionaries, 2013).

Thus the implication of the word ‘Constraints’ emphasises the associated challenges to designers and developers of home use medical devices in terms of user involvement. This challenge refers to the implications that costs and perceived costs have on a company’s ability to involve the end user in and throughout the design process.

Chapter six identified that the cost of user involvement is one of the most significant challenges to adopting usability principles including user involvement in home use medical device design. It could be argued that 'Financial Constraints' are closely linked with the challenge of 'Commerciality'. However there is a distinct difference between the two challenges towards applying usability principles. Financial Constraints refer to the purely cost aspect of applying formal and informal methods for user research. Whereas, Commerciality is concerned with the ability to create a profit, which includes the lead times of a device to remain competitive and the success of the device in the marketplace post launch for example.

Referring explicitly to financial issues and adopting a user centred process, one participant said:

*"If you are going to do it properly there is a huge cost and time." Participant #2.*

This cost, as explained by another participant in the study, was inhibitive to the uptake of what participants would consider as idealised practice.

*"I mean the most difficult thing is coping with restricted budgets and time scales…you have then got the complication of trying to do it all on a shoe string budget so maybe you don't have the luxury of getting as wide a group of subjects to interface with as you would like." Participant #4.*

In one participant's experience they found that the perceived costs for conducting 'human factors' was far greater than the actual costs to conduct such work:

*"We find that there is a perception by manufacturers that doing human factors data is an expensive and time consuming thing to do." Participant #7.*

As a consequence of the financial implications for conducting user research, the very importance of its role in the design process can be called into question according to one designer in the study:

*"…Cost is absolutely an issue because this is expensive and most of our clients don't like to pay the money and they will argue with us about whether it is important." Participant #9.*

**Core Issues**

- Proxies or representatives of device users are used in place of real end users due to the financial constraints to access real end users.
- Conducting user research early and iteratively will require additional cost upfront, which many of the smaller companies cannot afford.
- Typically smaller samples of users are involved than companies would like based on the financial constraints of the company.
- The number of medical devices that actually make it to production is actually very small; therefore companies are very risk averse when it comes to spending money.
- Very often the perceived costs put companies off before considering the implications of what the user research might open up for them
- Due to the costs of involving users in assessments and trials many companies look for cheaper or quicker alternatives that provide a 'good enough' option to meet regulatory approval.

***Challenge Four: Access to Participants***

Access in the context of this study is defined as follows:

*"The right or opportunity to approach or see someone."* (Oxford Dictionaries, 2013).

Thus the ability for companies (i.e. designers and developers) to access participants for user research can be a considerable challenge to industry. Gaining the active participation of the target or end users within the design process was revealed to be particularly challenging for designers in the study. In a case study on user involvement for patients with Epidermolysis Bullosa (EB) Brigdelal Ram *et al* found that access to vulnerable users and commercial pressures were challenging for user engagement. They state that 'pursuing the ideal of an iterative process of user engagement and product refinement is challenging in terms of both accessing vulnerable users and resourcing the process in the face of commercial pressures to get products into the market place.' (Bridgelal Ram *et al*, 2008).

If 'user centred' principles are to be adopted successfully for home use medical devices the process itself must involve and iterate with actual end users from conception through to production taking into consideration the real needs of end

users (IEC BS EN 62366, 2007). Accessing patients for devices to be used in the home environment, at the right time, in the right amounts and in the right profile for the specific device can therefore be very difficult for industry. On access issues one participant explained that:

*"It is not simply that people want to use input from users but rather that they can't get access to these people. So it is not so much the tools and the process and the reasons why you are doing it, it is just the pragmatics of well we don't know how to get to these people. We don't know how to effectively take time and use their input and get enough of it in the process to make it really work well." Participant #10.*

Another designer in the study referred to the difficulty to access patients in a voluntary manner. Once a profile for a specific user group or groups has been identified, this particular participant experienced difficulty in accessing the diversity of users at the same time as well as being willing to participate.

*"Yes it is quite difficult to get different patients around the table because they have to be voluntary." Participant #13.*

The challenge of approaching users for the purpose of research was also highlighted by another participant in the study. Participant three, a managing director with 11-15 years' experience in the field explained:

*"It is very difficult for, you know as a product designer if you are working for a medical device company you can't then really go straight to a user group or a focus group of potential users or consultations." Participant #3.*

He then added that:

*"Building up a profile of exactly what's required is again limited by this access to the right people…we never get to the end user. We will get to the clinician, we will get to the installer or we'll get to the carer possibly but we very rarely get to speak in detail with patient." Participant #3.*

This quote would suggest that access to real end users for home use medical devices (i.e. patients) is restricted to some designers. In the aforementioned study by Bridgelal Ram *et al*, it was identified that access to patients for researchers is less of an issue and challenge than it is for manufacturers. The authors state that 'as clinical

researchers' access to the user groups and research process ensures that the message of user needs is not 'lost or misinterpreted by the manufacturers.' (Bridgelal Ram *et al*, 2008).

Many of the designers in this study alluded to the difficulty of conducting user research with patients specifically. While it is evident that some designers in the study are able to access clinicians and carers for the purpose of user research, access to patients was considered much more of a challenge to designers in this study.

**Core Issues**

- Accessing the user profiles of a home use medical device can be very challenging for designers and developers of home use medical devices.
- Repeated access to the same participants for the purpose of iteration can be difficult.
- Accessing patient users who voluntarily participate in user research studies was identified as challenge to designers in the study.
- Locating and accessing patients that match a specific profile (e.g. Symptoms or Conditions) was perceived to be a challenge.
- Healthy patients were found to be much easier to access and more willing to participate in user research.
- Accessing patients across different countries (Member States) can be difficult, if a company plans to sell a product globally.
- Companies often use a third party to access patient users to overcome the challenge of gaining participation.
- Representative users are used in place of real end users when access is an issue.

***Challenge Five: Knowledge of Usability***

The term 'Knowledge' in the context of this study refers to issues related to an industry wide (i.e. different stakeholders) understanding of usability principles and conducting user research with patients in the home environment. Knowledge as defined by Oxford Dictionaries is as follows (Oxford Dictionaries, 2013):

“Facts, information, and skills acquired through experience or education; the theoretical or practical understanding of a subject”.

And

“Awareness or familiarity gained by experience of a fact or situation”.

The designers in this study opined that considerable time is spent educating clients, colleagues and participants (e.g. patient users) with no prior knowledge of the principles and justification of user research. One participant in the study said:

*“It is both our clients and product managers that we work with and it is also the end users themselves when we go out and actually interview people. I find that there is a serious lack of understanding of what this process is about and more so even than an unwillingness to participate.” Participant #10.*

In the case of this company, this participant experienced the challenge of educating persons to understand the process more significant than access issues previously described. He added that:

*“We spend at least, I would say, a quarter of the time explaining the process and explaining why this is relevant.” Participant #10.*

The difficulty in educating ‘clients, product managers and end users’ themselves was perceived challenging to his company due to the lack of common terms used in the practice of applying usability or ‘user centred’ principles. The participant explained previous examples from his own experience where adoption of the process he was advocating was met with difficulty:

*“This guy talks to you about stuff that you have never heard of before, he uses words that you have never heard of before and describes a process that you have never heard of before and you instantly have to accept it and see it has a value and play your role in it. A lot of people are just not comfortable with that.” Participant #10.*

Other participants in the study described how a lack of knowledge of usability principles presented challenges for user involvement. One designer explained that a company’s interpretation of usability for a medical device he had worked on

previously was considered as purely interface design and aesthetics. He explained that:

"*They [the client] wanted somebody to design the screen and that is their usability done…However, the interpretation of that is we will make the screen pretty. So there is not a necessarily thorough understanding yet of the whole user experience." Participant #1.*

According to some participants this issue was not limited to smaller companies. One participant, representing a design consultancy, had experience of working with larger organisations that has also demonstrated a lack of understanding and appreciation of the role of usability in professional and home use medical device design. This participant posited that:

*"Often at times we are working with Big Pharma [the pharmaceutical industry] and clients who themselves don't have the expertise to do this. Or don't know what they should be doing…so we spend a lot of time educating them." Participant #9.*

In consistencies with industry's understanding and interpretation of usability principles suggests that successful adoption is difficult for designers and developers in practice.

Perhaps the issue that current regulation in the United Kingdom does not mandate the principles of usability engineering is one of the reasons behind the lack of uptake by practicing designers. As previously stated IEC BS EN 62366: 2007 outlines specific design guidance for medical devices with respect to usability. However, without mandated requirements specifically stated within the regulations, the adoption of usability principles is expressed as a 'moral obligation' that denotes non-compliance as 'permissible' (Blumenthal, 2013). In an article on the use of auxiliary verbs, *'Shall vs. Should'* and their presence in quality management system (QMS) documentation, Blumenthal explains that the differences between the two terms are often overlooked (Blumnethal, 2013).

According to Merriam-Webster the auxiliary verb 'Shall' is 'used in laws, regulations, or directives to express what is mandatory.' (Merriam-Webster, 2013). In contrast, 'Should' is 'used in auxiliary function to express obligation, propriety, or

expediency.' (Merriam-Webster, 2013). Thus, as Blumenthal states, the term 'Should' allows 'document users to make their own judgment calls' (Blumenthal, 2013).

When asked about 'user centred design' principles one designer in the study with over 26 years' experience in medical device development explained that he was not familiar with the term:

*"User Centred Design {Pause} I am not familiar with it being put like that. No I have never really, you get the occasional customer appraisal, small marketing exercises done." Participant #12.*

The results of the interviews imply that there is a lack of universal understanding and appreciation on the principles and value of 'user centred' practices for home use medical devices. One participant in the study summarised this in the following statement:

*"It would be nice if people stopped looking at it as a checkbox exercise and looked as this will lead to a better product that we will sell more of." Participant #1.*

**Core Issues**

- User research is perceived by many to be a marketing exercise or market research.
- A recognised disparity of language between the design community for professional and home use medical devices.
- Some companies perceive the activity of user research to be a 'checkbox' activity as opposed to a process that will lead to a better product and benefit them financially.
- Uptake of usability principles is inhibited by the use of a process and 'jargon' terminology that stakeholders in the design process are not familiar with.
- Considerable time is spent educating individual on the concepts and value of a 'user centred' process that delays the time to market.
- The established medical model for conducting research obstructs the uptake of user research by Healthcare Professionals (HCPs).

***Challenge Six: Incentives for Adoption***

The term 'Incentives' in the context of this study refers to the factors that influence a company's decision to invest and adopt 'user centred' practices. Oxford Dictionaries define an incentive as 'a thing that motivates or encourages someone to do something' (Oxford Dictionaries, 2013). Six of the designers in the study referred to a lack of incentive or motivation that justified investing more money and time into conducting user research throughout product development.

One participant opined that, in his experience, some companies do not consider it valuable to invest in user research studies, as patients will use the devices that they are given:

*"A lot of companies don't consider it actually that important to talk to the customer, to talk to the end user, to talk to the person who is going to use the syringe driver because they'll use whatever they're given". Participant #3.*

Evidently the companies that this designer was referring to failed to see an incentive to invest in usability research. All six respondents who cited a lack of incentives to adopt usability in practice referred to the difficulty to apply cost-benefit analysis. Typically, companies are financially motivated; this was seen with the commerciality challenge for user involvement, so very often the decisions for conducting user research are dictated by a return on investment (ROI). One participant opined that:

*"It is very difficult to have an impact from a design point of view, on marketing and development within large organisations." Participant #6.*

Another participant explained that:

*"As an industry ergonomics suffers by not having lots and lots of good cost-benefit analysis." Participant #8.*

There is a need for usability research to develop improved evidence on the cost-benefits for conducting user research. Sharples *et al* state 'there is a clear need for the analysis and demonstration of the relationship between the goals of the device, its design and the consequences of its use.' (Sharples *et al*, 2012). Such evidence could provide further incentive and motivation for the uptake of usability principles in home use medical device design.

**Core Issues**

- It is difficult to assign a monetary value to usability and user satisfaction with respect to the financial gains for a company.
- Some manufacturers do not consider it important to involve the end user at all in the design process, as they believe they will make do with what is given to them.
- It is difficult for design as a discipline to have an impact on marketing and finance departments within a company.
- Currently the requirement to save money outweighs the perceived benefits of investing in early and iterative user research.
- Cost-benefit analysis is very difficult for companies to conduct within the realms of usability research and user satisfaction.

***Challenge Seven: Ethical Issues***

The use of the term ethics in the context of 'Ethical Issues' and its relevance to this study are defined as 'moral principles that govern a person's behaviour or the conducting of an activity' (Oxford Dictionaries, 2013). Thus, these issues in the design of home use medical devices refer to the necessary approvals and practices that must be in place by law within the United Kingdom (UK) for user research to be ethically conducted. It is regarded that any research involving patients or healthcare professionals can often be a lengthy and complicated process (Martin *et al*, 2008). In the UK and the NHS, permission to conduct research is made via an application to the National Research Ethics Service (NRES). NRES Research Ethics Committees (RECs) are responsible for the 'safeguard of rights, safety, dignity and wellbeing of people participating in research in the NHS (NRES, 2013). Wald has previously cited this issue as a barrier to research in the NHS, as all research involving NHS staff or patients requires an ethical review regardless of whether the research is interventional or not (Wald, 2004).

The consequence of 'lengthy' ethical reviews and the perceived bureaucracy in gaining ethical approval is that companies tend to look for alternative approaches to conducting user research with actual target populations. On ethical issues one participant said:

*"It is difficult and it depends on who you are involving and where you are involving them. If it is NHS staff, you can gain access to NHS staff without having to gain ethical approvals provided it is in their own time and they are willing to take part and happy to be involved." Participant #1.*

Provided the target healthcare professionals are available and willing to participate at the time of conducting user research, this alternative to gain ethical approval is an option adopted by some companies. However, for home use medical devices in the United Kingdom the real end users of such devices are typically patients and their families. In such cases, one designer in the study described how ethical approval could be avoided through the use of proxy or representative users:

*"So they end up using proxies…going to surgeons, going to experts and talking to them rather than talking to the user because getting to the user just takes too damn long. And not too long because they don't know where the user is [Access Issues] but too long because they can't get the agreement to go through." Participant #1.*

Other designers in the study described how the bureaucracy of ethical approval in the United Kingdom and the use of NHS patients influenced their design practice. When asked about gaining ethical approval for user research, one participant explained how he would typically avoid the process:

*"No it is underneath the radar for ethics. It is really in the experimental phase with enthusiastic colleagues if you like. So it is rather like Dr Jekyll experimenting on himself really." Participant #12.*

For this designer, conducting user research with actual end users of the device was typically replaced with internal studies with his own colleagues, including testing and using devices themselves as opposed to with actual end users.

**Core Issues**

- Gaining ethical approval for conducting user studies and testing in the United Kingdom was perceived as lengthy and restrictive.
- The study revealed that designers would typically search for alternative methods to conduct user research to avoid bureaucracy.

- Companies seek involvement from HCPs from the NHS in their own time and they are so willing to avoid ethical issues.
- The time taken or perceived time to attain ethical approval in the United Kingdom and NHS prevents the adoption of usability principles with device users.
- Proxies or representatives are often used in place of real end users, as it is quicker and less bureaucratic.
- Some designers conduct their own research on themselves rather than with end users.
- Personal situations make conducting research for some diagnostics challenging ethically.
- The hospital setting has a perception of clinical trials that makes gaining participation from HCPs challenging for user research.
- The default position of some HCPs is an unwillingness to participate in user research for fear of liability.

***Challenge Eight: Regulations***

Regulations are widely recognised as rules or directives that are 'made and maintained by an authority' (Oxford Dictionaries, 2013). Section 2.3 of this thesis described the current regulations in force in the UK under the recognised Competent Authority, the MHRA. Under the current regulations in the UK, usability engineering as outlined in the recognised harmonised standard IEC 62366:2007 outlines guidelines that are open to the interpretation of its users. Presently there are no mandatory usability requirements with respect to user research in medical device design. There are also no recognised specific regulations in the United Kingdom for home use medical devices with respect to usability.

As described in section 2.3, the current regulations mandate specific 'essential requirements' that refer to the safety and efficacy of medical devices. Satisfying these requirements is essential for a medical device to be launched onto the market in the UK and Europe.

Designers in this study opined that manufacturers of professional and home use medical devices focus on the satisfaction of safety and efficacy requirements as a priority. Usability considerations are typically considered towards the end of the

design and development process, as they are currently not a mandated requirement under the Medical Device Directive (MDD).

On the topic of regulation one consultancy in the study explained how typically the companies they worked with felt controlled by the regulatory requirements.

*"A very large majority of companies which we work with live in fear of, whether they have got regulatory compliance or not." Participant #1.*

In this designer's experience, clients were fearful of not meeting the regulatory requirements to get a device onto the market that usability was not considered a priority. Others argued that some of the regulations were open to interpretation that meant satisfying the requirements was challenging.

*"There is some interpretation, the regulations are open to some interpretation on numbers and the way, what a homogenous group is and all sorts of stuff." Participant #9.*

The interviews also revealed that some designers in the study considered the process of applying to the regulatory authority, the MHRA, as expensive.

*"It is just the process of applying to the MHRA is not cheap." Participant #12.*

Thus, designers were fearful of not satisfying the legal requirements regarding home use medical devices, which would require a costly re-submission to the competent authority for approval.

Not all designers in the study considered the current regulations to be a challenge for involving users in the design of home use medical devices however. One designer in the study opined that the current regulations were specific with regards to the regulatory requirements and thus meant compliance was achievable if one followed the documents.

*"I mean regulations aren't really a problem because they are quite specific so you always know what you are working with." Participant #4.*

However, one participant explained that the regulatory requirements were less clear when designing for the European Union (EU) market. Under the current MDD, different member states transpose the directive into specific regulations that can

mean compliance for devices sold throughout the EU is less consistent than meeting the regulatory requirements for the UK. After citing that the current regulations are open to interpretation, this designer added that:

*"Especially when you get into Europe where you can generally apply the same logic as the FDA but not quite the same." Participant #9.*

The study suggest that some designers perceived the guidance on usability for both professional and home use medical devices is open to interpretation and at times confusing for medical device developers. Designers in the study opined that priority is placed upon satisfying the regulatory requirements, the 'shall' statements in the regulation, with 'should' requirements allowing for permissible non-compliance, provided that justification is given.

**Core Issues**

- Designers and developers focus upon the mandatory regulatory requirements, often overlooking the obligatory requirements for usability considerations.
- Non-compliance with usability guidance is regarded as 'permissible' under the current regulatory requirements in the United Kingdom.
- Applications for regulatory approval through the MHRA are perceived to be expensive for device developers, enforcing the focus upon meeting the regulatory requirements in development.
- Following usability principles including the involvement of end users in the design process is considered a 'moral obligation' rather than necessity for regulatory requirement in the United Kingdom.

***Challenge Nine: Hierarchy of Users***

The term 'Hierarchy' in the context of this study refers to the hierarchical nature of stakeholders within the design and development process of a home use medical device. A hierarchy, as defined by Oxford Dictionaries, is 'a system in which members of an organization or society are ranked according to relative status or authority.' (Oxford Dictionaries, 2013). Previous research found in the literature review has described a potential hierarchy amongst the field of medical devices (Money *et al*, 2011). Money *et al* posited that the needs of users from the perspective of some manufacturers do not originate from patients themselves. Rather, patient

needs are often articulated through a hierarchy of healthcare professionals such as surgeons or clinical champions (Money *et al*, 2011). This was also found in case study two of this thesis which identified that individuals with purchasing powers were typically consulted during the design and development process rather than patient users themselves.

During the interviews for this study it was found that other designers referred to a hierarchy when capturing the needs of users in the field of home use medical devices. One designer in the study opined that the hierarchical nature of the medical device field affected his practice of user research, because senior HCPs were often resistant to the process he was advocating:

*"In a medical environment, it is fairly hierarchical. I find that people are a little more abrasive and they're just…they don't see the point of you asking them questions." Participant #10.*

He added that this 'characteristic' was not unique to the field of professional and home use medical devices, but posited that participation from some individuals within the hierarchy of HCPs was inhibitive to applying usability principles for design.

*"It is not the only field that has this characteristic but I find in medical, people are less interested in what you are doing and less open to being involved." Participant #10.*

Another designer in the study opined that individuals with purchasing power and access to budgets for medical devices were typically consulted over patients for the purpose of identifying or capturing user needs.

*"So you go down that hierarchy and then buyers do become more of an issue because they make big purchase decisions." Participant #9.*

This designer added that in some situations, as it is permissible to do so, HCPs were consulted in focus groups to identify the needs of their patients rather consulting or involving the patients themselves.

*"We might focus group nurses where we get 3 or 4 of them in just to cover the ground faster." Participant #9.*

The designer in this instance explained that this was a quicker method to understand the needs of end users rather than interact with the individuals directly. Similarly, as was described in the 'Access to Participants' section, one designer described how the clients he worked with preferred to consult and involve individuals from positions higher within the hierarchy consequently restricting the access to patient users.

*"We never get to the end user. We will get to the clinician, we will get to the installer or we'll get to the carer possibly but we very rarely get to speak in detail with patient." Participant #3.*

Some of the designers in this study opined that a hierarchy, based upon expertise and financial power, exists amongst the medical device industry. As a consequence for design, the involvement of end users was perceived by some designers to be of lesser value and necessity in the design of home use medical devices. Many of the designers in the study opined that they consult senior HCPs or buyers of devices to address their specific needs, for reasons of commerciality rather than involving the patient directly.

**Core Issues**

- Designers consult senior healthcare professionals (HCPs) to identify the needs of patient users for reasons of commerciality.
- Some designers in the study perceived HCPs to be unwilling and uninterested to participate in user research studies, as it was not considered important to them.
- In certain circumstances some consultancies were restricted to only consulting with senior HCPs to address the needs of end users.
- Some designers opined that individuals with purchasing power were often involved in the design process to meet their specific needs rather than the needs of end users.

***Challenge Ten: Diversity of Users***

The term 'User' as previously described throughout this thesis is defined in accordance with IEC BS EN 62366: 2007. Under the harmonised standard a user is defined as the person using (i.e. operating or handling) the medical device, which

includes and is not limited to, cleaners, maintainers and installers (IEC BS EN 62366: 2007). The standard's definition recognises that users can also be patients or laypersons (IEC BS EN 62366: 2007). Therefore it is understandable that users of home use medical devices can be any one of a multitude of people with a complex range of needs. One participant in this study explained:

*"So as you start to list all of these users as stakeholders you get a feel for the mine field that it all is to launch a product." Participant #4.*

In this respect designing with the needs of users in mind was identified as challenging for designers in the study. One participant described how devices could be used by patients with co-morbidities, multiple conditions that effect the interactions with devices, consequently presenting a challenge to accessing the diversity of device users for research:

*"If you get into cystic fibrosis or multiple sclerosis or something like that where you have co-morbidities as well. You have people who are able to use say an injection device for a while and then become incapable of using it. You have got to make sure that you are talking to people from that whole spectrum." Participant #9.*

This participant added that when designing for the European market in accordance with the current requirements there is a lack of diversity achieved which is typically regarded as acceptable to launch a product:

*"…Basically you are using 10 people in Germany and 10 people in Spain as a stand in for the entire European market…Whereas if you think of it in those terms, half of them are male, half of them female. So you have got 5 men and 5 women standing in for the whole of Europe." Participant #9.*

**Core Issues**

- Identifying and accessing the diversity of device users for home use medical device design was perceived as challenge for the sector.
- Engaging with patients with comorbidities was identified as both challenging but essential to understanding the diverse range of patient capabilities.
- Satisfying the current requirements from a regulatory perspective does not ensure that the diversity of device users is considered.

***Challenge Eleven: Intellectual Property Considerations***

The final challenge identified at interview referred to Intellectual Property (IP). The Intellectual Property Office (IPO) describes IP as 'any form of original creation that can be bought or sold' (IP, 2013). According to the IPO there are four main types of IP rights; Patents, Trade Marks, Designs and Copyright. Two designers within this study described how IP presented a challenge to their company in relation to having 'freedom to operate'. One participant explained:

*"One thing that I would actually like to add to the complexity is the intellectual property world. It is highly complicated… I would say it is one area of my experience that still throws up surprises." Participant #6.*

He added that:

*"It [Intellectual Property] can be a massive barrier in terms of worldwide capability, freedom to operate and also freedom to supply to the market." Participant #6.*

Another participant in the study explained that 'Freedom to Operate' was a challenge in the sector shared this perception of IP:

*"The biggest problem with an inhaler is not, you know, I need to have IP on this. It's I need to be able to have freedom to operate. Freedom to operate is a massive problem." Participant #9.*

Consequently settlements between organisations sometimes have to rely on negotiations between lawyers:

*"In effect it can come down to negotiations between organisations as to who does what and I have worked on many projects which have been dormant for a very long time and with very good tools and research behind them and it is pretty much, unfortunately in my opinion down to lawyers at the end whether it actually makes it or not." Participant #6.*

**Core Issues**

- Designers in the study opined that 'freedom to operate' around existing IP was a challenge for the home use medical device sector.

- Negotiations between lawyers can ultimately dictate whether projects will go ahead on the grounds of intellectual property agreements.

### 7.11.2 The Perceptions of Design Guidance

The context in which the term 'Design Guidance' is used here refers to literature that has been specifically developed to assist the designer or developers in conducting user needs research, including the identification of needs or improving the usability of devices.

While many of the designers in this study (62%) opined that they adopted a 'user centred design' process, the understanding and interpretation of this process was diverse, as has been previously presented. On this topic one participant in the study described that despite designers often having a level of knowledge on ergonomic principles, the concept of 'designing for ourselves' is still extant:

*"One of the biggest problems with what we do is that we are designing for people and we are people. We design for ourselves. It's a classic mistake but it still goes on, even though everyone has possibly read an 'ergo' [ergonomics] book, it still goes on today." Participant #8.*

Stephen Pheasant and Christine Haslegrave described this concept in what is known as the Five Fundamental Fallacies in their book titled *'Bodyspace: Anthropometry, Ergonomics and the Design of Work'* (Pheasant & Haslegrave, 2006). On designing for one self, Pheasant and Haslegrave said:

*"The designer considers the matter tries out the prototype and concludes that it 'feels alright to me', with the clear implication that if it is satisfactory 'for me' it will be for other people too". (Pheasant & Haslegrave, 2006).*

Designing in such a way fails to account for the recognised diversity of home use medical device users (e.g. size, weight, strength, visual acuity, dexterity, cognitive capability etc.). That is before considering the environment for which the device is to be used and tasks that must be performed.

The five fallacies described by Pheasant and Haslegrave include 'two principle themes'. The first of these themes describes the 'contrast between the investigative

methods of the empirical sciences and the creative problem solving methods of the designer' (Pheasant & Haslegrave, 2006). The second theme within the five fallacies is one of 'human diversity', which Pheasant and Haslegrave describe as 'the single most important characteristic of people' in the world of design and practical affairs (Pheasant & Haslegrave, 2006). The Five Fallacies are presented in Table 7.15.

**Table 7.15: The Five Fundamental Fallacies (Pheasant & Haslegrave, 2006).**

| | |
|---|---|
| **1.** | This design is satisfactory for me – it will, therefore, be satisfactory for everybody else. |
| **2.** | This design is satisfactory for the average person – it will, therefore, be satisfactory for everybody else. |
| **3.** | The variability of human beings is so great that it cannot possibly be catered for in any design – but since people are wonderfully adaptable it doesn't matter. |
| **4.** | Ergonomics is expensive and since products are actually purchased on appearance and styling, ergonomic considerations may conveniently be ignored. |
| **5.** | Ergonomics is an excellent idea. I always design things with ergonomics in mind – but I do it intuitively and rely on my common sense so I don't need tables of data. |

In the context of this study it is arguable that some of the responses made by participants mirror the themes of the fifth fallacy in Table 7.15 (Pheasant & Haslegrave, 2006).

It is often commonplace for manufacturers and design consultancies to market their services, products and methods as 'user centred' or user friendly. In total eight designers in this study reportedly followed a 'user centred design' process towards home use medical device development. Despite this, 46% of designers in the study opined that they did not follow the available usability guidance, as they believed it to either be 'common sense' or lacking in practical value.

One designer in this study felt that much of the guidance and literature they had seen on the topic of user research was simply 'common sense'. This participant felt that sufficient user research could be carried out with 'a quick 10 minutes on Google'.

This company for whom this participant was Managing Director held a sceptical view of the value of such guidance in practice. He described design guidance as:

*"Common sense branded in another way" Participant #2.*

Another designer in the study felt that the available guidance is perhaps more suitable for academics as opposed to designers in industry.

*"I guess they are possibly more of an academic interest than perhaps of use on a practical project." Participant #11.*

On this theme some participants cogitated that the available guidance suffered from a lack of practical value and would therefore choose not to make use of such material or in some cases not look for such guidance at all.

*"I don't look for dedicated designer information…No I don't get the quality of information I want is the blunt answer really" Participant #12*

Evidently some designers in the study held a negative perception of the value that design guidance could provide for them or their company. One theme that was common to 83% of the designers that did not follow design guidance was the issue of experience in the field. These participants felt that experience from working in the field was more valuable in terms of understanding the needs of users than any form of approach or method that could be provided within design guidance. When asked whether one designer in the study used any particular design guidance he said:

*"I can't recall anything we have used recently. I mean we have got quite an experienced team that have been doing this for years so we generally use our own internal resources to get together and figure out an approach that might be useful." Participant #4*

This designer then added:

*"We rely on our experience of what has worked in the past." Participant #4*

Due to the inherent complexity and diversity of home use medical devices the designers in this study implied that designing a successful device can only be achieved through greater experience and an understanding developed over years of working in the industry.

*"It is more experienced based because we can be dealing with quite a range of requirements. The requirements have to be developed by the experienced team and include a lot of variable inputs into that and that is predominantly through experience." Participant #6*

This finding supports claims within existing literature. In his thesis, Gupta found that designers of home use medical devices regarded experience to be more valuable than any form of usability guidance (Gupta, 2007). One designer in Gupta's study felt that 75% of designing for home use medical devices was attributable to experience (Gupta, 2007).

The results from this study suggest scepticism of the practical value that the currently available guidance provides to designers and developers of home use medical devices. This scepticism was particularly evident from designers with over 15 years' experience in the field. This could perhaps be due to the development of one's own skills and interpretations of what is required within projects and preferred practices.

Relying on one's own intuition and experiences however can create harm to the end user, as assumptions can find their way into design practice, which can have negative consequences. When an activity becomes unconscious by means of repeated execution, unforeseen or unrecognised errors can occur. This is particularly evident when people learn to drive for the first time. As individuals gain more skill at driving they become less aware of the task they are performing to the point where a whole journey can be completed without the driver being aware of how they made that journey.

Designing a product, whatever it may be, cannot take place unconsciously to the designer. Good design practice should as closely as possible follow a formal process that challenges preconceived ideas. One participant in this study said:

*"It is very easy to be misguided by what people have done before on the proposition that they knew exactly what they were doing." Participant #12*

This very quote makes a strong argument for having an early exploratory phase with device users and iteration throughout design. Understanding the problem and the needs of the users at the very beginning will then dictate the design process and ultimately the final solution.

It is understood that the medical device market is very much a technology driven domain thus the capabilities of devices are ever changing and improving for home users (Cifter, 2011; Gupta, 2007; Martin *et al*, 2008; Money *et al*, 2012).

Donald Norman posited in, *The Design of Everyday Things,* that technology offers the potential to make life easier and more enjoyable with each new technology providing increased benefits (Norman, 1998). Paradoxically, added complexities also arise increasing the difficulties and frustrations to device users (Norman, 1998).

For new and sophisticated medical devices migrating into the home there is always an inherent complexity brought about through miniaturisation and the capabilities of technologies that were not possible in previous years. Designers should consider that whenever the number of functions and required operations exceeds the number of controls, the device will be complicated for the user (Norman, 1998). This defines the so called 'Paradox of Technology' whereby, on the one hand, we have a technology that simplifies a task through providing greater function, but on the other, complicates life for the user by making the device harder to learn and harder to use (Norman, 1998). Only by applying sound principles to design can this balance be managed to achieve a device that meets the needs of the end user.

On 'common sense' in design, Pheasant and Haslegrave posited that:

*"I would only add that common sense sometimes seems remarkably rare" (Pheasant & Haslegrave, 2006).*

The role of the designer in the delivery of a medical device cannot stop at the point of just 'good enough'. Referring to usability testing of a medical device by one trained healthcare professional, one designer in this study said:

*"You wouldn't believe the mistakes that are made". Participant #9.*

He added:

*"Most people I would have thought would have figured out the way to use this but this person held it like that [demonstrated an incorrect action]. So the mouthpiece was clearly the wrong shape, like that and she used it. I was gob-smacked. What made it more shocking was that wasn't a patient that was a nurse who had 20 years' experience. We were so surprised we actually got her, at the end of the interview, we got her to train one of us the way she would train a user to see how she trained it in case we just missed something and that was the way she used it. That is someone who is out there right now teaching people to use it the wrong way and those people are not getting a dose. No medication. You wouldn't believe it." Interview Participant #9*

Evidently this designer has experienced first-hand the errors that users of home use medical devices can make, however this designer still considered the issue of designing for the end user as 'common sense'.

It is without question that experience of the designer and an appreciation of these use scenarios has a role to play in design. This research has not been conducted to question the expertise, competence or knowledge of the designers in this study. However, recognising the likelihood of use error occurring in well-established products by trained professionals presents a case for adoption of idealised design practice.

Pheasant and Haslegrave do concede that there is an element of truth in the five fundamental fallacies. They stated that "human beings are indeed very adaptable" and that "they will put up with a great deal and might not necessarily complain" (Pheasant & Haslgrave, 2006).

While humans are adaptable and develop workarounds, sometimes without a conscious awareness of doing so (Holtzblatt & Beyer, 1993), for home use medical device design this can compromise the safety of patients when devices are misunderstood and used incorrectly. Designing devices that are intuitive to use requires manufacturers to conduct research with real end users, which this study has identified is a challenging process for industry.

According to Pheasant and Haslegrave design reflects society in the sense that the objects of the designer are influenced by the world in which they are created (Pheasant & Haslegrave, 2006). Thus the practice of design and adoption of idealised practice (i.e. making products and devices as good as they can be) is recognised as a compromise on the basis of commerciality and the ability to draw a profit. This is arguably ubiquitous throughout the design of all products and services that operate as a business.

This research has revealed that many of the challenges for the adoption of usability principles and the involvement of users in the design process are inhibited by the lack of incentives for companies to invest in user research. The eleven challenges identified in this study largely refer to organisational challenges and the relationships between stakeholders within the design and development process of a home use medical device. Participant six in the study described the commercial reality of the industry in the following quote:

*"The fundamental thing is that the statistics on the number of design developments and pharmaceutical developments that actually make it to production are very slim. So I would say that the commercial pressures on the pharmaceutical world, partly driven by governments, haven't actually been very good for R&D." Interview Participant #6.*

With a decline in the number of developments successfully reaching the market there is increased pressure upon companies to keep costs under control. Now more than ever, every development decision comes under fine scrutiny from marketing and financial departments. In many companies these departments have the budgetary control and as such have great influence over design decisions. The participants in this study expressed that due to a lack of ability to express the benefits of involving users in the process in monetary terms it was very difficult to get the marketing and financial teams on board.

In light of this, investments in home use medical devices are perceived as a risk to manufacturers. This was of course identified in the idealised practice case study presented in Chapter four where one consultant said:

*"I suppose with anything it's about commercial viability. The thing is it should be about risk reduction and competitive advantage. What I mean is not risk reduction to the people using it but risk reduction to the company in investing in this and gaining a product that is likely to gain more market acceptance and likely to give better advantages over other products that currently exist." Case Study 1.*

Consequently, a company might launch a product knowing that it is not as good as it could be and potentially look to make improvements in an updated model. For usability issues however it may well be that the perceived costs of improvement are much higher than actual costs. Pheasant and Haslegrave argued that beyond all the considerations for design the simple fact remains "that making something the right size is often no more expensive than making it the wrong size" (Pheasant & Haslegrave, 2006). On this theme one participant in the study opined that the clients he had worked with typically perceived the costs of conducting user research to be much higher than the actual costs involved.

*"We find that there is a perception by manufacturers that doing human factors data is an expensive and time-consuming thing to do. We find that with pharmaceutical companies because they have got a very strong mental model that clinical studies are huge and expensive and take a long time." Participant #7.*

In this designer's experience, there is a misperception about user research for the purpose of usability studies and clinical research involving patients. To compensate for this the participant explained how he would educate clients on process of user research and the associated benefits.

*"We try to educate them [clients] that human factors studies are much smaller, much quicker and don't need to be lots of people. You can test them in 5 or 6 or 7 or 8 people and that would be perfectly adequate. So that is one thing we try to sell that the benefits outweigh the costs. The costs aren't anywhere near as great as our potential client's think they are." Participant #7.*

This participant did concede however that selling the benefits of adopting a usability engineering process was part of 'twin track' approach. He explained that the generation of data for future submissions to the regulatory authorities was the 'easier sell' to clients to conduct user research. This would suggest that the advocacy of the

benefits for user research do not in itself provide sufficient incentive for manufactures to adopt such practice. Rather the enforcement of regulatory requirements that are mandated by law has greater influence on changing design practice.

### 7.11.3 The Design Process

Each participant in the study described the key design stages involved in the design process of a home use medical device (See Section 7.10.3). Figure 7.2 and Figure 7.3 present a schematic comparison of the design processes adopted by participants in this study.

The results revealed that participants who reportedly followed design guidance were more consistent with their involvement of users in the design process. It is not possible from this study to state whether this trend is statistically significant. Instead this study presents the findings that are indicative of current practicing designers in the field of home use medical devices. The comparison of Figure 7.2 and Figure 7.3 indicate that those who did not follow the available design guidance were less likely to involving users during the early phase of the design process and evaluation phase.

The design processes cited by participants suggest that user involvement at what is commonly referred to as the concept stage or 'conceptualisation' is low. This part of the process is typically located towards the middle of a design process once a specification has been established. Perhaps the reason for the low levels of user involvement during design conception is attributable to companies developing ideas internally before approaching users for feedback for future developments. This stage of the process is where the designer or developer of a home use medical device is translating the user needs or insights into practical design solutions and therefore it could be argued that there is little need for user involvement at this phase.

### 7.11.4 The Understanding of Users and their Needs

The designers understanding and definition of the term user has been identified as critical to this research. Previous studies have recognised that the term user can relate to a wide variety of people (Shah & Robinson, 2008; Shah *et al*, 2009). One designer in this study said:

*"I think philosophically we would look at the very wide range of the list. So we would probably include in that the people that are going to service the machines, the ones who clean it…Possibly I think also the families of patients as well. So that is something that comes up, we are doing a device at the moment and the patients are unconscious when they are on the machine [haemodialysis] so it is actually the families are the ones who experience it." Participant #11.*

In this quote the designer recognises that the users of home use medical devices expands beyond the traditional groups of healthcare professionals and patients (Shah & Robinson, 2008). The appreciation of servicing, maintenance and family member's supports that the users of such devices are a diverse population and considerations of this cross section of users is important for design (Privitera *et al*, 2009b). In the context of this study one designer felt that there is often confusion between customers and users.

*"We really make the distinction between customers and users, which is the next phase [of the process], so user requirements versus customer requirements, we try to explain to people that it's important to realise that users are not customers. I think a lot of companies and a lot of people who do design confuse the two way too much and I think the customers are not users." Participant #10.*

This designer makes a distinction between the two groups, customers and users, however for 'consumer medical devices' as defined by the FDA, the customer can also simultaneously represent the user (FDA, 2009).

**Translating User Insights into Design Solutions**

During the interview process participants were asked to discuss how the insights gained from their own user research informed the final design solution. The aim of these questions was to explore the manner in which these insights translated to formal user requirements. Analysis of the data revealed six different themes of translating user insights into design requirements, which are discussed below:

**Inherent Designer Quality –** Designers in the study opined that the very nature of user requirements translation from user research is partly attributable to an inherent quality that designers as practitioners possess. One participant said:

*"I think to some degree that is kind of part of what the designers role is." Participant #1*

This designer suggested that through their own educational background one develops experience and a set of skills that equips them to identify actual needs of end users. This goes beyond simply asking what the user wants from a product. It is the process of understanding the wider context of device use that will influence the final design solution. However, the insights of this context can only be accurately identified through the involvement of representative users in the design process.

*"It is sitting down with the user to understand; what's going on, what the user environment is like, what their daily routine is like, how do they interact with the technology that existed, and trying to use that information to develop enough empathy and understanding of the situation to come up with a solution." Participant #1*

This quote above highlights the importance to explore the wider context of device use and its implications for design. In doing so it leads coherently into the second identified theme for user needs translation, which refers to gaining a detailed understanding of the fundamental principles of ergonomics and human factors.

***Detailed Understanding of the User, the Task and the Environment* –** Designers in the study explained that in order to successfully translate insights into needs, there has to be a consideration for the fundamental principles of ergonomics: User, Task, Environment.

*"…Understand who the users are, understand the task and understand the environment." Participant #8.*

Another participant in the study felt that it is important to understand the needs of users in general as opposed to asking questions about a specific design or development opportunity.

*"So it is really more often a case of really understanding where they are more generally. Whether their needs are, as I say, at a basic level rather than specifically ask them questions about a new technique or opportunity." Participant #1*

**Gaining Expert Opinion –** Some participants in the study opined that they relied on expert opinions to translate the needs of their device users. One participant described how they would use clinicians to understand user needs based on their experience and familiarity of the market.

*"Yes that is where clinicians come in handy because clinicians by and large are familiar with a broad range of products on the market." Participant #12*

***Employing an Agency or External Company –*** Other participants explained how they would recruit a consultancy to conduct in depth interviews with device users externally. Thus, some companies rely on other specialists to translate the insights into actual device needs.

*"Generally we would recruit specialist interviewers to do that, so usability studies." Participant #2.*

***Educating Users –*** Many participants described the process of translating user insights as one that required an education of users.

*"It is an education process." Participant #8.*

For some this meant 'facilitating' dialect with users to assist them in arriving upon a solution.

*"…"If you could do that, and it lead onto that, what would you think about that?" So part of it is education as well as questioning." Participant #4.*

*"I certainly wouldn't try and dictate but we do try and facilitate conversation and discussion so they arrive at the right decision with our help." Participant #8.*

Participants in the study suggested that educating users throughout the process of user research was particularly important in domains where the technology or techniques were novel to them.

***Observation Techniques*** – The final theme identified referred to observation of device use. Many of the designers in the study opined that in order to understand the differences between what users' say they do versus what they really do it was necessary to observe users in practice. Section 7.10.4 of the results revealed observational methods to be the most frequently cited method for user research by

participants. Participants in the study believed that in order to understand genuine user needs observation methods were an essential part of the design process.

*"I mean the best way to get round that is to observe what people do when they are handling devices." Participant #7.*

The participant who described that his company would recruit a specialist consultancy to conduct user research explained that he would refrain from involving designers directly in the research process.

*"It is important that designers don't do the research because they will lead the witness. So it is important that they observe." Participant #2.*

Despite this, he added that in order to ensure that the needs of users were translated to the design team they would use two-way mirrors or record interviews with participants so that footage could be viewed later.

*"So usually it is a one-to-one interview as a design team, we usually sit behind two-way mirrors or video it. It is really important for the designers to understand the difficulty patients are having because you wouldn't believe how difficult some patients find it to use devices." Participant #2.*

A total of six different themes were cited by participants in this study for translating user insights into actual needs and design solutions. While many of the participants provided responses to these questions at interview there was a consensus that translating needs from insights is not an exact science per se. Many of the designers in the study expressed a difficulty to explain, explicitly how they translate user insights and needs into design requirements. This is perhaps summed up in the following quote made by one participant in the study.

*'It is one of those where you have no definitive answer' Participant #1.*

### 7.11.5 The Use of Design Feedback

The active collection of design feedback from users was explored with participants. On design feedback one participant explained that they use nurses who are experienced in training patients as a medium to gain user feedback:

*"Besides complaints we have quite good contact with our distributors so if they have people in the field. So for instance in the Netherlands there are diabetic nurses with experience with our device. They actually go to the patients and they explain how it is used, how the device is used. From them it is quite a valuable, quite a good resource for possible improvements." Participant #13.*

Another participant representing a design consultancy explained that they would typically be impartial to the collection of design feedback from users, as their clients would perform this activity. When asked whether this participant actively collected feedback he said:

*"No not formally. {Pause} There is obviously the feedback we get from the user studies but it is not actually us [the consultancy] collecting it. Our customers [clients] do that [feedback collection] we don't actually get involved in it. Quiet often and a lot of the time, the work we do is under non-disclosure so we wouldn't be allowed to do that." Participant #2.*

Evidently this designer was restricted from engaging in the collection of design feedback from users due to the confidentiality agreements made with clients. Others regarded the active collection of feedback from users as the regulatory requirement to collect and analyse complaints.

*"In terms of, is there a process by which this is done for design reasons? Then I would say the answer is generally no. Is there feedback? Yes, there is feedback because there is the complaints procedure." Participant #9.*

He added:

*"Any drug delivery company has to have that in place. There must be a complaints procedure and that must be collected and that must be fed back. If there are device failures it very quickly becomes apparent. If they are more subjective then no. If people find something difficult but can still use it that doesn't really get collected until someone is to design an improvement." Participant #9.*

Evidently there is priority placed upon the safety and efficacy of a device when compared with usability issues for device users. This designer states that the consideration of use issues once a product has been launched is typically not

considered unless an improved design is to be made in the future.

This research suggests that there is potential for improved information sharing between designers, developers and users in relation to usability issues for home use medical devices. This study has indicated that currently design feedback, in relation to the usability of a device, is not widely collected by designers and developers of home use medical devices from device users.

## 7.12 Proposed Interventions

In light of the findings of this study, and research of as a whole, a series of interventions have been identified to address the challenges towards adopting usability principles in practice for home use medical devices. This research suggests that current design perspectives and practice towards home use medical device design lacks enforceable incentives for manufacturers to adopt usability principles in development and to iterate with their device users. The studies of this thesis has revealed that an advocacy of the benefits for adopting usability principles and guidance is not sufficient to change the way in which home use medical devices are designed for their end users.

To refer back to the previous chapter it was suggested that one of three possible scenarios could explain the reasons behind the current approaches taken by designers. This included the following:

- Designers are aware of the principles and methods of user needs research but do not apply them.
- Designers are not aware of the relevant methods and so cannot apply them.
- Designers are aware of the principles and methods for user needs research but apply them sub-optimally.

The findings of this study suggest that scenario three would explain current practice to home use medical device design. Many of the designers in this study opined that there were aware of the principles and practices for user needs research however were unable to apply them in practice because of the revealed challenges towards involving users and a lack of incentives to adopt idealised practice.

In light of this, three interventions specific to the home use medical device industry and its stakeholders have been identified. The following section introduces the proposed interventions of this research, which will be addressed further in the next chapter.

### Intervention One – A Regulatory Update

Under current regulation in the United Kingdom there is no recognised regulation specific to the design of home use medical devices and their potential users. Furthermore, there are no recognised mandated requirements for manufacturers to consider usability in the design of professional or home use medical devices. This research has indicated that current practice towards home use medical device design and the involvement of users within the design process is dictated by the commerciality of the industry. In light of this, intervention one of this research proposes a change in the current regulation of home use medical devices within the United Kingdom. The introduction of mandated requirements for home use medical device design would improve the quality and consistency of the devices designed and also clarify the requirements of manufacturers in the design and development process. This study has indicated that some manufacturers perceive the current regulations and standards to be open to interpretation and thus this research calls for clarification on what is required by manufacturers.

### Intervention Two – Endorsing Usability

Currently there is no recognised endorsement or certification for devices of improved usability. This research has highlighted that the perceived and published benefits of following usability principles in the design of home use medical devices fails to incentivise manufacturers to adopt such practices. The second intervention of this research therefore calls for an increased recognition of usability within the certification of home use medical devices. It is believed that by endorsing devices that meet a specific standard in terms of usability and suitability for target populations, devices will be more usable and understandable for their users. Similarly, manufacturers of devices will receive recognition for improving the usability of their devices that in turn could raise the standard and quality of devices industry wide. This could take the form of an amendment to the Medical Technologies Evaluation (MTE) programme currently performed by the National

Institute for Health and Care Excellence (NICE). Under the MTE programme NICE select and evaluate new and innovative devices for adoption into the NHS (NHS, 2013). The current evaluation process by NICE does not account for usability within the assessment criteria which presents an opportunity for further development. This will be explored further in Chapter eight.

**Intervention Three – Patient User Review Forum**

This study suggests that design feedback from end users (e.g. patients) of home use medical devices is currently underutilised in the United Kingdom. The designers in this study opined that design feedback, including usability issues, from users would only be collected post launch if an updated device were to be developed. This study revealed that designers would rarely actively collect design feedback from end users after launching a device onto the market. In light of this, this research proposes the development of a 'patient user review forum' that enables device users to provide feedback on device related, usability issue. This resource would enable patient users of home use medical devices to interact with one another, sharing information on different devices used for specific conditions. This resource could then be of significant value to manufacturers who would have direct access to their device users. The review forum would enable manufacturers to understand how device users are coping with their devices leading to potential development opportunities.

The three interventions presented here are the culmination of the research to this point of study. Each of the interventions describes a different approach to addressing the challenges identified in this chapter that aim to incentivise a change in current design practice towards home use medical devices. To ascertain the value and potency of these interventions for industry the following chapter will address the views of different stakeholders in the home use medical device industry.

## 7.13 Ethical Considerations

The fundamental issue concerning ethics when conducting interviews is that the participants involved should not be harmed in any way by the research or questioning (Gray, 2009). Respondent have the right to terminate an interview at any stage should they so wish and this must be made explicit before the commencement of the interview. The most efficient procedure of dealing with the ethical considerations

and rights of participants is to provide a Participant Information Sheet (see Appendix 12) that explains explicitly the research, the necessary information and expectations for participation in the study. Once participants were aware of the requirements of the interview and the nature of the questions they were provided with a copy of the informed consent document (see Appendix 13).

## 7.14 Reliability and Validity

To address the reliability of the data presented in this chapter, the three questions identified in Chapter three and also addressed in Chapter six will now be discussed in relation to the context of this study (Easterby-Smith *et al*, 2008).

1. **Will the measures yield the same results on other occasions?**
   All reasonable steps have been taken to conduct this study in a manner that is open and replicable. No results have been manipulated, modified or deleted in the presentation of this study. All of the information conveyed in this chapter is indicative to how it was collected at interview from participants currently operating in the home use medical device industry. The presentation of the methodology, recruitment, interview protocol and results enables any interested researcher to repeat the study if they so wish.
2. **Will similar observations be reached by other observers?**
   The interview methodology described within this chapter makes exact replication of the study unlikely. Despite this, if one were to repeat this study with participants from the home use medical device industry using the content analysis process outlined in the methodology it is believed that many of the challenges reported in this chapter would be revealed again. As previously described all reasonable steps have been taken to make this study as reliable and valid. The study was both pre-tested and piloted before the interview protocol was presented to participants within this study.
3. **Is there transparency in how sense was made from the raw data?**
   The use of content analysis to identify the salient themes within this study was identified and described before conducting this study. The methodology used to interview the participants in this study (e.g. interview protocol) is presented within the Appendix 14 of this report. All of the figures relating to

the sources and citations for each of the results collected at interview are presented within this chapter.

## 7.15 Limitations

As with the previous chapters the limitations of this study were considered and are discussed here as a conclusion to this chapter.

One limitation to consider with the findings of this study is the issue of self-selection by participants who were willing to take part in the research. Chapter six of this research discussed the implications of self-selection on the results of the online survey. Due to the methodology of this study, participants were recruited using similar approaches to that of Chapter six. In light of this the results of this study are the views of participants that volunteered to participate in this study. With this in mind, there is a need to consider the potential for bias in the reporting of the results based on prior experience and perspectives of home use medical device design.

Another limitation to consider is the use of content analysis as a method of analysing the transcripts. Flick argues that a 'categorisation of text based on theories may obscure the view of the contents rather than facilitate analysing the text in its depth and underlying meanings' (Flick, 2006). Furthermore, the use of paraphrasing can remove the initial meanings behind the text in cases where it is used to not only explain basic text but also replaces it (Flick, 2006).

For the purposes of this study however the use of paraphrasing, in the sense of replacing wording to explain meaning, was not adopted. All text within the results and discussion of this chapter is presented as it was explained to the interviewer. The process of categorisation was planned and described before the interviews were conducted and the coding process has been presented to demonstrate how the categories were developed.

## 7.16 Future Work

As an output to this chapter necessary further work has been identified. The discussion section of this chapter introduced three interventions to address the challenges towards the adoption of usability principles and involvement of users in home use medical device design. The following chapter within this thesis must

address these interventions further and validate the practical value of the interventions with different stakeholders of home use medical devices. In order to ascertain how the interventions of this research could be implemented in practice it is necessary to explore the benefits and constraints of each intervention with the difference individuals affected by the propositions of this research. Conducting this work will identify a leading strategy to change current design perspective and practice towards home use medical devices and will reveal opportunities for future development.

## 7.17 Conclusions

A total of thirteen semi-structured interviews were conducted with designers of home use medical devices. All interviews were recorded verbatim and fully transcribed for analysis. Content analysis of the interview transcripts was performed using Nvivo 10 to identify themes within the responses made by participants. The analysis allowed the qualitative data to be analysed quantitatively and comparisons between salient themes to be made.

The aim of this study was to answer the second research question of this research, which was as follows:

***Research Question Two: What are the challenges for industry to involving users in the design process of home use medical devices?***

This study revealed eleven specific challenges towards the involvement of users in the design process of home use medical devices.

The challenges revealed in this study, in order of citation, were as follows: *Commerciality, Client Relationships, Financial Constraints, Access to Participants, Knowledge of Usability, Incentives, Ethical Issues, Regulations, Hierarchy of Users, Diversity of Users, Intellectual Property Considerations.*

The study discussed the nature of each challenge and how it inhibits the involvement of users in the design process of a home use medical device. This study suggests that home use medical devices are currently designed based on the commerciality of industry, which prevents the involvement and iteration with real end users in the design process. The study suggests that home use medical device design in the

United Kingdom lacks an enforceable incentive for designers, developers and manufacturers to adopt the principles of usability and involve users within their design process.

As a summary to the results of this study, three interventions are proposed to incentivise a change in current practice towards home use medical device design. The proposed interventions are as follows:

***Intervention One – A Regulatory Update Towards Home Use Medical Device Design in the United Kingdom.***

***Intervention Two – An Endorsement or Certification for Usability for Home Use Medical Devices.***

***Intervention Three – A Patient User Review Forum for Home Use Medical Devices.***

Further research must now explore the practicalities of these interventions with the various stakeholders involved in home use medical device development.

# Chapter 8
# Proposed Interventions: Stakeholder Workshop

The explanatory study in the previous chapter presented the challenges faced by designers and developers of home use medical devices to involve users in the design process. The chapter described the practical constraints faced by designers in industry to adopting the principles advocated and outlined in current design guidance (IEC BS EN 62366: 2007; ANSI/AAMI HE75: 2009). The previous chapter identified a lack of uptake by industry of usability principles for home use medical devices, which is supported by existing literature. As a conclusion to the chapter, three possible interventions were identified to overcome the challenges faced by designers by enforcing the approaches outlined in the guidance documents and harmonised standards. The following chapter describes the development of those interventions and presents a study with industry professionals from the field of home use medical devices. The study answers the final research question of the thesis and proposes incentives for a change in current design practice for home use medical devices.

## 8.1 Introduction

The following chapter aims to answer the final research question of this thesis, which is as follows:

***Research Question Three: How can usability for home use medical devices be incentivised for industry*?**

Using the understanding and knowledge of the thesis to this point the following validation study explores the proposed interventions of the research with industry professionals (i.e. stakeholders). The previous chapter described how in order to change current design practice and perspectives with respect to usability and user involvement, a change in the incentives for adopting such an approach is required.

Three interventions were identified as possible solutions towards changing current practice: a Regulatory Update, An Endorsement for Usability and a Social Media Platform for Patient Users (User Voice).

Each intervention has a shared focus, which is to offer an incentive to change the way in which home use medical devices are currently designed for the needs of their end users. The aim of the study is to propose the incentives of this research to stakeholders within the field. The stakeholders must be relevant to the field of home use medical device design and selection must be based on the relevance of the interventions. This validation study proposes that involving and discussing the recommendations of this research with practicing stakeholders will identify the intervention with the most value to the field to be developed further.

## 8.2 Rationale

This thesis has identified that current design practice for home use medical devices fails to offer a significant incentive for designers and manufacturers to adopt the design principles outlined in guidance documents such as IEC BS EN 62366: 2007 and ANSI/AAMI HE75: 2009 in the United Kingdom. In the United States of America (USA) the Food and Drug Administration (FDA) addressed the issue of designing home use medical devices by publishing a guidance document, *Design Considerations for Devices Intended for Home Use* (FDA, 2012). In the UK there is currently no such guidance published by the MHRA outlining design requirements for home use medical devices. As a consequence medical devices for use by patients in the home environment remain regulated under the same requirements for devices intended for use by professionals. This is despite extensive research acknowledging that these populations are markedly different (Gupta, 2007; Cifter, 2011; Martin *et al*, 2008; Money *et al*, 2011).

Adoption of the current usability standard for medical devices, *IEC BS EN 62366: 2007 Application of Usability Engineering to Medical Devices*, is a harmonised standard of the Medical Device Directive (MDD) and perceived by designers as a 'moral obligation' (See previous chapter). Furthermore, non-compliance with the harmonised standard is permissible provided that the manufacturer duly justifies the decision.

In a field that is widely recognised as being technology and commercially driven, the adoption of usability guidance lacks emphasis and priority in the design process.

The findings of this thesis therefore posit that in order to change current design practice, with respect to usability considerations, in the United Kingdom greater emphasis must be directed upon the enactment of usability principles by designers and manufacturers. The following study presents the proposals of this research and addresses the need for new incentives for the design of usable and understandable home use medical devices.

## 8.3 Proposed Interventions

The following section presents the three interventions that are proposed in the study in more detail.

### 8.3.1 Intervention One: Regulatory Update

The first proposed intervention of this research calls for a regulatory update with respect to usability requirements. As previously described, the current regulatory system in the United Kingdom specifies the application of usability engineering as a 'Should' requirement for manufacturers and developers of medical devices, both for professional and home use. Thus, the first intervention proposes to incentivise a change in current design practice by enforcing a legal requirement for usability requirements. For example, IEC BS EN 62366: 2007 states: 'usability engineering professionals should become involved at a projects inception' of which such individuals can be 'employees of the organisation or outside consultants'. This is a voluntary requirement and one that is not mandated by law. Thus, the proposal to change the regulation on usability considerations could call for a 'qualified person' to be involved from inception and throughout the design and development process of home use medical devices.

The proposed amendment to the regulations is aligned with the current proposals for a major overhaul in medical device regulation in the UK. At present there are on-going discussions into new proposals for medical device regulation that aspire to make the regulatory process more transparent and consistent across the different

member states. In the proposals for change by the European Commission it states that: 'In an internal market with 32 participating countries and subject to constant technological and scientific progress, substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objective of the Directives' (EC, 2013). The main objective of the regulations being the safety of medical devices and their free movement within the internal market (EC, 2013).

One of the recognised amendments under the new proposed medical device regulations is the introduction of a 'Qualified Person' (QP). The QP must be within the manufacturer's organisation and is responsible for regulatory compliance. The EC state that 'similar requirements exist in EU legislation on medicinal products', thus the introduction of a QP makes the regulatory compliance process more consistent across the multitude of devices and drugs on the market today. A QP as recognised by the EC is defined as follows:

**Definition of a Qualified Person under the new Proposals (EC, 2013).**

*Manufacturers shall have available within their organisation at least one qualified person who possesses expert knowledge in the field of medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:*

> ***(a) A** diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;*
>
> ***(b) Five** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.*

The current intention is for the new regulations to come into force in May 2014, although the transition period might see the new regulations not coming in to enactment until 2018-2020.

Intervention one is the first recommendation of this research that calls for the introduction of a 'qualified person' in the field of usability, ergonomics or human

factors to inform the design process. The introduction of mandated requirements for usability and a possible QP at each manufacturer, or alternatively available on a consultancy basis, will ensure that necessary user considerations are satisfied and potential for use errors are not overlooked.

### 8.3.2 Intervention Two: Endorsing Usability

The second proposed intervention calls for an endorsement for usability by recognised professionals that acknowledges devices that meet a specific standard. The previous chapter introduced the idea of an amendment to the current Medical Technologies Evaluation (MTE) Programme conducted by the National Institute for Health and Care Excellence (NICE). The MTE programme 'selects and evaluates new or innovative medical technologies' assisting the NHS to adopt 'efficient and effective medical devices and diagnostics more rapidly and consistently' (NICE, 2013). Thus, satisfying the requirements of the MTE programme can aid manufacturers in having their product or device adopted by the NHS in the UK.

The aims of the MTE programme are as follows (NICE, 2013):

- To promote faster uptake of new medical technologies in the NHS.
- To encourage collaborative research, in both industry and the NHS, to generate evidence on the clinical utility and/or healthcare system benefits of selected technologies.

At present the MTE programme does not account for usability in the assessment criteria for new technologies and innovations. Prioritisation for the referral of technology appraisals falls into the following four categories: Population, Disease Severity, Resource Impact and Claimed Therapeutic Benefit (NICE, 2010).

In contrast to intervention one where it is proposed that usability requirements are mandated, intervention two proposes to endorse usable and understandable devices for patient benefit. The inclusion of 'usability engineering professionals' on the selection and appraisal committee for new devices and innovations to be adopted into the NHS, could incentivise a more 'user centred' approach for manufacturers of home use medical devices. In addition to identifying potentially costly and harmful

use errors during development, the introduction of usability to the appraisal programme would aid entry in to the NHS market space.

### 8.3.3 Intervention Three: Patient User Review Forum

The third proposed intervention of this research offers the concept of a social media platform for patient users of home use medical devices to review and post feedback on device usability. While interventions one and two share an emphasis upon enforcing a change in current design practice, intervention three proposes to influence a change through the user's voice.

In the past decade there has been a significant rise in the use of social media by consumers and businesses. Social Media platforms are now is regarded as a ubiquitous tool in the marketing of brands and organisations and current trends have seen the technology become more sophisticated and strategic (Pick, 2013). According to Pick, 97% of all consumers search for local businesses online. Wirthman adds however that while the majority of companies use social media for marketing and sales purposes 'it can be an even more effective tool for customer service' (Wirthman, 2013). Wirthman posits that:

*'When companies are listening, they can also quickly respond to customer requests and complaints. As many companies have learned the hard way, unanswered complaints can go viral, causing real damage to a company's brand.'*

If companies are proactive in responding to their customers through social media it is believed to be beneficial for future business. The NM Incite report 2012 entitled 'State of Social Customer Service' found that 71% percent of consumers receiving a quick response from a brand on social media would likely recommend that brand to others (NM, 2012). The report also states that approximately one in three users of social media 'prefer to reach out to a brand for customer service' than through more conventional means such as over the telephone (NM, 2012). Consequently the power of social media in terms of audience and benefits for understanding the marketplace and users of products and devices is highly valuable for business.

The power of user voice for medical devices has previously been adopted through an online resource known as Which Medical Device (www.whichmedicaldevice.com).

The Which Medical Device website features specific information about medical devices developed by clinicians for clinicians. The aim of the site is to share information 'about medical devices to help make better decisions and use devices well' (Which Medical Device, 2013). This resource however is currently limited to clinicians and professional use medical devices.

Examples of other social media platforms for patients also currently exist. Patients Like Me is a website resource that allows patients to share experiences, compare treatments and track healthcare over time (Patients Like Me, 2013). Through shared experiences and data contributions, Patients Like Me, is a valuable resource for patients and others to research specific conditions and treatments. The proposed intervention of this research aims to build on this concept of sharing information between patients to deliver a valuable resource to both patients and industry.

Intervention three proposes a social media platform for patient users of home use medical devices to provide feedback and comments on experiences with devices they have used. The platform would therefore allow other patients with the same condition or receiving similar treatments to find out about other patients who have used the same or similar devices. Patients would be allowed to rank their device in terms of specific characteristics, including aesthetics and usability, thus enabling comparisons of different devices available on the market and informing decisions on which device most suits the users' needs. Sharing patient feedback through social media could then allow manufacturers to respond to patient concerns or issues whilst also identifying potential opportunities for future development.

The following section of the study now presents the methodology and describes how the interventions of this research were introduced to industry professionals from the field of home use medical devices.

## 8.4 Methodology

With the three proposals identified it was necessary to validate the recommendations of the research with individuals practicing in the field of home use medical devices. Gray defines evaluations as the 'systematic collection of data about the characteristics of a programme, product, policy or service' (Gray, 2009). The process

of evaluation itself, as described by Warr *et al*, often involves the exploration of 'what needs to be changed, the procedures that are most likely to bring about this change, and whether there is evidence that change has occurred." (Warr *et al*, 1970). While the purpose of basic research can be to discover new knowledge, evaluative studies are concerned with the application of existing knowledge to 'inform and guide practical action' (Gray, 2009).

Easterby-Smith describes four different schools of thought with respect to evaluations: Experimental, Systems, Illuminative and Goal-Free (Easterby-Smith, 1994). To which Gray adds: Decision Making, Goal-Based, Professional Review and Interventionist (Gray, 2009). A schematic of these evaluations is presented in Figure 8.1.

**Figure 8.1: Types of Evaluation (Adapted from Easterby-Smith, 1994)**

**Experimental Evaluation**

An experimental approach to evaluation aims to demonstrate that any changes observed in behaviours or outcomes are attributable to the intervention (Gray, 2009). This approach to evaluation is focused, typically, on quantitative measurement and

thus can involve control groups that are often associated with experimental research. Easterby-Smith warns against such an approach if sample sizes are not sufficiently large however (Easterby-Smith, 1994). Due to the interpretivist nature of this research an experimental approach to evaluation was considered inappropriate in this case. Such an approach would require an experimental methodology adopted throughout the research, which as described in Chapter three of this thesis is not appropriate for the epistemology and ontology of the researcher.

**Systems Evaluation**

In contrast, in a systems evaluation there is an emphasis for specifying the objectives of the evaluation including outcomes and then providing feedback on the outcomes to those providing training (Gray, 2009). Gray adds however that one of the drawbacks for such evaluations is their 'mechanistic view of the world' and that objectives tend to be selected by one particular group of individuals with a vested interest. Thus, a systems approach can fail to recognise the 'subtleties and complexities' of a system.

To evaluate the impact of the interventions for this research requires a specific range of individuals from the home use medical device field. While certain individuals in the study will have a vested interested in the proposals (e.g. Designers and Developers), other participants would experience a change in behaviour and working practices (e.g. Healthcare Professionals). Understanding the influence of the proposals from both of these perspectives is necessary to evaluate the impact of the interventions. With this in mind a systems approach is not suitable as an evaluation method for this research.

**Illuminative Evaluation**

An illuminative approach to evaluation adopts a much more flexible approach than those previously described. In contrast to a focus upon measurement, an illuminative evaluation seeks to gain the views of participants as it recognises that there are multiple perspectives that relate to any one matter under scrutiny (Gray, 2009). Rather than aiming to achieve pre-specified outcomes this form of evaluation seeks to 'promote communal awareness' about a body of research. It is the flexible nature

of an illuminative evaluation that is often associated with qualitative research including methods such as in-depth interviews and direct observations.

One of the recognised drawbacks in such an approach, as described by Gray, is that clients or sponsors of a project may want more than 'illumination' (Gray, 2009). While Gray posits that illuminative evaluations do not always lead to action, it is possible for research of this kind to address action in its proposals and recommendations. Another argument against illumination as an evaluation method is that, as with case study research, the views can be open to subjectivity based on the views of the evaluator. To compensate for this possibility, experts in the field of study can be involved in the evaluation process to provide feedback on the relevance and suitability of the recommendations.

**Interventionist Evaluation**

An interventionist approach incorporates a range of different approaches to evaluation. Gray refers to two specific types of interventionist evaluation: Responsive and Utilisation (Gray, 2009). A responsive evaluation 'concentrates on a programme's activities rather than its planned intentions' through exploring the different stakeholder perspectives involved (Gray, 2009). A utilisation approach is focused on the 'importance of identifying the motives of key decision makers' and the types of information to be collected (Gray, 2009). Thus, in a utilisation focused evaluation the evaluator must involve stakeholders before, during and after the research to understand what they need to know and the means by which the emerged knowledge and data may be put to use.

Both responsive and utilisation focused evaluations share the commitment to achieving change and impact on a specific domain and the individuals within it. One criticism of this form of evaluation is the belief that the approach may become too adaptive as evaluators become too involved with clients or stakeholders within the process to remain objective. Thus, the evaluator and researcher must remain objective throughout the research programme as to not be influenced by potential bias or leading opinions.

**Chosen Evaluation Method**

Gray describes that the philosophy underlying the 'schools of thought' described by Easterby-Smith, including ontology and epistemology, are implicit in the approaches chosen for evaluation (Gray, 2009). Thus one must consider their philosophical position and nature of the research before decided upon a suitable evaluative approach.

Chapter three of this research described the epistemology and ontology of this research. It was concluded that the philosophy of this research is most closely related to interpretivism and constructionism. That is, the natural reality including the laws of science and the social reality are intrinsically different. This philosophical perspective called for the mixed methods approach described throughout this thesis.

According to Gray, in constructivist or more naturalistic approaches evaluators might work closely with practitioners in a collaborative manner to act not only as an evaluator but also as a facilitator of change (Gray, 2009). With this in mind a constructivist approach to evaluation has been selected for the nature of this research. Illuminative and interventionist as previously described are the most appropriate methods for this research in that both approaches seek to gain the perspectives of individuals (stakeholders) within the programme (i.e. Home Use Medical Device Design).

The following section will now explore different data collection tools for evaluations that are recognised under more constructivist approaches to evaluations.

### 8.4.1 Opinionnaire

Evaluation tools or strategies as described in Chapter three include a wide range of techniques include common examples such as questionnaires and interviews. One such example of a tool for evaluation, which is recognised as a variant of a questionnaires, is known as an 'opinionnaire' (Campbell, 1997). Campbell posits that an opinionnaire differs from a questionnaire in that it elicits participant opinion about a specific context or programme. In an opinionnaire type evaluation participants are asked to indicate their level of disagreement or agreement with different statements about a programme followed by providing written comments to support their

opinion. Campbell does warn however that reliance must not be placed upon the numerical ratings collected by such an evaluation as the data of 'feelings and opinions collected remain subjective' (Campbell, 1997).

One drawback of such evaluations however, from a constructivist perspective, is the lack of direct involvement and collaboration between evaluator and participant. Distributing a questionnaire or 'opinionnaire' to stakeholders fails to address important discussions about the adoption of proposals in practice between the different stakeholders. A strategy that allows for collaboration not only between evaluator and participants but also between participant and participant is fundamental to understanding how the interventions of this research impact upon the multitude of stakeholder relationships in the field.

### 8.4.2 Group Interview

Group interviews refer to a type of interview strategy that are typically non-standardised and involve two or more people (Saunders *et al*, 2007). Saunders states that group interviews typically involve between four and eight participants, but can extend to upwards of twelve, depending on the nature of the topic under study and participants required (Saunders *et al*, 2009).

When conducting such interviews it is vital that each participant has the opportunity to state their opinion and answer the questions of the interviewer. Saunders states that where 'one or two people dominate the discussion' the interviewer should seek to reduce these contributions and invite other participants to share their thoughts (Saunders *et al*, 2009).

In order to ascertain different stakeholder perspectives on the interventions of this research a group interview strategy was identified as the most appropriate strategy for this validatory study. Given the diverse nature of participants in this study it is recommended that each participant is aware of each other's contributions and relevance to the research. Saunders *et al* state that a shared understanding of the purpose of the research and the individual's contributions will ensure that there is an accurate understanding of the discussions at hand (Saunders *et al*, 2009). With this in mind the design of the group interview must include a presentation on the

background, context and implications of the research with respect to the different stakeholders present.

Due to the nature of this study the group interview strategy will be described as a stakeholder workshop to clarify to participants the nature of their involvement in the research.

## 8.5 Design

An interview structure was devised for a stakeholder workshop to be conducted at Loughborough University's Design School. This location was selected on the basis that the environment was neutral to the participants attending. Saunders *et al* advise against selecting an environment where participants may not feel relaxed and there is a likelihood of interruption or being overheard (Saunders *et al*, 2009).

Due to the availability of intended participants, from the range of backgrounds required for this evaluation, a limit of 1 hour 30 minutes was selected for the study. It was felt that should the stakeholder workshop be any longer in duration participant recruitment would be difficult.

To ensure that all participants present understood the context and purpose of the evaluation, a summary presentation on the findings of Chapters 4, 5, 6 and 7 would be provided at the beginning of the workshop. Specific questions concerning the interventions would then be required to ensure the discussions following the presentation were focused on the purpose of the evaluation. Finally a group discussion would be necessary to ascertain whether there was a consensus between all participants and, if not, where differences in opinion lay. With these outcomes and requirements of the evaluation in mind a design for the group interview was developed and is provided below in Figure 8.2.

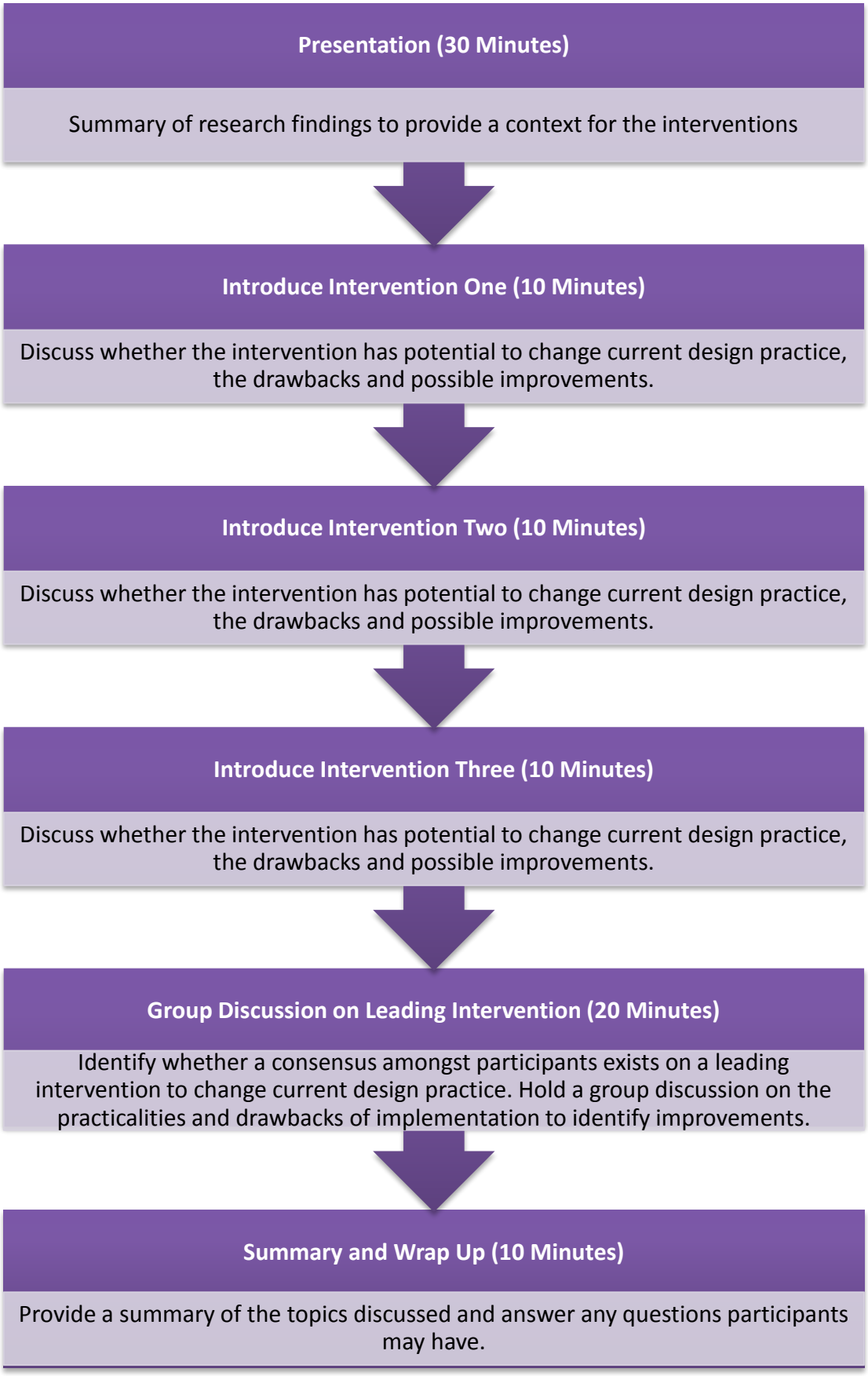



**Figure 8.2: Stakeholder Workshop Design**

## 8.6 Piloting

The stakeholder workshop was piloted twice with academics at Loughborough University to gain feedback on the content, timings and possible improvements. Minor changes to the question wording were made specifically in relation to the interventions of the study. The duration of the presentation was highlighted as a critical component to keeping the audience interested and engaged for the group discussion at the end. To ensure that the interest of participants was maintained throughout the group interview it was proposed that the number of slides in the presentation was reduced. Following the pilot the recommendations were implemented into the final design before conducting the workshop with the stakeholders of the study.

## 8.8 Recruitment

In order to evaluate the efficacy and value of the proposed interventions of the research a diverse array of individuals from the field of home use medical devices was required. The impact of each intervention extends beyond the role of the designer or developer alone. For this reason it was necessary to recruit representatives of Healthcare Professionals, Patients and Regulatory Experts to evaluate the value of the proposed interventions.

**Healthcare Professional Recruitment** – The Leicester Royal Infirmary (LRI) was contacted regarding the study in October 2013. Due to the focus of this research on home use medical device design it was considered most appropriate to contact the Diabetes Clinic at the LRI as Diabetes represents a condition that is regularly treated in the home environment by patients themselves. HCPs responsible for training and prescribing patients in the use of devices such as insulin pumps and insulin pens were recruited for the workshop. Each participant from the clinic had extensive experience in patient care including first-hand experience of use errors and design problems with existing devices. In total three HCPs from the local diabetes clinic attended the workshop.

**Patient Recruitment** – Patient recruitment for the study was very difficult as participation of patients from the NHS would require an time intensive ethical

approval by the National Research Ethics Service (NRES), as previously described in Chapter Seven. Due to time constraints this approval was not achievable at this point of study. Despite this patient representation was achieved at the stakeholder workshop. During the introductions of each participant at the workshop it was highlighted that three of the participants present were diabetic and take insulin to control their blood glucose levels. In this respect these three participants simultaneously represented experts in their domain whilst having empathy for the patient perspective based on their own experiences as users of home use medical devices.

**Regulatory Experts** – A range of medical device regulatory professionals were contacted about the stakeholder workshop. These individuals were identified through networks created throughout the period of study and through the online professional network, Linked In. Gaining participation of regulatory professionals is particularly difficult as their availability is limited. One participant from a regulatory background was present at the workshop.

**Designer and Manufacturer Recruitment** –Participants from the online survey and interview study were contacted regarding the stakeholder workshop. Due to the time constraints and requirement to complete the thesis, the date proposed for the workshop inhibited a number of designers and manufacturers attending on the day. In total two participants, representing different companies represented the designer and manufacturer perspective.

A total of six participants attended the workshop held in November 2013. The participants included: Three HCPs (including two patient representations), one industrial designer, one manufacturer (also acting as a patient representative) and one regulatory expert.

## 8.9 Analysis

All discussions at the workshop were recorded. The audio recording was later transcribed verbatim to eliminate any paraphrasing or potential for bias based on the subjective interpretation of the researcher. All of the responses to the questions for each intervention were grouped into three specific categories; Benefits, Drawbacks

and Improvements. Following the group discussion of each intervention, the responses to the leading intervention were then grouped and organised.

## 8.10 Results

Each intervention was introduced separately to participants to allow specific comments and discussions to pursue without being presented with too much information initially. The following section reports the results of the discussions for each intervention in the order that they were presented to participants. Each intervention is presented with the grouped suggestions and concerns in the results section. The discussion section of the chapter builds on these themes and describes the benefits, drawbacks and suggested improvements.

Each participant present at the workshop including the interviewer was assigned a reference code: Healthcare Professionals (HCP 1, 2 and 3), Regulatory Expert (RE), Industrial Designer (ID), Manufacturer (M). In circumstances where the participant simultaneously represented the patient perspective they were assigned *P*. The number of participants that made comments, suggestions or concerns for each intervention is provided at the end of each sentence in the following section.

**Intervention One – A Regulatory Update**

**Suggestions**

**Mandated Usability Engineering (UE) File Submission** – To enforce the requirement to consistently deliver UE principles for home use medical devices it was suggested that a UE file become a mandated requirement in the UK (ID) (RE).

*"In the EU, particularly at the moment there is no expectation that you submit a usability engineering file which is very different from the US where it is an integral part of your submission. I know from our experience with many clients they won't do usability work because they don't need to submit it in Europe and cross their fingers and just hope they are never asked for it." (RE).*

**Pre-Approval Inspections for Usability** – It was suggested that the current regulatory system in the UK should be aligned with the rigour required by the

pharmaceutical industry and Food and Drug Administration in the US (ID) (M) **P** (RE).

*"I must admit I favour something much more akin to the pharmaceutical regulatory environment. Where you do have pre-approval inspections, you have unannounced inspections by regulatory authorities like the MHRA, FDA and so on." (RE).*

**Improved Requirements for Manufacturers to Achieve Regulatory Approval** – It was identified that to coincide with a change in regulatory requirements for usability there should equally be improved information available to manufacturers on what is required and how to gain approval (ID) (RE).

*"I think one concern I would have would be if it was enforced it needs to be clearer to manufacturers what they need to do to get approval. Because all of the regulations at the moment, or sorry, all of the processes which have been returning in the user guidelines assume that you are designing a user interface or usability for a digital product." (ID).*

**Concerns**

**Applying the Regulation in Practice** – A concern about the application of the regulation in practice was raised. Two participants believed that some manufacturers would set out to meet the regulatory requirements as a 'tick box' exercise (ID)(RE):

*"I can see a drawback in that if you make it a legal requirement that is fine, but it is how you apply that legal requirement. So you could take a tick box approach and they will say yes we have done the bits that are in the legal requirements and we still have a device that is not good [in terms of usability] shall we say but you still have all the boxes ticked. Then you would have a scenario where the pieces of paper are not worth their weight." (RE).*

*"If you enforce it legally people will do whatever they have to in order to get that tick box and they will perceive it as a tick box exercise, your proposal of it just being good design it will be a case of what do we need to do to just get this through. It will just be the same as putting a label on it." (ID).*

**Repeated use of 'Professional Patients' Failing to account for Patient Diversity** – One HCP in the study suggested that increasing the requirement for user involvement will result in the same users being involved in the design process time again (HCP 3).

*"It is tremendously difficulty though isn't it because it is like a clinical drug trial. In a drug trial you will do a number of studies with X number of patients and you will decide on the criteria of those, what sort of group of patients in terms of their age, whether they have comorbidities or what stage they are with their diabetes, whether they are newly diagnosed or whatever. So my worry would be that you would enforce this regulation and then there would be like a group of professional patients almost that would come and how would they get the diversity of and again it is actually when you get it out there to the wider market that you realise well actually it is no good for this group of patients, it doesn't work well with that group of patients so even if you had that regulation how would you diversity of overview of users?" (HCP 3).*

**Increased Regulatory Pressure could 'Stifle' Innovation** – The manufacturer present felt that increasing the regulatory requirements for industry could result in companies not entering the development process (M) *P*.

*"I think now the oft quoted figure for bringing a new molecule to market in pharma is about a billion, give or take a bit, so the risk because of the increasing regulatory requirement gets bigger and bigger and that is why pharma won't invest in orphan or rare orphan diseases now because the risk is too high. So to me, to a degree that stifles innovation and I think there is a danger that as this progress' then the innovation goes out of it because the risk rewards becomes disproportionate. And I think that is perhaps a little left field from what we are talking about but that would concern me. Downstream people are looking at it and thinking actually it is too regulated it is not worth enter the development." (M) *P*.*

## Intervention Two – Certified Endorsement for Usability

### Suggestions

**The Endorsement Should Extend to Manufacturing Processes** – One participant felt that rather endorsing products alone a certification for usability should consider the manufacturers processes too (ID).

*"I wonder if NICE were to look at the Human Factors Engineering process of the manufacturer as opposed to the product itself because I wonder what would happen if you had got a top star rating for the usability of a product and then it went on to kill someone, how would they then justify that? Whereas if you have said that the manufacturer has actually gone through a diligent process here and they have submitted evidence and we think that they have done everything that they possibly can then that might be a safer way of doing it. That might carry more weight as well when you are looking at buying devices because it is less subjective." (ID).*

**Opinion Leaders to Advocate Usability** – One participant suggested that in order endorse usability principles and user involvement requires an advocacy of the principles by opinion leaders in the field that can influence policy makers:

*"I think it is one of those where you almost have to build advocacy. You have to get people who are respected opinion leaders, the same as you do in Pharma, who actually say that the usability factor is important in that and you almost need to lobby and push upwards" (M) *P*.*

### Concerns

**Budgetary Constraints for Healthcare Professionals** – 50% of participants at the workshop perceived that devices endorsed for usability would be more expensive and as a result HCPs would not prescribe them. Participants opined that the cheaper device would be selected as HCPs are concerned with budgets (ID) (M) (RE).

*"I guess the question is will the prescribing GP then prescribe a slightly more expensive inhaler being conscious of their budget." (RE).*

*"I think when I heard this article, the guy that was speaking said that 60% of all aerosol inhalers are not used properly and it is probably about 20% effective. So if*

*you then think that particular drug is not effective 80% of the time the cost for the actual healthcare, realistically if you can offset the cost of a better-designed product that people can use against the efficacy and the adherence of use then it would be there." (ID).*

*"Yes it is a very difficult argument for the NHS, well to get through the NHS because I have seen it in different guises previously and if you say well it is going to cost you 5-10% more, people are going to be using it 30-40% more often they won't take it because doesn't come off their budget. They cannot see it on the budget line and they are very short sighted. It is almost like you need a cultural change within the NHS, because the most expensive drug is the one that stays in the drawer. We have banded that around for years. But the NHS still go with well it is only £5 a month and the one you want to sell me is £10." (M) *P*.*

**Inconsistent Approvals between the MHRA and NICE could cause tension** – Three participants opined concerns about device receiving regulatory approval by the MHRA but not being endorsed by the proposed NICE amendment. The requirement for two different processes of approval could therefore result in tensions between manufacturers (ID) (M) *P* (RE).

*"If you have a situation where you have a device that is approved by the MHRA but NICE say no and understandably get quite confused and irate. You have a manufacturer that says well we have got approval for this device but NICE don't approve it for the NHS." (RE).*

*"It is an interesting point. In pharma speak, the equivalent of this I think is a TAG, which is Technology Appraisal Guidance from NICE and theoretically once that has been approved by NICE, CCG's or commissioners have 90 days to implement it and they don't. They absolutely don't because they will say, and I am working with a product at the moment where the list price is £26,000 a year and that has just got a TAG from NICE back in July and it is commissioned, it is specialised commissioned so it is the NHS England who have commissioned it but they still won't get it used even though NICE have said, and it is a legal requirement that within 90 days you have got to have this product available to patients and again they don't do it. So I think the fact that NICE have gone from rubber stamp, they will still say I have got a finite budget. My budget in this area is X million pounds per year, this is going to*

*cost me X + Y and that means that something else has got to go to balance the books and I think that is a fundamental issue on stuff like this because theoretically it should make all the difference but I have seen it twice in the last two years were NICE have put a TAG through and people have gone we can't afford it, what are you going to do." (M) *P**.

*"I have seen a similar thing as well where a product, which I have worked on has not been NICE approved and the predecessor has. So everyone is supposed to be using where possible but when you speak to users and you are carrying out research for the next product they don't like using it because it is more difficult to use than the competitor one which hasn't been NICE approved but they have to use this one because they have got it and they have been told too. So if it is going to be an endorsement then for that product usability has to be a big selling point for it. It has to actually follow through it cannot just be a case of well some people think it is better. It cannot be just clinically more advantageous to use it; it has to be all round more beneficial to people. Otherwise I think it just gets tarnished with a rubber stamp when it doesn't necessarily mean it is in the best interests for everyone." (ID).*

**Intervention Three – Patient User Device Forum**

**Suggestions**

**Collaboration with a Professional Body** – It was suggested that the review forum for patient users should be attached to a professional body to make the content more powerful impactful and to give the forum status (HCP 3).

*"I just wondered if you could have the review forum as part of the charitable organisation. So patients that were registered with the organisation were invited, because obviously we have got a huge amount of devices within diabetes, we have also got it in respiratory disease and what have you. If you use the professional bodies and you have an arm of that I think it would be a really good way to access these individuals but also people are less likely to just put rubbish on there. And you could actually get the charitable organisation itself to have a sort of bio of every device, so if we talk about insulin pen devices, GOP devices and can describe the device and people were invited to comment on the usability in a form of template." (HCP 3).*

*"It makes it more impactful I think. People are also more likely to already be registered. I think with Diabetes UK there are already thousands, I don't know, but there are a lot of members with the charity. There are also healthcare professionals as well. So there could be a section for them that might include reasons why they don't use a particular device anymore because I find it is difficult to teach, there are too many steps. I found this difficult. I don't know the right dose." (HCP 3).*

**Concerns**

**Limited Diversity of Users Posting Content and Feedback** – Some participants in the workshop opined that such a resource would not access the diversity of home use medical device users. It was believed that while some device users would share content online there would be a cohort of patients experiencing difficulties or using devices incorrectly that do not want to share information (ID) (HCP 3).

*"The problem you get with it is that it is only the interested users that will actually post content. People who are really frustrated or have got poor compliance and poor management of diabetes are not going to put a video up of it. They are going to be the ones where the device is still sat in their bag and they are out doing whatever they want to do. You only get one side of the story; you don't get the whole thing. I think it goes a long way but it is not a complete solution." (ID).*

**Quality and Relevance of the Content** – One HCP opined that the content posted by patients would have to be controlled to restrict abusive or derogatory messages being shared (HCP 3).

*"I mean there is lots of rubbish on the internet isn't there. A lot of derogatory and abuse, all sorts. I am just wondering how you would try and formalise it into something that was structured, perhaps people would have to be registered in some way to post content so that it wasn't just anonymous rubbish going on there." (HCP 3).*

**Leading Intervention – Group Discussion**

All participants were asked two questions to identify the leading intervention of the research. Participants were initially asked which intervention would change current design practice for home use medical devices with respect to usability. The results to this question are presented in Table 8.1:

**Table 8.1: Leading Intervention (Short Term).**

| Participant | Intervention One: Regulatory Update | Intervention Two: Endorsement for Usability | Intervention Three: Patient User Review Forum |
|---|---|---|---|
| Healthcare Professional 1 *P* | **Yes** | **No** | **No** |
| Healthcare Professional 2 | **Yes** | **No** | **No** |
| Healthcare Professional 3 | **Yes** | **No** | **No** |
| Industrial Designer | **Yes** | **No** | **No** |
| Manufacturer *P* | **Yes** | **No** | **No** |
| Regulatory Expert | **Yes** | **No** | **No** |

Participants were then asked which intervention in their opinion had the most potential to change design practice in the future. The results to this question are presented in Table 8.2 below:

**Table 8.2: Leading Intervention (Long Term).**

| Participant | Intervention One: Regulatory Update | Intervention Two: Endorsement for Usability | Intervention Three: Patient User Review Forum |
|---|---|---|---|
| Healthcare Professional 1 *P* | **No** | **No** | **Yes** |
| Healthcare Professional 2 | **No** | **No** | **Yes** |
| Healthcare Professional 3 | **No** | **No** | **Yes** |
| Industrial Designer | **No** | **No** | **Yes** |
| Manufacturer *P* | **No** | **No** | **Yes** |
| Regulatory Expert | **No** | **No** | **Yes** |

A consensus amongst the stakeholders present was reached. The workshop indicated that the most impactful intervention, in the short term, to change current design practice with respect to usability for home use medical devices would be a change in the current regulatory requirements in the United Kingdom (Intervention One).

However, as a longer term strategy the intervention with the most potential to change design practice with respect to usability considerations for the future, the workshop revealed Intervention Three: A Patient User Review Forum by consensus to be the most valuable approach.

The following section of the chapter provides the discussion of these results, including the implications of these results for the wider research arena and the practicalities of implementing the interventions of this research.

## 8.11 Discussion

A group consensus identified that Intervention One, a regulatory update for usability, would change current design practice for home use medical devices. A mandated requirement to satisfy usability-engineering principles in the United Kingdom was revealed as the leading short-term intervention to change the way in which home use medical devices are designed for the needs of their end users. However, the workshop also revealed that a long-term strategy in the form of Intervention Three, a

patient user review forum, represented the most potential for changing design practice in the future.

Concerns for Intervention One included the application of the regulation in practice, which some believed, may 'stifle' innovation in the sector. Due to a perceived risk of failing to meet the regulatory requirement, one manufacturer at the workshop opined that companies may choose not to enter the market. In response to this concern participants were asked if a call for tighter regulation, in line with the current proposals for the Medical Device Directive, would raise the standard of usability significantly enough to warrant increased scrutiny and requirements (EC, 2013). On this topic one participant said:

*"I personally think that it is better. If there is an expectation that you are not going to get a device through without doing some form of usability, essentially following the American model of ramping it up over time. I think having the requirements embodied in the legislation and the guidance documents and talking with people in the human factors group in CDRH they have started to help people really understand what they need and keeping things back when they are not there." (RE).*

It was suggested that the regulations for usability and human factors should be more closely aligned with the Food and Drug Administrations (FDA) model in the US. If such changes were imposed it would mean that regulations globally were more aligned improving the distribution between markets, which is one of the recognised limitations under the current medical device regulations in Europe (EC, 2013).

Others perceived that changing the regulations on usability and user involvement specifically would result in a group of 'professional patients' being recruited for projects based on interested parties and self-selection. One solution to this issue could be to mandate the definition of the target population for a device at the beginning of the design process. The regulatory expert present at the workshop suggested that by defining the user population at the beginning of the process the regulatory approval could then only be applicable to that population of users.

*"Say your users are pre-teens/teens with diabetes then your marketing authorisation should not be for everyone else in the diabetes community." (RE).*

It was suggested that should this intervention be imposed then there is a requirement for clearer information for manufacturers on how to satisfy the requirements for usability. Stakeholders in the workshop perceived the current guidance for usability to be targeted specifically at user interface design or graphical user interfaces (GUI's). One participant opined that while such guidance is useful for some home use medical devices, there are many instances where medical devices, both professional and home use, do not include an interface. Thus, it is difficult for manufacturers to interpret the information within usability guidance documents and apply it in different scenarios for the multitude of medical devices on the market.

*"So it could be a diagnostic or heart-beat meter that in itself doesn't translate very well to things like a breast implant which is still a medical device but you haven't got a screen on it so how do you ensure that is safe to use and that people have got a usability engineering process which applies to a completely different type of device." (ID).*

Chapter Seven of this thesis identified scepticism from some practicing designers towards the practical value of current design guidance, which in turn resulted in poor compliance with such documents. The workshop supports this and highlighted a lack of device specific guidance documents, with two participants describing a focus for usability requirements upon GUI's and computer interaction. With the range of medical devices on the market today, approximately 500,000 globally, it is unrealistic to expect design guidance to be available for every type of medical device. However, there is a need for clearer information on the processes and strategies for adopting usability engineering principles for home use medical devices. As this field represents a rapidly growing market globally, the UK must develop valuable, supportive guidance and regulations for home use medical device development.

Some participants opined that the interventions of the study do not have to be applied exclusively. It was suggested that the interventions could be combined to enforce the requirements upon manufacturers and users of home use medical devices to raise the standard of usability in design. The group proposed that intervention one and three should be applied simultaneously to have more emphasis and impact upon usability in the medical device industry as a whole. Adopting the two interventions

simultaneously would invoke the short and long term changes to the industry as previously described.

While this study does not address the explicit changes to the regulations in the United Kingdom with respect to home use medical device design it calls for an increased recognition for mandated requirements for usability. The current system for adopting the principles within harmonised standards (e.g. IEC BS EN 62366:2007) is not a sufficient incentive to manufacturers to adopt a usability engineering process. The challenges identified in Chapter Seven of this thesis are too restrictive upon companies to adopt the principles advocated by an idealised practice. This study suggests that the alignment of regulatory requirements alongside the FDA in the US would be beneficial for home use medical devices designed in the United Kingdom.

Aside from a regulatory change to home use medical device usability, the stakeholder workshop indicated the perceived value of an increased recognition for the user voice in medical device development. The workshop revealed that changing perceptions and advocacy of usability in the future would benefit from patient reviews, feedback and experiences of home use medical devices.

One participant at the workshop indicated that patient collaboration with a professional body would add to the quality and relevance of the information shared by users. The example given by this participant referred to Diabetes UK, a leading charity organisation that 'cares, connects with and campaigns on behalf of every person affected by or at risk of diabetes' (Diabetes UK, 2013). One benefit of such an organisation for the design of home use medical devices is the established network of device users registered with the organisation.

Registered members of charity organisations are not just limited to patients themselves. By implementing a patient review forum for device users to provide feedback on the design and usability of home use medical devices through a recognised charity organisation would allow for users, healthcare professionals and manufacturers to all connect with one another.

One of the challenges to involving users identified in Chapter seven of this thesis referred to the ability of industry to locate and access patients directly. An advantage

of developing a patient user review forum for device users would provide a network of potential patients for industry to contact for the purpose of user research. This was however also identified as a concern to participants at the workshop. While there may be a recognised increase in the recognition and adoption of patient involvement in the design process, the stakeholders opined that there might be an issue with repeated or 'professional' users. Consequently, companies might use the same device users for the purpose of user research to overcome the difficulties of accessing suitable and representative users. As a result the quality of user research conducted by industry could be compromised due to a lack of diversity amongst device users.

This issue however could be addressed through the medical device regulations as previously described. In light of the proposal to align the requirements in the UK with that of the FDA in the US, the marketing authorisation and testing with device users could then dictate who the intended user population is for a particular device. Thus, a company would not be able to repeatedly use the same device users for the purpose of user research for devices of a different intended purpose, user population or environment.

In order to implement the combined strategy (i.e. Intervention One and Three) proposed by this study, future research must address the commercial implications of enactment. For the purpose of this study it was not possible to explore the costs involved in changing the regulatory requirements for home use medical devices. Chapter nine of this research will explore this issue in more detail as it presents the overview and synthesis of this research. The chapter discusses the meaning behind the findings of this research from a regional, national and international perspective.

## 8.12 Ethical Considerations

Each participant was made aware of the nature of the workshop and context of the research on first contact for recruitment purposes. Prior to the beginning of the stakeholder workshop each participant was provided with a participant information sheet to read (see Appendix 12). On reading the information sheets participants were then provided with an informed consent form to complete before participation in the study (see Appendix 13). All participants were made aware of their rights to withdraw from the study at any time.

## 8.13 Risk Assessments

Due to the nature of the workshop being held in a neutral environment (Loughborough Design School) the participants were made aware on the participant information sheet that they would only be exposed to the minimum associated risks of working in an office environment. On the day of the workshop all participants were informed of the evacuation procedures in light of an emergency. The fire exits and assembly points were indicated to participants from the outset of their arrival.

## 8.14 Limitations

The stakeholder workshop was held with different representatives of the home use medical device field. While every effort to recruit as many stakeholders as possible was made, the availability of the required individuals for the purpose of the study resulted in six participants attending on the day. Due to the time constraints upon the researcher it was not possible to postpone the event further to access more participants. While patient representation at the workshop was achieved more patient representation, including vulnerable patients, would have been desired. The views of these individuals could have been valuable with respect to intervention three and social media resources.

Having HCPs present at the workshop was very important to the discussions with practicing designers and manufacturers. All HCPs were recruited through the local diabetes clinic in Leicester. As previously described Diabetes represents a domain of healthcare that requires frequent treatment and management by patients in the home environment. With this in mind the HCPs present were indicative of the stakeholders required by the study. Despite this, it is important to recognise that these participants all represent the same field and therefore participation of HCPs from other fields would be useful for this workshop study.

Another recognised limitation of the workshop study is the use of self-selection sampling whereby individuals express their desire to take part in the research. For the purpose of this study it was necessary to recruit individuals from the field of home use medical devices that both considered the design of such devices to be important and were willing to devote their own time to take part in the workshop (Saunders *et*

*al*, 2009). For these reasons the use of self-selection was considered appropriate. Despite this, the research recognises that those individuals who are willing to take part do not necessarily represent the entire population of practitioners in the field.

## 8.15 Conclusions

A stakeholder workshop was designed and conducted with industry professionals from across the field of home use medical devices. A total of six participants attended the stakeholder workshop in November 2013. Participants included: Three Healthcare Professionals, a Regulatory Expert, an Industrial Designer and a Manufacturer. The three interventions of this research thesis were presented to practicing stakeholders to gain practical feedback on the value of the proposals for industry and patient users of home use medical devices. The interventions included: A Regulatory Update for Home Use Medical Devices (e.g. Mandated Requirements for Usability), An Endorsement for Usability (e.g. Certification of Usable Devices) and a Patient User Review Forum (e.g. User Voice).

There was a consensus agreement amongst participants that the most effective intervention to change current design practice for home use medical devices would be a change to the regulatory requirements. This research suggests that in order to change current design perspectives and practice towards usability of home use medical devices requires mandated requirements for designers and developers.

This workshop also indicated that intervention three, a social media platform for patient users of home use medical devices, has potential to change design perspectives practice in the future. All participants were in agreement that a dual strategy, implementing a regulatory update (Intervention one) and a patient user review forum (Intervention three) would be the most effective strategy, based on the findings of this research, to change current perspectives and the manner in which home use medical devices are currently designed.

The recommendation from this work is to conduct further study into the practicalities of updating the regulations with respect to usability in the United Kingdom. This work suggests an alignment with current regulatory requirements in the United States by the Food and Drug Administration would raise the standard of usability in home use medical devices in the United Kingdom.

The following chapter will now present the overview and synthesis of the findings in this thesis. The chapter will explore and discuss the implications of this research on a broader context and the meaning behind the results presented throughout this research.

# Chapter 9
# Overview and Synthesis

## 9.1 Introduction

The purpose of this research has been to ascertain current design perspectives on the involvement of users in the design process of home use medical devices in order to understand the incentives for adopting user centred practices. Chapters 4, 5, 6, 7 and 8 have all provided information and knowledge that was essential to answering the research questions of this thesis.

The previous chapter concluded that a dual strategy, including a change in current medical device regulation and an increased advocacy of the users' voice, could change current design perspectives and practice towards home use medical device design. In light of this knowledge, the following chapter presents an overview and synthesis of this research exploring some of the practical implications and barriers on a regional, national and international level.

The chapter includes a discussion on the barriers towards introducing the proposed interventions of this research in practice and includes possible areas for future research to be conducted by others in this field.

## 9.2 Regional Considerations

The scope of this research has addressed current design perspectives and practice of home use medical device companies based within the United Kingdom. The implications of this research including the recommendations outlined in the previous chapter however inevitably experience differences and difficulties on a regional and local level will.

**Clinical Commissioning Groups (CCGs)**

Prior to the establishment of Clinical Commissioning Groups (CCGs), Primary Care Trusts (PCTs) used to commission most NHS services and controlled 80% of the

NHS budget (NHS, 2013a). On April 1st 2013, PCTs were abolished and replaced by CCGs.

CCGs now commission most of the hospital and community NHS services in the areas for which they are responsible (NHS, 2013b). NHS England oversees all CCGs and is responsible for commissioning primary care services such as GP and dental services as well as some specialist hospital services (NHS, 2013b).

It is understood that home use medical devices are currently accessed, purchased or loaned by their users in many different ways (National Research Council, 2011). In light of this, it is conceivable that the provision and accessibility of specific home use medical devices may not be consistent to all device users based on their geographical location and demographics for example.

In the stakeholder workshop of this research, one manufacturer opined that while there might be demonstrable evidence of improvements in device usability, the cost to the individuals responsible for procurement would dictate whether that device finds its way to the patient. Chapter eight suggested that while a device might be easier to understand or use, if the cost is too high then procurement teams will not be interested because the benefit it not seen within their own budgets. Thus, the workshop indicated that in order to change current design practice would require a change in the current regulations towards usability in the United Kingdom (UK) to overcome the commerciality of the sector. This would mean that designers and developers had a duty by law to fulfil usability requirements as opposed to having a moral obligation to do so, which is the current situation in the UK.

It is believed that such a change could make the design and delivery of home use medical devices more consistent, safe and usable for their users across the UK. One must consider however that if devices of improved usability are more expensive to develop and subsequently to purchase, then selection and adoption by CCGs and users themselves may be inhibited. This applies not only to CCGs and individuals responsible for procurement decisions but also to device users themselves who purchase ‘consumer medical devices’. If devices are made too expensive for their users then the benefits of improving usability will not be experienced by the end users themselves. Consequently, patient users of home use medical devices may look

for cheaper alternative devices that could compromise patient safety within the home environment.

It is hoped that the current restructuring of CCGs will bring ‘greater consistency and fairness in access and provision for patients’ (NHS England, 2013). Thus, the differences in provision of devices to patients are intended to be more consistent on a regional and local level than they were previously. However, if CCGs are to adopt devices that are more expensive to develop, then there is a requirement for the procurement process to be reviewed specifically.

Currently CCGs identify and select preferred devices (e.g. Blood Glucose Meters) based on specific criteria for a region. At present there is no standardised approach towards the procurement of devices for patients. As a result each CCG will select different preferred devices based on the needs of the region for which they are responsible. This will include the characteristics and demographics of the population within a specific region, including cultural and generational differences. Preferred devices are then prescribed to patients within that region based on the selection and decisions made by the CCG.

With this in mind there is a need for increased evidence, support and advocacy of usability within the CCG procurement process in order to ensure that patients are prescribed with devices designed for their needs. In order for usability to be featured within the procurement process, manufacturers must clearly be able to demonstrate the associated patient benefits of a usable device over its competition. This raises two very important issues for the adoption of this research, which refer to validity and accessibility.

The validity of usability evidence within both design and procurement processes of home use medical devices would be fundamental to changing industry wide perspectives and practice. As was identified in Chapter seven of this research, the industry’s knowledge of usability was revealed to be one of the challenges towards involving users in the design process of a home use medical device. This suggests that accessibility, including the use of terms such as ‘usability’ and ‘user centred design’ will present challenges on a local level where there is less support and understanding of such work. In light of this there is a need to develop a means of

dissemination at the regional and local level to both educate and support those individuals within the stakeholder network presented in Chapter five.

One recognised organisation that operates on a national and regional level to support the design and development of high quality research proposals is the Research Design Service (RDS), which will now be discussed.

**The National Institute for Health Research (NIHR) Research Design Service (RDS)**

Chapters four and seven of this research revealed that there is a lack of consistency in the use and understanding of specific terms relating to usability amongst the design community. With this in mind, mandated requirements for usability within the current medical device regulations will expose similar difficulties to individuals on a regional level outside of design disciplines too. For example, phrases such as usability, accessibility and user research are open to very different interpretations between designers, healthcare professionals and patients. Consequently, phraseology will affect the implementation of the interventions for this research. It would be necessary to support this transition at the local level through CCGs and services such as the Research Design Service (RDS).

The Research Design Service in the East Midlands provides free advice on research design to researchers who are developing proposals for open, national, peer-reviewed funding competitions for applied health or social care research.

The stakeholder workshop presented in Chapter eight of this research indicated that usability and human factors issues for both professional and home use medical devices could benefit from clearer guidance, information and requirements for manufacturers. This is supported by previous research that has attempted to address these gaps (Cifter, 2001; Gupta, 2007).

The RDS support researchers in involving patients and carers throughout all stages of the research process and could therefore support information dissemination amongst local organisations to assist them with user engagement in research. Similarly, on a local level the services of Healthwatch England could be a valuable resource in the transition towards usability considerations for home use medical devices on a local level.

**Healthwatch England**

Healthwatch England is an independent consumer champion that gathers and represents the public's views on health and social care services (Healthwatch, 2013). Healthwatch operates on both national and local levels to ensure that the views of the service users including the public are taken into account. Chapter eight of this research suggested that the role of the user's voice in the design and development of home use medical devices could be valuable as a long-term strategy towards changing industry wide perspective and practice towards usability.

In order to implement the proposals of intervention three of this research it would be necessary to establish a network of patient users of home use medical devices to provide feedback and share experiences with manufacturers and users of such devices. Under the current remit of Healthwatch England, this process of feedback dissemination could be supported by their engagement with patients and the public. It is reported that Healthwatch England possess 'significant statutory powers' to ensure that the voice of consumers are 'strengthened and heard' by commissioners and regulators of healthcare services (Healthwatch, 2013). Consequently there is potential for an affiliation of a patient user feedback forum for home use medical devices with Healthwatch England that could increase the emphasis and advocacy of usability considerations for manufacturers.

Medilink also possess significant potential for information dissemination and support opportunities for companies on a regional level if the interventions of this research were to be invoked.

**Medilink Regional Organisations**

Chapter Six of this research suggested that education on the principles and practice of user research in home use medical device design was not considered a challenge to designers in the study. Despite this finding, it is conceivable that smaller or less experienced companies would require support in adoption of usability engineering. As previously described, Medilink UK is comprised of eight different regional organisations that support designers and manufacturers in the delivery of viable technologies for the healthcare sector from concept to commercialisation. Medilink UK host a wide range of event across the UK to support companies in the

commercialisation of medical devices and therefore present a significant opportunity to support advocacy and a change in current medical device regulation. To overcome the challenges of accessing and supporting small start-up companies with little experience in designing and developing home use medical devices, Medilink UK could be endorsed to advocate, train and support companies on the role and principles of usability. While usability professionals would be necessary to provide the relevant training, nationwide Medilink events could present the ideal opportunity to market and hold such events for an established network of industry members.

**Key Regional Issues**

- Accessibility of terms such as; Usability, User Centred Design and Human Factors to unfamiliar audiences will require support in the transition towards implementing the proposals of this research.
- Information dissemination on usability considerations will require the support of regional organisations to assist in the implementation of a new regulation for home use medical devices on a local level.
- Improved evidence and explicit requirements for manufacturers will be necessary to support industry in the adoption of proposed mandated requirements for usability.

## 9.3 National Considerations

The previous section discussed the issues relating to the accessibility of implementing a change in practice towards usability on a local level. The following section now explores the implementation of the interventions for this research on a national level including the organisations affected by a change in regulation towards home use medical devices.

**Care Quality Commission (CQC)**

The CQC are responsible for making sure ‘hospitals, care homes, dental and GP surgeries, and all other care services in England provide people with safe, effective, compassionate and high-quality care’. The CQC then encourage improvements in care, including the services within patient’s homes to ensure they meet national standards (CQC, 2013). The CQC achieve this through ‘inspecting services and

publishing the results' to inform service users and help them make better decisions about their care (CQC, 2013).

Intervention Three of this research calls for the development of a patient user review forum to inform patients about the devices they use and to assist manufacturers in understanding the requirements and needs of their end users. In this respect intervention three of this research shares similarities with that of the CQC in attempting to offer improved care for patients through the sharing of information online.

It is believed that by making information relating to usability and design accessible for patient users in the home environment, it will improve the quality of devices delivered to those patients. The CQC could facilitate the collection and dissemination of public views towards home use medical devices as part of their remit towards building better relationships with the public and regulators. Part of the CQCs proposals for the next three years is a focus upon improving the relationships and awareness of their work on a public level. In their document entitled, *Raising Standards, Putting People First – Our Strategy for 2013 to 2016*, the CQC state that they intend to 'promote greater public understanding and awareness' of their work through improving public information, how they listen and act upon views and experiences of care (CQC, 2013b). Engaging with patient users and regulators of home use medical devices will increase public awareness of usability issues in design. Thus interventions one and three complement one another in a dual strategy approach towards changing current design practice for home use medical devices.

Ultimately, however, if there is to be a change in the regulation of home use medical devices in the UK then the Medicines and Healthcare Regulatory Agency (MHRA) are crucial to implementation.

**The Medicines and Healthcare Regulatory Agency (MHRA)**

The MHRA is the recognised Competent Authority (CA) from the UK. The remit of the MHRA therefore is to ensure that all medicines and medical devices in the UK work are 'acceptably safe' (MHRA, 2013). Under the current legislation in the UK, the MHRA govern the legislative obligations on 'manufacturers to ensure that their devices are safe and fit for their intended purpose before they are CE marked and

placed on the market in any EU member state' (MHRA, 2013). Thus, if the proposals of this research were to be imposed the MHRA would need to be trained, supported and efficient in the governance of the new mandated requirements for usability. This would include the 'enforcement and surveillance' of devices placed on the market and the development of guidance to assist manufacturers in criteria necessary to meet the requirements of the new regulation.

The designers in Chapters seven and eight of this research opined that current guidance towards designing home use medical devices lacked practical value for industry. This research has indicated that some designers were unclear about the necessary requirements for usability in the design of home use medical devices. Furthermore, some designers opined that the current design guidance for usability is predominately focused on interface design. In light of this, the findings of this research calls for clearer, mandated requirements that manufacturers, designers and developers alike have to consider in the design process of a home use medical device. It is believed that explicit requirements will improve the quality of home use medical devices by making the considerations for usability more consistent.

**Monitor**

Monitor is recognised as the sector regulator for health services in England. The role of Monitor is to 'protect and promote the interests of patients by ensuring that the whole sector works for their benefit' (NHS, 2013d). On a national scale, Monitor therefore has huge potential to highlight, monitor and disseminate information about the role of usability for medical device design. Chapter eight of this research indicated that in order for usability to be enforced within the UK then there would need to be an increased advocacy from a professional organisation. Consequently, the importance of usability in the design of home use medical devices could be driven upwards by influential practitioners in the field to overcome the current lack of incentives to adopt such an approach.

**National Institute of Health and Care Excellence (NICE)**

Intervention two of this research described the role of the Medical Technologies Evaluation (MTE) programme performed by the National Institute of Health and Care Excellence. Under the current remit of the MTE programme there is no

recognition for usability considerations in the selection and evaluation of devices for adoption in the NHS and endorsed by NICE.

In order for usability to be incorporated in the MTE programme it would require some significant changes to the assessment process itself and the committee that select, evaluate and approve devices for adoption in the NHS.

Presently the MTE programme is focused upon two primary considerations in their decision-making (NICE, 2011). These include:

I. **Benefit to Patients:** whether the medical technology has measurable benefit to patients over currently available NHS technologies, measured by relevant outcome indicators.
II. **Benefit to the NHS:** whether the impact of the medical technology is likely to reduce the burden on NHS staff or reduce resource use (for example staff or facilities) compared with current management.

It is reported that in order to safely design for the diversity of home use medical device users it requires the diligent application of usability principles and the involvement of users through the design process (ANSI/AAMI HE75: 2009; IEC BS EN 62366:2007). This is supported by extensive research and literature that has previously addressed the application of usability towards medical devices more generally (Martin *et al*, 2008; MATCH, 2003; Martin & Barnett, 2012; Money *et al*, 2011; Rose *et al*, 2007; Sawyer, 1996; Vincent & Blandford, 2011; Zhang *et al*, 2003). In light of this, this research suggests that usability has a role to play within the MTE programme by NICE in that the principles of such an approach offer significant benefits to patients.

The assessment of usability within the MTE programme however would require new expertise (i.e. usability professionals) on the programme committee. These professionals could then make recommendations based on the usability testing and evidence submitted by manufacturers to determine whether a device is worthy for adoption and approval. At present the selection committee for the MTE programme consists of approximately 25 individuals with different expertise (NICE, 2011a). This includes clinicians who use and are involved in the development of medical technologies, regulators, scientists and others experience in the medical technology

sector (NICE, 2011a). Given the diversity of the MTE programme committee it is conceivable that usability professionals could be incorporated into the panel with little extra costs to provide the service. Indeed, the guidance already outlines that such professionals can be drafted into the process.

As previously discussed one of the recognised benefits of the MTE programme is the ease of entry and adoption of medical technologies into the NHS in the UK. Thus, the introduction of usability into the MTE programme could facilitate a change in the procurement decisions made by the NHS increasing the recognition of the value of usability considerations in design to the healthcare sector. It is believed that should manufacturers have an increased likelihood market adoption within the NHS by adopting the principles of usability engineering then the devices will be improved for patient users in the home environment. Devices that are more usable and understandable for patients are much more likely be used by patients, consequently reducing the likelihood of device abandonment (Batavia & Hammer, 1990).

Despite this, Chapter eight of this research suggested that a change to the current MTE programme would not be sufficient in changing design practice for home use medical devices. The stakeholder workshop of this research indicated that intervention two of this research might change the way in which some companies operate but it would not be sufficient in changing industry wide practice. Thus, it was concluded that in order to change design practice of home use medical devices would require a change in the regulation of such devices.

Changing the regulations of home use medical devices in the UK would have significant consequences on industry as a whole. As previously described, presently there is a major overhaul of the medical device regulations in the UK. Within the EC document, *Proposal for a Regulation of the European Parliament and of the Council on Medical Devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/*2009, changes to the legal elements are outlined (EC, 2013).

In light of this, a change in the regulation of home use medical devices would present similar implications for industry. Changes for industry would include CE marking (i.e. Free Movement of Devices within the EU), Device Classifications and Conformity Assessments, Clinical Evaluations and Investigations, Vigilance and

Market Surveillance, Governance and Budgetary considerations. Arguably the most significant of these elements on the potential to implement a change towards mandated requirements for usability are the budgetary implications for industry. Section 9.5 of this chapter addresses the barriers to implementing the proposals of this research.

**Notified Bodies (NBs)**

According to the European Commission (EC), proper functioning of Notified Bodies is crucial in ensuring a 'high level of health and safety protection' and confidence amongst citizens after recently recognised severe criticism (EC, 2013). Under the new regulations proposed for the UK it is outlined that national authorities responsible for NBs will have specific, 'stricter and detailed criteria' that are subject to 'joint assessments' with the commission (EC, 2013). In light of this, NBs will become increasingly scrutinised in their assessments of manufacturers at Union Level. The role of the NB therefore could be a valuable asset in the implementation of this research. If NBs were qualified in the assessment of the usability engineering process by incorporating usability professionals onto their panel of assessors then this would provide opportunity for a new regulation to be established and managed on a national level.

**Key National Issues**

- National dissemination of information and requirements for a new regulation for usability would require the support of organisations such as NICE, MHRA and the CQC to be effectively implemented.
- Notified Bodies or an alternative national body would have to be qualified in assessing new mandated requirements for usability in the design of home use medical devices.
- Nationwide advocacy of usability could be endorsed and promoted by Monitor or the CQC in the UK.

## 9.4 International Considerations

Further afield there are implications from the recommendations of this research internationally. While the recommendations of this research propose a similar alignment of global requirements for usability and human factors with the requirements of the Food and Drug Administration (FDA) in the United States (US) there are practical constraints upon adopting this in practice. This section explores the international implications of this research in relation to the European Commission and the FDA.

**Centre for Devices and Radiological Health (CDRH) and the Food and Drug Administration (FDA)**

The Centre for Devices and Radiological Health (CDRH) is 'responsible for protecting and promoting the public health' in the US by ensuring 'patients and providers have timely and continued access to safe, effective and high-quality medical devices and safe radiation-emitting products' (FDA, 2013a).

The CDRH are responsible for providing 'understandable and accessible science-based information' for consumers, patients, carers and providers in relation to the products they oversee. The CDRH believe that making device related information accessible to consumers and patients assures confidence to the US market in they regulate (FDA, 2013a).

It was not within the scope of this research to explore the regulatory system in the US as this research has been focused upon the design of home use medical devices in the UK. However, the findings of this research suggest that the design and regulation of medical devices in the UK could benefit significantly from the US market. Some of the designers in this research opined that the US market for home use medical devices is more advanced than that of the UK. This is arguably supported by the development of the FDA's Home Use Initiative and the recent publication *Draft Guidance for Industry and Food and Drug Administration Staff – Design Considerations for Devices Intended for Home Use* (FDA, 2012). Currently, in the UK there have been no such recognised publications by the regulator the MHRA. As part of further research to be conducted by others it would be interesting to explore the differences in the way that the MHRA and FDA regulate the design and development of home use medical devices. A comparison with an exemplar device

designed under MHRA regulation against an FDA regulated device might reveal opportunities for the strengths of both regulators practices to be harmonised.

**European Commission (EC)**

The European Commission (EC) is the organisation responsible for the governance of the European Union (EU). According to the EC website, the EC represents the interests of the EU as whole (EC, 2013). The role of the EC is to propose 'new legislation to the European Parliament and the council of the European Union' to ensure that EU law is correctly applied by its member countries' or states (EC, 2013).

With this in mind, a change in the regulatory requirements of manufacturers in the UK, as proposed by this research, will call for the same changes across the EU. The EC would be responsible to ensure that any new regulation, which would be applicable to all EU member states, is consistently implemented and enacted in each member state. This will require the harmonisation of member states to ensure that each competent authority is preforming and legislating as required by the regulation. Within the current proposals for a major regulatory overhaul in the UK this is addressed with the establishment of a new committee known as the Medical Device Coordination Group (MDCG).

**Medical Device Coordination Group (MDCG)**

Under the current proposals for a new medical device regulatory system in the UK it is proposed that a new committee will be established. The MDCG will be made up of appointed members by their Member States 'due to their role and experience in the field of medical devices and chaired by the Commission' (EC, 2013). According to the EC, the MDCG and various subgroups will establish forums for which discussions with stakeholders will be held (EC, 2013). It is believed that such a committee will ensure a harmonised interpretation and governance of future regulation across the EU.

Usability considerations therefore could be potent at the EU level if there were to be representation of usability professionals within the MDCG. Appointed professionals experienced in usability engineering or human factors for medical devices could be

consulted at an EU level to ensure the guidance and mandated requirements are interpreted correctly across all member states.

**Key International Issues**

- Consistent implementation across all 32 member states within the European Union (EU) will require the support and governance of the European Commission (EC).
- The appointment of usability professionals on the proposed Medical Device Coordination Group will ensure that usability is interpreted and enforced across all member states.
- A comparative study of MHRA regulation and FDA regulation would reveal possible opportunities to harmonise the strength of each organisation to deliver safe, usable and understandable home use medical devices.

## 9.5 Barriers to Implementation

The purpose of this research has been to identify the practical challenges to industry for adopting usability principles for home use medical device design to incentivise a change in current practice. In the same vein there is a need to consider the challenges to practically implementing the proposed interventions of this research.

This chapter has discussed the regional, national and international implications of this research and its propositions. Chapter eight presented a workshop, which explored some of the perceived constraints for different stakeholders that make up the home use medical device field. Aside from the barriers perceived by the stakeholders in the study there are other potential barriers to the proposals of this research, which will now be discussed.

**Increased Costs to Develop Home Use Medical Devices**

One barrier to implementing a change through mandated requirements for usability for home use medical devices are the additional costs imposed upon manufacturers and industry holistically. Changing the current regulations with respect to usability will increase the costs of development for manufacturers. A manufacturer may have to invest in training for existing employees or new staff on the implementation and requirements of the new regulation. There are also additional costs to manufacturers

in locating, recruiting and accessing device users for any necessary usability testing with actual end users. One must consider however that if a company is already adopting the principles of IEC BS EN 62366: 2008 then it is unlikely that any significant additional costs will be incurred.

For companies that are not currently investing in usability it is foreseeable that they may have to recruit new employees with experience in usability and human factors issues for medical devices. This will be both difficult and expensive for small companies with finite resources. Alternatively companies could commission a reputable consultancy to conduct their user research on their behalf. There are many companies that currently adopt this approach and some of the design consultancies that offer such services were involved in this research.

**Costs of Establishing and Managing a New Regulation**

The development of a new regulatory framework is inevitably expensive for a government to introduce into the UK. The effective implementation of a regulation will require the commissioning of staff to manage and develop the framework for medical devices including supporting member states in the effective and efficient implementation across the different EU member states. As previously described there will be a significant cost to regional and national organisations in supporting a regulatory change both in terms of technical and logistical support.

**Costs of Training and Assessing for Manufacturers**

The vigilance and market surveillance of a new regulation will incur costs to assess the performance and conformance of manufacturers in meeting their legal obligations. In order to ensure the assessments performed by NBs are consistent it will be necessary to conduct frequent training sessions and meetings on a national scale. Collaboration on such a scale will by necessity result in added costs for manufacturers, government and the health service.

**The Accessibility of Usability**

The acceptability and accessibility of mandated requirements for usability in the design of home use medical devices will in itself present challenges to industry. The very need for this research and the work conducted by others in the field of medical device design is due in part to a lack of industry wide understanding about the

purpose, need and implementation of user research in the design and development of medical devices. With this in mind, it is necessary to increase the advocacy and knowledge of industry practitioners, outside of the design field, about the importance and value of usability and human factors.

Currently the phraseology of the sector is not consistent and professionals in the field use many terms interchangeably which lacks a coherent message about what usability and human factors are trying to achieve in practice. This was highlighted in many of the studies of this research, which has called for a change in current design practice. Chapters seven and eight revealed that the designers in this research perceived current design guidance to lack practical value in the design of home use medical devices. Consequently it was opined that a new regulation for home use medical devices would need clearer and specific requirements for device manufacturers. The stakeholder workshop of this research indicated that the current guidance for usability towards medical device design is focused primarily on interface design, which is not applicable or appropriate for many of the devices currently used in the home environment. In light of this, it was opined that many manufacturers are currently uncertain about what is required by current legislation for usability considerations.

This suggests that the implementation of usability in practice is currently inconsistent for medical devices as the requirements for manufacturers are unclear. There is a need for clarity in the terms, principles and requirements of usability towards home use medical device design. This research calls for this clarification through the introduction of a new regulation in the UK for mandated usability considerations.

The following chapter will now present the conclusions of this thesis and the identification of possible future work.

# Chapter 10 Conclusions and Future Work

## 10.1 Introduction

This chapter presents the main contributions to knowledge that have been established throughout this thesis and period of study at Loughborough University. The chapter includes a summary of the research questions answered within this thesis and the recommendations for future work in the field of home use medical devices. Finally, a critique of the study chapters is presented before the main conclusions are drawn.

## 10.2 Conclusions and Contributions to Knowledge

The following section provides a summative conclusion to each research question addressed in this thesis and the main contributions to knowledge.

### 10.2.1 An Understanding of Design Practice towards User Involvement in Home Use Medical Device Design.

Research Question One aspired to ascertain:

***How do designers consider and involve users in home use medical device development?***

The research answered this research question through the following chapters: A literature review into existing research (Chapter Two), An idealised practice case study (Chapter Four), A stakeholder network case study (Chapter Five), An online survey study (Chapter Six) and an in-depth interview study (Chapter Seven).

The findings of this research indicated that current design practice for involving users in home use medical device design was diverse and consequently comparisons of the approaches taken were difficult. Chapter Six of this research suggested that user involvement in the design process of a home use medical device was often

retrospective with the highest levels of involvement occurring post product development and during product testing.

Chapter six of this research proposed three different scenarios to explain current approaches to design in industry for home use medical devices. These scenario were as follows:

***Scenario One: Designers are aware of the principles and methods for user needs research but do not apply them***.

**OR**

***Scenario Two: Designers are not aware of the relevant methods and so cannot apply them at all.***

**OR**

***Scenario Three: Designers are aware of the principles and methods for user needs research but apply them sub-optimally.***

Through exploring these issues further with participants, Chapter seven revealed that scenario three provided the most appropriate explanation for current design practice towards home use medical devices and their users. Chapter seven revealed that participants in this research were aware of the principles and practice of user research but applied the principles sub-optimally in practice based on external factors for home use medical device development. These factors refer to specific challenges towards user involvement in home use medical device design, which were addressed in Research Question Two of this research.

**Contribution to knowledge**

The research found that companies who reportedly did not follow usability guidance varied greatly in their approaches towards involving users in the design process of a home use medical device. In contrast, companies that reportedly followed usability guidance were revealed to involve users more often and more consistently throughout the design process.

Due to the number of participants in this study wide assertions on the significance of these findings cannot be made. However, the findings of this research imply that

some designers, developers and manufacturers of home use medical devices have a perception that their experience and existing knowledge of intended users is good enough to omit the use of formal usability methods and principles. Furthermore in some cases a manufacturer may omit the involvement of the intended user population at all. That is not to say that one cannot perform a user centred design process without involving users directly, as sufficient knowledge of the intended user population may already exist. However, this research has identified that some designers and manufacturers of home use medical devices believe their knowledge to be sufficient in cases where more engagement with users and formal usability principles is required.

Consequently this thesis positions that a notion of procedural user centred design is undermining the value of the established discipline which advocates the challenging of any preconceptions a designer or developer may have of the final product. This research calls for the challenging of this inherent bias we as humans all share and posits that the adoption of established design principles encourages one to approach each development in a different light and question the preconceptions brought forward from a previous project.

These findings and their implications were carried forward into the second and third research questions of this research to ascertain how best to incentivise a change in current design practice.

### 10.2.2 The Challenges of Involving Users in the Design Process of a Home Use Medical Device.

Research Question Two aspired to ascertain:

***What are the challenges for industry to involving users in the design process of home use medical devices?***

This research question was addressed through the following chapters: A literature review into existing research (Chapter Two), An idealised practice case study (Chapter Four), An online survey study (Chapter Six) and an in-depth interview study (Chapter Seven).

The research identified and described eleven challenges towards involving users in the design process of a home use medical device in the United Kingdom. This represents a contribution to existing knowledge in the field of home use medical devices. Although previous studies have addressed the challenges of home use medical device development holistically, there was no evidence found in the literature that specifically focused on the challenges to industry to involving users and adopting usability principles in home use medical device development. The challenges identified in Chapter Eight of this thesis were as follows: *Commerciality, Client Relationships, Financial Constraints, Access to Participants, Knowledge of Usability, Incentives for Adoption, Ethical Issues, Regulations, Hierarchy of Users, Diversity of Users and Intellectual Property Considerations*.

**Contribution to knowledge**

The research indicated that there currently lacks an enforceable incentive for manufacturers and developers of home use medical devices to invest in usability in the UK. The application of 'usability engineering' set out in the internationally harmonised standard IEC BS EN 62366:2007 is recognised as a moral obligation only for companies to follow. Under current regulation in the United Kingdom usability considerations in home use medical device development are not mandatory for manufacturers. Consequently, manufacturers are able to attain regulatory approval for a device with limited consideration for the users and their needs within the home environment.

This research suggests that some designers of home use medical devices are sceptical of current usability guidance and its practical value in the UK. In light of this, many designers and developers of home use medical devices adopt practices that are seen as 'just good enough' or sufficient to meet regulatory requirements rather than an approach to develop an improved device. This research posits that such an approach to design leads to devices on the market that may be safe to their users from a regulatory perspective, yet ineffective to the intended user population which is detrimental to patients, the manufacturer's reputation and the economy. Furthermore, adopting such an approach to design could be costly to the manufacturer in the future in terms of device recalls and complaints. It should be added that meeting the requirements of 'safety and effectiveness' is a formal requirement by the Food and

Drug Administration in the United States, thus adopting an ethos of 'just good enough' design is not only dangerous but commercially restrictive to manufacturers.

It is therefore proposed that further research in this field should explore beyond offering further guidance in attempt to support practicing designers and look at alternative routes towards changing current approaches to the design of home use medical devices.

In light of these findings, research question three of this research set out to establish ways of incentivising a change in industry's approach.

### 10.2.3 A Proposed Intervention to Change Current Perspectives and Practice of Usability for Home Use Medical Devices.

Research Question Three aspired to ascertain:

***How can usability for home use medical devices be incentivised for industry in the United Kingdom?***

This research question was addressed through the following chapters: In-depth interview study (Chapter Seven) and a stakeholder workshop (Chapter Eight).

Chapter Seven of this research identified three potential interventions to change current designer perspectives and practice towards home use medical device development in the UK. Each intervention was based on the principle to offer an enforceable incentive to adopt usability principles in home use medical device development. The proposed interventions of this research were as follows:

***Intervention One: A Regulatory Update Towards Home Use Medical Device Design in the United Kingdom.***

***Intervention Two: An Endorsement or Certification for Usability for Home Use Medical Devices.***

***Intervention Three: A Patient User Review Forum for Home Use Medical Devices.***

Chapter Eight of this thesis presented a stakeholder workshop held with industry professionals from the field of home use medical devices. A group consensus indicated that a dual strategy (i.e. a combination of Intervention One and Three) of

short and long-term interventions presented the most scope for changing design perspectives and practice towards home use medical device design in the future.

This research proposes a dual intervention including a change in the current regulations in the UK and the development of a social media platform that enables patient users to provide feedback and review home use medical devices.

**Contribution to knowledge**

Chapter eight highlighted that stakeholders in the study perceived a short-term strategy of aligning UK regulation with that of the FDA in the United States was the most effective strategy to change current designer perspectives and practice towards home use medical device development. The stakeholder workshop indicated that usability engineering should become a mandated requirement in the UK for home use medical device submissions to the MHRA. Mandating usability was identified as the leading incentive to change current design practice for home use medical devices.

The stakeholder workshop presented in chapter eight, suggested that a long-term strategy to increase user involvement in home use medical device design would benefit considerably from a social media platform (review website) for patient users. The development of a resource for patient users would educate patients on the design of such devices and allow them to compare experiences and information on devices with other users. It was identified that manufacturers would also benefit from such a resource as they could access direct feedback from their device users, which was identified as one of the challenges within this research. The workshop indicated that a review platform could raise the standard of usability by introducing competition amongst manufacturers to deliver devices of improved usability.

Chapter eight explored with industry professionals how the interventions would be implemented in practice to offer benefits to patients, manufacturers and industry as a whole. The study also considered the drawbacks of the proposals. This included the costs to implement changes in current regulations and the cost for manufacturers to achieve regulatory approval under the new proposals. During the period of study however, proposals for a major regulatory overhaul were proposed in the United Kingdom. Changes to the regulatory system have been criticised for increased costs and bureaucracy however yet they are regarded as necessary for the safety and

wellbeing of patients. The interventions of this research are proposed amendments to this regulatory update and therefore limit the costs to mandate usability. It was indicated that while the upfront costs for development to manufacturers may be higher, the opportunity costs in improved device safety could counter balance this in the long-term. It was not possible within the scope of this research to provide estimates on the cost implications for the imposing the interventions of this research. It is recommended as part of some future research to conduct cost-benefit analysis into the involvement of users in the design process of a home use medical device to establish the cost implications of such a change to development.

## 10.3 Future Work

In light of the contributions to knowledge presented within this thesis opportunities for potential future research have been identified. The following section describes possible future work to be conducted by others interested in the field of home use medical device design.

### 10.3.1 Development of Requirements for a Usability Assessment for Home Use Medical Devices.

In order to invoke a regulatory update for home use medical devices it is necessary to develop a proposal for usability requirements for home use medical devices. This research indicated that this proposal could be aligned with the Food and Drug Administration's (FDA) pre-market approval authorisation. As part of the submission for regulatory approval it was proposed that manufacturers should be assessed upon their application of a Usability Engineering Process (UEP). This would then allow for manufacturers of a UEP to be certified to that affect and could subsequently gain an endorsement for their device.

Further research could explore the differences in mandated requirements for home use medical devices between the UK and US to establish how the regulations could become aligned and more consistent to deliver safe, usable and understandable devices. This would also result in the added benefit of reduced costs to manufacturers too.

### 10.3.2 Development of a Social Media Platform for Patient Users of Home Use Medical Devices.

The findings of this research indicated that the development of a social media resource for patient users of home use medical devices could be considerably valuable in changing current perspectives and practice towards home use medical device design. Research could explore the information that patient users would like to assist them in selecting a suitable medical device for their own personal needs. Chapter eight of this research indicated that such a resource could be affiliated to specific organisations such as Diabetes UK, which would then benefit from the established network of members.

A patient user review forum would provide a medium between designers and users to share vital information relating to the use and design of a device. The forum could then potentially improve the quality of feedback provided by patient users of home use medical devices as well as allowing manufacturers to enact upon their feedback in future developments.

### 10.3.3 Exploration of Challenges towards User Involvement with a Wider Population of Designers and Developers.

The scope of this research was focused upon companies currently operating and designing home use medical devices in the UK. With this in mind further research could explore the design of home use medical devices in other member states and the US, Canada and Australia for example. An international comparison of home use medical device design could reveal opportunities to improve the process of design and application of usability engineering worldwide.

Further research could also address the issues and findings presented within this thesis on a larger scale. One of the limitations of this research is the number of participants recruited for each study that makes generalisations and assertions to a wider population inappropriate. If a population of home use medical device design companies based within the UK is known, then it would be possible to establish a suitable sample of participants to draw significant and reliable conclusions from the findings.

## 10.4 Critique of Study Chapters

***Chapter Four - Case Study One: Towards Idealised Practice***

Chapter Four of this thesis presented a case study, which aimed to ascertain a theoretical idealised practice towards home use medical device design. The idealised design process was developed in collaboration with a leading UK based design consultancy with research ties to a university. Despite this, it is important to recognise that the idealised practice is only theoretical and presents a single case view of design practice for home use medical devices. To make wider assertions about a 'best' practice process would require broader industry and academic input, arguably on an international level to understand the full extent of complexities and methods towards home use medical device design in practice.

***Chapter Five - Case Study Two: A Stakeholder Network***

Chapter five of this thesis presented a stakeholder network from a company operating in the home use medical device market in the UK. The case study presented the perceived stakeholders (i.e. users) involved in the process of delivering diabetes related devices to patients within the home environment. The process therefore refers to the influential stakeholders that have an influence upon the devices used by patients specifically. Despite this however it is important to consider that this case study is another example of a single case. Therefore, other companies operating in the home use market may perceive different stakeholders or users to be more important (i.e. higher in the hierarchy) in the delivery process of a medical device to their patients.

Another possible criticism of the case study presented in Chapter five is that it does not address the process of design per se, rather the case study explores the prescribing model. However this approach was considered valuable for the research as the stakeholder network was focused upon the influential stakeholders in the delivery process of home use medical devices that current dominate the market space. If there was more time available it would be very interesting to explore how this process of delivery to market differs to that of a 'consumer medical device' bought by users themselves. It should be added that the process of design itself (holistically) was explored in much greater detail in other chapters.

***Chapter Six – Online Survey Study: Designers and Manufacturers Perspectives***

Chapter six of this thesis presented an online survey of designers and manufacturers perspectives towards home use medical device design. One of the limitations for the study was the use of purposive and snowball sampling strategies. Participants in the study were self-selecting and thus it could be argued that the results of the survey represent the views of interested individuals only. Despite this however, the survey revealed a diverse set of results towards the perceptions of user involvement in home use medical device design. This could suggest that the respondents to the survey were indicative of a diverse range of the designer population however it is recognised that wider assertions cannot be made.

Another limitation identified within chapter six was a restriction upon the depth revealed by the use of a questionnaire strategy. In hindsight, other strategies may have been more appropriate for the audience of this research. In particular the use of semi-structured interviews in Chapter seven of this research was found to be very useful in revealing a greater understanding of current practice towards home use medical device design. Paradoxically, the strategy of chapter six was essential in identifying and establishing a rapport with participants for chapter seven.

***Chapter Seven – In-depth Interview Study: Understanding Current Practice***

Chapter seven of this thesis presented the interviews of this research, which revealed a greater understanding of current designer perspectives towards home use medical device design in the UK. A criticism of the findings in this study however could be the limited number of participants that were interviewed. An extensive recruitment effort for companies operating in the home use market was conducted throughout the period of study. Despite this, participants were difficult to locate and recruit. This is perhaps because participation in this research was voluntary with little incentive for participants to take part other than to further the knowledge within academia. Furthermore, many of the designers and developers contacted as part of this research reported either to have insufficient time to participate or were restricted by confidentiality agreements with their clients. If this research was to be performed by others with a greater budget to conduct such work then perhaps participants could be provided with a financial incentive for participation. Despite this, Guest *et al* posit that saturation can occur within twelve interviews (Guest *et al*, 2006) and thus the

sample achieved for chapter seven was consider suitable for a population that is notoriously difficult to access.

As with the previous studies of this research, the interviewees of this study were self-selected. This was considered necessary due to the difficulty to access participants in the field, however it is recognised that this has implications for the results. Indeed, if greater quotas of participants were recruited for involvement in the research then a random sample of the parent population may have been selected.

***Chapter Eight – Stakeholder Workshop: Proposed Interventions***

Chapter eight of this research presented a stakeholder workshop on the proposed interventions of this research. The workshop explored the practicalities of applying the findings of this research with different practitioners in the field of home use medical devices. A possible criticism of the study however is the presence of three practitioners representing the diabetes marketplace. While diabetes represents a significant amount of devices currently used in the home it is important to consider that practitioners from this field represent a single view from a diagnosis perspective. To combat this other practitioners with extensive experience including a breadth of devices should be included in the workshop. It could also be argued that as diabetes management and treatments cover such a range of devices, these professionals' opinions were highly relevant for the purpose of the study.

Another criticism of the workshop presented in chapter eight could be targeted at the number of practitioners present. The workshop aimed to ascertain as many perspectives as possible to assess to the interventions of this research with the individuals for which the proposals were concerned. Due to the time constraints on project completion a single workshop was held in November 2013. This limited the number of participants that could attend on the day. If there were more time to conduct this research then participants may have been offered alternative dates that could have improved attendance. One must consider however that the number of participants for a group interview should ideally remain between six and eight in order for the facilitator or interviewer to be in control of the discussions. Thus the number of participants present at the stakeholder workshop was considered appropriate for the nature of the discussions and design of the study.

## 10.5 Concluding Summary

To draw a conclusion on this research, submitted as a thesis for the degree of Doctor of Philosophy, it is proposed that the application of usability principles and involvement of users in the design process should become a mandated requirement for manufacturers of home use medical devices in the United Kingdom. Understanding the needs, expectations and capabilities of device users is a fundamental requirement to delivering safe, usable and understandable home use medical devices both now and in the future.

This research has indicated that current design practice lacks an enforceable incentive for medical device manufacturers in the United Kingdom to invest in research with device users. The research indicates that the reported benefits of involving users in the design process are not sufficiently potent to change the ways in which home use medical devices are designed.

The research has identified eleven different challenges reported by designers towards involving users in the design process of a home use medical device. In order to address these challenges a series of interventions were developed to incentivise the uptake of usability principles amongst industry practitioners.

The findings of this research propose that the introduction of mandatory requirements for manufacturers to address usability early and throughout the design process of a home use medical device will lead to improved home use medical devices in the United Kingdom. It is believed that a change in the regulation of usability requirements for manufacturers will lead to reduced costs to the National Health Service through reduced training and device abandonment from patients and an improved commerciality for manufacturers through better device sales and reputation.

# Chapter 11 References

**Alam, I. (2002).** An Exploratory Investigation of User Involvement in New Service Development. *Journal of the Academy of Marketing Science*, *30*(3), 250–261. doi:10.1177/0092070302303006

**Alexander, K. & Clarkson, P.J, (2000).** Good design practice for medical devices and equipment, Part II: Design for validation. *Journal of medical engineering technology*, 24(2), pp.53-62. Available at: http://informahealthcare.com/doi/abs/10.1080/030919000409311.

**Amoore, J, & Ingram, P. (2002).** Quality improvement report: Learning from adverse incidents involving medical devices. *BMJ (Clinical research ed.)*, *325*(7358), 272–275.

**ANSI/AAMI HE75, (2009).** American National Standard. Human Factors Engineering – Design of Medical Devices.

**Asl, B, (2004)**. Applying Product Design Methods to Medical Device Design With a Case Study on Home Care Devices. A Dissertation Submitted to the Department: Industrial Design Major: Industrial Design. *Strategy*.

**Batavia, A.I. & Hammer, G.S, (1990).** Toward the development of consumer-based criteria for the evaluation of assistive devices. *Journal Of Rehabilitation Research And Development*, 27(4), pp.425-436. Available at: http://www.rehab.research.va.gov/jour/90/27/4/pdf/batavia.pdf.

**Blessing, L.T.M. & Chakrabarti, A, (2009).** *DRM, a Design Research Methodology*, Springer Verlag. Available at: http://books.google.com/books?hl=en&lr=&id=KdR4OmWtQdIC&oi=fnd&pg=PA1&dq=DRM,+a+Design+Research+Methodology&ots=Ocn1JOFcN1&sig=pc7NahqVKKe8U0_ugmMUAbtYm98.

**Blumenthal, C, (2013).** ASQ Website. Shall Vs. Should article by Cynthia Blumnethal. Available at < http://asq.org/standards-shall-should>. Last viewed: November 2013.

**Bodenheimer, T, (2005).** High and rising health care costs. Part 1: seeking an explanation. Annals of internal medicine, 142(10), pp.847-854.

**Brace, N, Kemp, R, Snelgar, R, (2012).** SPSS for Psychologists. Palgrave Macmillan.

**Braungart, M. & McDonough, W, (2008)**. Cradle to Cradle – Remaking the Way We Make Things. Jonathon Cape. London.

**Bridgelal Ram, M, Grocott, P.R. & Weir, H.C.M, (2008)**. Issues and challenges of involving users in medical device development. *Health expectations an international journal of public participation in health care and health policy*, 11(1), pp.63-71. Available at: http://dx.doi.org/10.1111/j.1369-7625.2007.00464.x.

**Buckle, P, Clarkson, P. J, Coleman, R, Ward, J, & Anderson, J, (2006)**. Patient safety, systems design and ergonomics. *Applied Ergonomics*, 37(4), pp.491-500. Available at: http://www.ncbi.nlm.nih.gov/pubmed/16753132.

**Caccibue, P. C, (2004)** Guide to Applying Human Factors Methods. Human Error and Accident Management in Safety Critical Systems.

**Campbell, C.P, (1997).** Training course/program evaluation: principles and practice. Journal of European Industrial Training, 22(8): 323-44.

**Cifter, A,S, (2011)**. An inclusive approach towards designing medical devices for use in the home environment. A thesis submitted for the degree of Doctor of Philosophy. School of Engineering and Design. Brunel University.

**Coghlan, D. & Brannick, T. (2005).** 'Doing Action Research in Your Own Organisation (2nd Edn). London: Sage.

**Coleman, R, Clarkson, J, Dong, H, & Cassim, J, (2007**). Design for Inclusivity – A Practical Guide to Accessible Innovative and User-Centred Design. Gower.

**Craven, M. P, & Martin, J. L, (2010).** How does the healthcare industry involve users in medical device development? Pointers for UbiHealth. *International Workshop on Ubiquitous Computing for Pervasive Healthcare Applications*, (September), 7–10. Retrieved from http://www.ubicomp.org/ubicomp2004/.

**Crotty, M, (1998)** The Foundation of Social Research: Meaning and Perspectives in the Research Process. London: Sage.

**CQC, (2013).** Care Quality Commission Website. Available at: http://www.cqc.org.uk.

**CQC, (2013b).** Raising Standards, Putting People First – Our Strategy for 2013 to 2016. Care Quality Commission. Available at: http://www.cqc.org.uk/sites/default/files/media/documents/20130503_cqc_strategy_2013_final_cm_tagged.pdf.

**De Vaus, D, (2001)**. Research Design in Social Research. Sage Publications Ltd. 2001.

**Diabetes UK, (2013).** Diabetes UK Website. Available at: http://www.diabetes.org.uk

**Dixon, D, Brown, A, Meenan, B. J, & Eatock, J, (2006)** Experiences of new product development in the medical device industry. *Medical Device Technology*, 17(3), pp.20-22. Available at: http://www.mendeley.com/research/experiences-new-product-development-medical-device-industry/.

**Dreyfuss, H, (1955)**. *Designing for People*, Simon and Schuster. Available at: http://www.amazon.ca/exec/obidos/redirect?tag=citeulike09-20&amp.

**Easterby-Smith, M, Thorpe, R, Jackson, P. and Lowe, A. (2008)** Management Research (3rd Edn). London: Sage.

**Eatock, J, Dixon, D. & Young, T, 2009**. An exploratory survey of current practice in the medical device industry. *Journal of Manufacturing Technology Management*, 20(2), p.218-234. Available at: http://www.emeraldinsight.com/10.1108/17410380910929637.

**EC, (2003).** Commission Recommendation of 6 May 2003 Concerning the definition of Micro, Small and Medium-sized Enterprises. (2003/361/EC). Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF.

**EC, (2007). European Commission.** MDD 2007/47/EEC - Medical Device Directive. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML (Last Viewed: June 2013).

**EC, (2012). European Commission.** - Medical Device Regulations. Available at: http://ec.europa.eu/health/medical-devices/regulatory-framework/index_en.htm Last viewed: 08/10/2012.

**EC, (2013). European Commission.** Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. Available at: http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/com/2012/0542/COM_COM%282012%290542_EN.pdf

**EMDT, (2002)** Designing Devices that Delight (Special Report) EMDT European Medical Device Technology. May 1st 2002.

**FDA, (1997).** Design Control Guidance for Medical Device Manufacturers. Food and Drug Administration. Centre for Devices and Radiological Health. Available at: http://www.fda.gov/downloads/MedicalDevices/.../ucm070642.pdf Relating to: FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001.

**FDA, (2008).** How Human Factors Lead to Medical Device Adverse Events. Article by Suzanne Rich reprinted from June Nursing 2008, Volume 38, Number 6, Pages 62-63. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm070185.htm. [Last Viewed: December 2013].

**FDA, (2010)**. Food and Drug Administration. Medical Device Home Use Initiative. FDA Centre for Devices and Radiological Health.

**FDA, (2012).** Food and Drug Administration. Draft Guidance for Industry and Food and Drug Administration Staff. Design Considerations for Devices Intended for Home Use. Document Issued on December 12, 2012. Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM331681.pdf.

**FDA, (2013).** Food and Drug Administration Website. Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/default.htm (Last Viewed: June 2013).

**FDA, (2013a)** Food and Drug Administration (FDA). CDRH Mission, Vision and Shared Values. Available at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/.

**Flick, U. (2006).** An Introduction to Qualitative Research, 3rd Edn. London: Sage.

**Fowler, F.J, (2002)**. Survey Research Methods. *Third Edition. Floyd J. Fowler, Jr. Applied Social Research Methods Series. Volume 1. Sage Publications 2002.*

**Friedman, K. (2003)**. Theory Construction in Design Research: Criteria, Approaches and Methods. Design Studies Vol 24 No. 6 November 2003. Elsevier Ltd.

**French, M, (2010).** Conceptual Design for Engineers. Third Edition. Springer-Verlag London Limited 2010.

**Gilman, B.L, Brewer, J.E. & Kroll, M.W, (2009)**. Medical device design process. *Conference Proceedings of the International Conference of IEEE Engineering in Medicine and Biology Society*, 2009, pp.5609-5612. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19964397.

**Gough, K. J, (2006).** Creating User Centred Creative Design Tools for the Packaging Industry Using Video Ethnographic Research Techniques, *Designing Accessible Technology*, J Clarkson, P Langdon and P Robinson (eds.),London, Springer.

**Gould, J.D. & Lewis, C, (1987)**. Designing for Usability. In R. M. Baecker *et al*, eds. *Readings in Human Computer Interaction Towards the Year 2000*.

**Gillham, B, (2000)**. *Developing a questionnaire*, Continuum. Available at: http://books.google.com/books?hl=en&lr=&id=ACsRmvaJ9J4C&pgis=1.

**Gillham, B, (2005)**. Research Interviewing: The range of techniques. Open University Press, McGraw-Hill Education.

**Gray, D.E, (2009)**. Doing Research in the Real World, Sage Publications Ltd. Available at: http://books.google.com/books?id=l4dEQTQl1NYC&pgis=1.

**Guest, G, Bunce, A, & Johnson, L, (2006).** How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability. *Field Methods*. doi:10.1177/1525822X05279903.

**Gulliksen, J, Boivie, I. & Goransson, B, (2006)**: Usability professionals – current practices and future development. Interacting with Computers 2006, 18:568-600.

**Gupta, S, (2007)**. Design and delivery of medical devices for home-use: drivers and challenges. *Department of Engineering*. Cambridge University.

**Hakim, C, (2000)**. Research Design: Successful designs for social and economic research. Routledge London and New York.

**Hall, W.A. & Callery, P, (2001).** Enhancing the rigor of grounded theory: incorporating reflexivity and relationality', Qualitative Health Research, 11(2): 257-72.

**Healthwatch, (2013).** Healthwatch England Website. Available at: http://www.healthwatch.co.uk

**Holtzblatt, K. & Beyer, H, (1993).** Making customer-centered design work for teams. Communications of the ACM, 36(10), pp.93-103. Available at: http://doi.acm.org/10.1145/163430.164050.

**IDEO, (2002).** Method Cards for IDEO – 51-Card Deck to Inspire Design. Available at: http://www.ideo.com/work/method-cards (Last viewed: April 2013).

**IEC BS EN 62366, (2007).** IEC BS EN 62366:2007 – Medical Devices – Application of Usability Engineering to Medical Devices. British Standards Institute. EN 62366: 2008.

**IP, (2013).** Intellectual Property Office. The Intellectual Property Office Website. Available at: http://www.ipo.gov.uk. (Last Viewed: November 2013).

**ISO 14971, (2007).** Medical Devices – Application of Risk Management to Medical Devices. Available at: http://www.iso.org/iso/catalogue_detail?csnumber=38193.

**ISO DIS 9241, (2011).** Ergonomics of Human System Interaction. Available at: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=52938

**Johnson, A, (2007).** Insulin Flop Costs Pfizer $2.8 Billion. The Wall Street Journal. Available at: http://online.wsj.com/article/SB119269071993163273.html (Last Viewed: June 2013).

**Johnson, P. & Clark, M, (2006).** 'Mapping the terrain: an overview of business and management research methodologies', in P. Johnson and M. Clark. (eds). Business and Management Research Methodologies. London: Sage.

**Johnson, R.B. & Onweungbuzie, A.J, (2004).** Mixed Methods Research: A Research Paradigm whose time has come', Educational Researcher, 33(7):14-26.

**Johnson, R.B, Onwuegbuzie, A.J. & Turner, L.A, (2007).** 'Toward a definition of mixed methods research', Journal of Mixed Methods Research, 1(2): 112-33.

**Jordan, P.W, (1998)**. *An Introduction to Usability* J. Diaz & F. Orejas, eds, Taylor & Francis. Available at: http://www.useit.com/alertbox/20030825.html.

**Kaufman-Rivi, D, Collins-Mitchell, J, & Jetley, R. (2010).** Design considerations for medical devices in the home environment. *Biomedical instrumentation & technology / Association for the Advancement of Medical Instrumentation, Suppl Home*, 21–6. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/22049603.

**Kristensson, P, Matthing, J, & Magnusson, P. R. (2003).** Managing User Involvement in Service Innovation: Experiments with Innovating End Users. *Journal of Service Research*. doi:10.1177/1094670503257028.

**Lang, A.R, Martin, J.L, Sharples, S, & Crowe, J.A, (2013).** The effect of design on the usability and real world effectiveness of medical devices: A case study with adolescent users. *Applied Ergonomics*, null(null). Available at: http://dx.doi.org/10.1016/j.apergo.2013.02.001.

**Lehoux, P, Hivon, M, Williams-Jones, B, & Urbach, D, (2011).** The worlds and modalities of engagement of design participants: A qualitative case study of three medical innovations. *Design Studies*, 32(4), pp.313-332. Available at: http://linkinghub.elsevier.com/retrieve/pii/S0142694X11000020.

**Maguire, M, (2001).** Methods to support human-centred design. International Journal of Human-computer studies, 55(4), pp.587-634. Available at: http://linkinghub.elsevier.com/retrieve/pii/S1071581901905038.

**Martin, J.L, Norris, B.J, Murphy, E, & Crowe, J.A, (2008).** Medical device development: the challenge for ergonomics. *Applied Ergonomics*, 39(3), pp.271-283. Available at: http://www.sciencedirect.com/science/journal/00036870.

**Martin, J.L, & Barnett, J, (2012)**. Integrating the results of user research into medical device development: insights from a case study. BMC Medical Informatics and Decision Making 2012, 12:74 Available at: http://www.biomedcentral.com/1472-6947/12/74.

**MATCH, (2003).** The Multidisciplinary Assessment of Technology Centre for Healthcare Website. Available at: http://www.match.ac.uk/ (Last viewed: June 2013).

**MATCH, (2010)** Design for patient safety: User testing in the development of medical devices. The Multidisciplinary Assessment of Technology Centre for Healthcare. National Patient Safety Agency, London, UK. Available at: http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=74946.

**Maxwell, J.A, (2005)**. Qualitative Research Design: An Interactive Approach. 2nd Edition. Thousand Oaks, CA: Sage.

**McDonagh-Philp, D, (1998).** 'Gender and design: Towards an appropriate research methodology'. In *Proceedings of the 5th National Conference on Product Design Education*, Glamorgan University, July 1998.

**Medilink, (2012).** Medilink Website. Available at: http://www.medilink.co.uk/ (Date viewed: July 2012).

**Medina, L.A, Wysk, R.A, & Kremer, G.E.O, (2012)**. Supporting medical device development: a standard product design process model, Journal of Engineering Design, DOI:10.1080/09544828.2012.676635 http://dx.doi.org/10.1080/09544828.2012.676635.

**Merriam Webster, (2013).** *Merriam-Webster.com*. Merriam-Webster, n.d. Web. 13 Nov. 2013. <http://www.merriam-webster.com>

**MHRA, (2006)** The Notified Body. Bulletin No. 6. Amended January 2006. Competent Authority (UK).

**MHRA, (2008)** Conformity Assessment Procedures. Medical Devices Regulations. Bulletin No. 4. Updated March 2008. Competent Authority (UK).

**MHRA, (2010)** The Classification Rules. Bulletin No. 10. Updated June 2011. Competent Authority (UK).

**MHRA, (2011a)** Reporting adverse incidents and disseminating medical device alerts. Published March 2011, Website only. Competent Authority (UK).

**MHRA, (2011b)** Report on Devices Adverse Incidents in 2010. Published October 2011. Competent Authority (UK).

**MHRA, (2013)**. MHRA Website. Medical Device Regulations. Available at: http://www.mhra.gov.uk/Howweregulate/Devices/index.htm. (Last viewed: December 2013).

**Money, A.G, Barnett, J, Kuljis, J, Craven, M. P, Martin, J.L, & Young, T, (2011).** The role of the user within the medical device design and development process: medical device manufacturers' perspectives. *BMC Medical Informatics and Decision Making*, 11(1), p.15. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3058010&tool=pmcentrez&rendertype=abstract.

**Morris, T, & Wood, S, (1991)** 'Testing the Survey Method: Continuity and Change in British Industrial Relations', Work Employment and Society, Vol 5, No. 2, pp 259-82.

**National Research Council, (2011).** *Health Care Comes Home: The Human Factors.* Committee on the Role of Human Factors in Home Health Care, Board on Human-Systems Integration, Division of Behavioural and Social Sciences and Education. Washington, DC: The National Academies Press.

**NHS, (2013a).** The NHS in England. NHS Structure. Available at: http://www.nhs.uk/NHSEngland/thenhs/about/Pages/nhsstructure.aspx.

**NHS, (2013b).** About the NHS. CCG Outcomes. Available at: http://www.nhs.uk/NHSEngland/thenhs/about/Pages/ccg-outcomes.aspx.

**NHS Improving Quality, (2013).** Equality for All: Delivering Safe Care – Seven Days a Week. NHS Improving Quality. Published July 2013. Available at: http://www.nhsiq.nhs.uk/resource-search/publications/nhs-imp-seven-days.aspx

**NICE, (2010).** National Institute for Health and Care Excellence. NICE Website. Technology Appraisal Topic Selection. Available at: http://www.nice.org.uk/media/088/B2/NewTAPrioritisationCriteriaAgreedByMinister.pdf.

**NICE, (2011).** National Institute for Health and Care Excellence. Medical Technologies Evaluation Programme Methods Guide. Issue Date: April 2011. Available at: http://www.nice.org.uk/media/3A6/09/MedicalTechnologiesEvaluationProgrammeMethodsGuideMarch2012.pdf.

**NICE, (2011a).** National Institute for Health and Care Excellence. NICE Website. Medical Technologies Evaluation Programme: Process Guide. Available at: http://www.nice.org.uk/media/3A6/14/MedicalTechnologiesEvaluationProgrammeProcessGuideMarch2012.pdf.

**NICE, (2013).** National Institute for Health and Care Excellence. NICE Website. Medical Technologies Evaluation Programme (MTEP) Available at: http://www.nice.org.uk/MT.

**NM, (2012).** NM Incite State of Social Customer Service Report. Available at: http://soulofbrands.files.wordpress.com/2012/11/nm-incite-report-the-state-of-social-customer-service-2012.pdf. [Last Viewed: November 2013].

**Norman, D.A, (1998).** *The Design of Everyday Things*. First MIT Press edition, London, England.

**Norman, D.A, (2004)**. *Emotional Design* B. Books, ed, Basic Books. Available at: http://portal.acm.org/ft_gateway.cfm?id=966013&type=html. [24/09/12].

**NRES, (2013).** National Research Ethics Service Website. Available at: http://www.nres.nhs.uk/about-the-national-research-ethics-service/about-recs/role-of-recs/. Last viewed: November 2013.

**ONS, (2012)**. 2011 Census – Population and Household Estimates for England and Wales, March 2011. Office for National Statistics. Available at: http://www.ons.gov.uk/ons/dcp171778_270487.pdf.

**Oxford Dictionaries, (2013).** Oxford University Press, n.d. Web. Available at: <http://www.oxforddictionaries.com>. Last viewed: December 2013.

**Pallant, J, (2010)**. *SPSS Survival Manual: A step by step guide to data analysis using SPSS*, Open University Press. Available at: http://www.amazon.de/dp/0335242391.

**Papanek, V, (1985).** *Design for the Real World: Human Ecology and Social Change* Reprinted, ed, Academy Chicago Publishers. Available at: http://books.google.com/books?id=gf5TAAAAMAAJ&pgis=1.

**Patients Like Me, (2013).** Patients Like Me Website. Available at: http://www.patientslikeme.com

**Pheasant, S. & Haslegrave, C.M, (2006).** *Bodyspace: Anthropometry, Ergonomics, and the Design of Work*, Taylor & Francis. Available at: http://books.google.com/books?hl=en&lr=&id=nwfvSbuyBdMC&pgis=1.

**Pick, T, (2013).** 103 Compelling Social Media and Marketing Statistics for 2013. Business 2 Community Website. Available at: http://www.business2community.com/social-media/103-compelling-social-media-marketing-statistics-2013-2014-0679246. [Last Viewed: November 2013].

**Popper, K.R. (1968).** The Logic of Scientific Discovery, 2nd Edn. London: Hutchinson.

**Privitera, M. B, Design, M, & Johnson, J. (2009a).** Interconnections of basic science research and product development in medical device design. *Conference Proceedings of the International Conference of IEEE Engineering in Medicine and Biology Society, 2009*, 5595–5598. Retrieved from http://www.mendeley.com/research/interconnections-of-basic-science-research-and-product-development-in-medical-device-design/.

**Privitera, M. B, Design, M, & Murray, D. L. (2009b).** Applied ergonomics: determining user needs in medical device design. *Conference Proceedings of the International Conference of IEEE Engineering in Medicine and Biology Society, 2009*(101243413), 5606–5608. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/19964396.

**Putnam, H. (1990).** *Realism with a Human Face*. *History*. Harvard University Press. doi:10.2307/2220250.

**QMED, (2012)** Serious Adverse Events Triple in Three Years: Is Risk or Reporting to Blame? By Nora Iluri, founder and CEO, Claimed and Device Matters. Available at: http://www.qmed.com/mpmn/medtechpulse/serious-adverse-events-triple-three-years-risk-or-reporting-blame (Last viewed: October 2012).

**Quotec, (2010)** – Commercialising Medical Devices Report. A Guide for UK Based Small Companies. January (2010). Available at: http://www.quotec.co.uk/attachments/article/37/Commercialising%20Medical%20Devices.pdf.

**Robson, C, (2011)**. Real World Research. John Wiley & Sons Ltd. Third Edition.

**Rose, T, Blake, C, Norris, B, & Lowe, C. (2007).** Improving patient safety through device design and usability. In P. D. Bust (Ed.), *Contemporary Ergonomics*. Taylor & Francis.

**Saunders, M, Lewis, P. & Thornhill, A, (2009).** Research Methods for Business Students. Pearson Education. Fifth Edition.

**Sawyer, D, (1996)**. *Do It By Design: An Introduction to Human Factors in Medical Devices*, U.S. Food and Drugs Administration, Centre for Devices and Radiological Health.

**Shah, A, & Alshawi, S, (2010).** The role of user requirements in medical device development. Information Systems, 2010, 1-25. Retrieved from http://bura.brunel.ac.uk/handle/2438/4363.

**Shah, S.G.S. and Robinson, I, (2008)** 'Medical device technologies: who is the user?', *Int. J. Healthcare Technology and Management*, Vol. 9, No. 2, pp.181–197. DOI: 10.1504/IJHTM.2008.017372.

**Shah, S.G.S, Robinson, I. & AlShawi, S, (2009).** Developing medical device technologies from users' perspectives: a theoretical framework for involving users in the development process. *International Journal of Technology Assessment in Health Care*, 25(4), pp.514-521. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19845981.

**Sharples, S, Martin, J.L, Lang, A.R, Craven, M.P, O'Neill, S, & Barnett, J, (2012).** Medical Device Design in Context: a Model of User-device Interaction and Consequences. Displays.

**Strauss, A. L, & Corbin, J, (1998).** Basics of Qualitative Research, 2nd Edn. Thousand Oaks, CA: Sage.

**Survey Monkey, (2013).** Online Survey and Questionnaire Tool. Available at: https://www.surveymonkey.com.

**Thomas, D.R, (2003).** A General Inductive Approach for Qualitative Data Analysis. *Population English Edition*, 27(2), pp.237-246. Available at: http://tobermory.cc.strath.ac.uk/erica/module6_reader/unit2/thomas2003inductiveanalysis.pdf.

**Turieo, M. J, Devine, M. A, Hasler, R, Kaye, R and Rogers, W. A, (2004).** Human Factors Considerations in the Migration of Medical Devices from Clinical to Homecare Settings. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* 2004 48: 1685 DOI: 10.1177/154193120404801512.

**(UL, 2012).** Home Healthcare Equipment: An Overview. UL LLC. Published 2012. Available at: http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0CDwQFjAC&url=http%3A%2F%2Fwww.frost.com%2Fprod%2Fservlet%2Fcpo%2F251073197&ei=YMyyUqKPJIuUhQfttIDADg&usg=AFQjCNEX32Mh1gGD_DddSi1tjwvRyKzxyg.

**Usability Net Website, (2003).** Tools and Methods. Available at: http://www.usabilitynet.org/tools.htm (Last viewed: June 2013).

**Vincent, C, & Blandford, A, (2011)**. Designing for Safety and Usability: User Centred Techniques in Medical Device Design Practice. Presented at meeting Human Factors and Ergonomics. Public Paper No. 24. EPSRC Programme Grant EP/G059063/1. UCLIC, University College London, Gower Street, London, WC1E 6BT, UK. 2011.

**Wald, D. S. (2004).** Bureaucracy of ethics applications. *BMJ : British Medical Journal*, *329*(7460), 282–284.

**Ward, J.R, & Clarkson, P.J, (2004).** An analysis of medical device-related errors: prevalence and possible solutions. *Journal of medical engineering technology*, 28(1), pp.2-21. Available at: http://www.ncbi.nlm.nih.gov/pubmed/14660181.

**Warr, P, Bird, M. and Rackman, N. (1970).** Evaluation of Management Training. Aldershot: Gower.

**Williams, T, & May, T, (1996).** Introduction to the Philosophy of Social Research. London: Routledge.

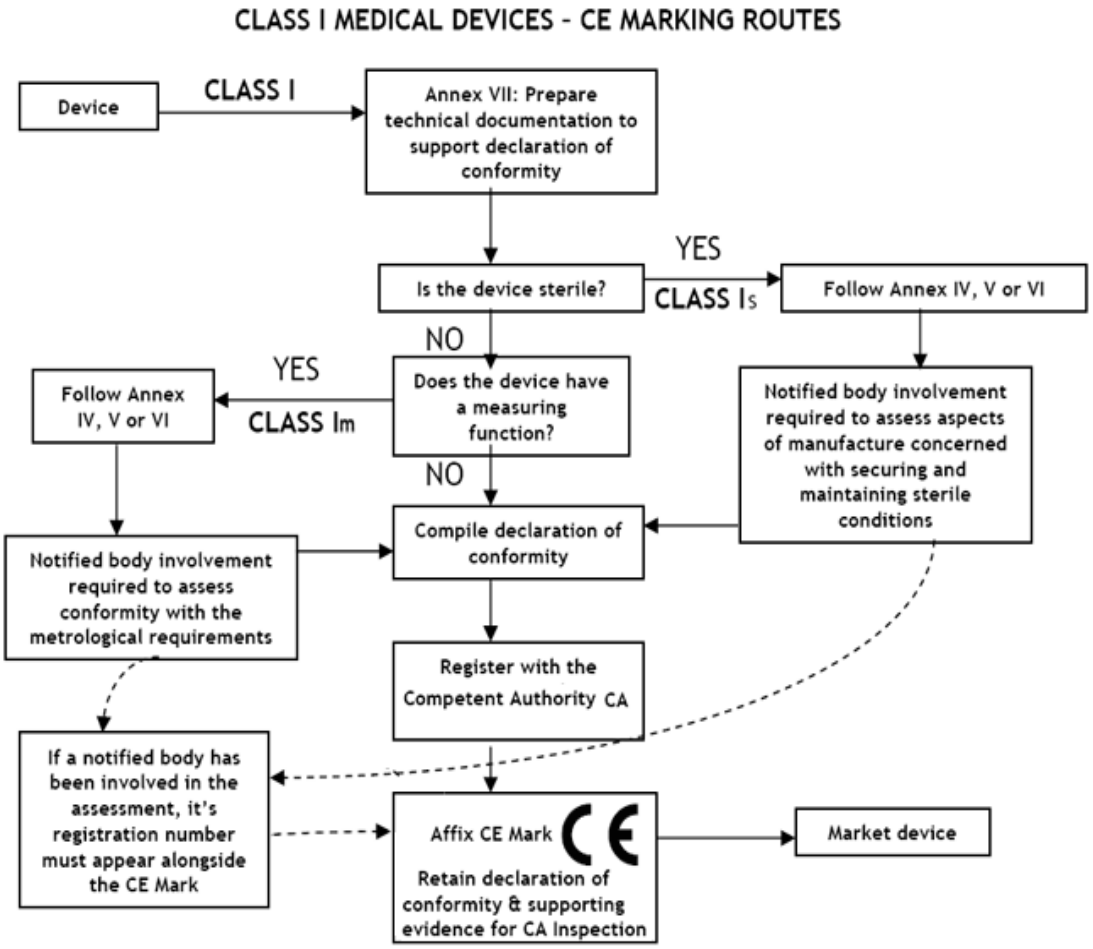
**Wirthman, L, (2013).** Why Businesses Should Listen to Customers on Social Media. Forbes Website. Available at: http://www.forbes.com/sites/ups/2013/08/08/why-businesses-should-listen-to-customers-on-social-media/. [Last Viewed: November 2013].

**Zhang, J, Johnson, T.R, Patel, V.L, Paige, D.L, & Kubose, T, (2003).** Using usability heuristics to evaluate patient safety of medical devices. J. Biomed. Inf. 36, 23–30.

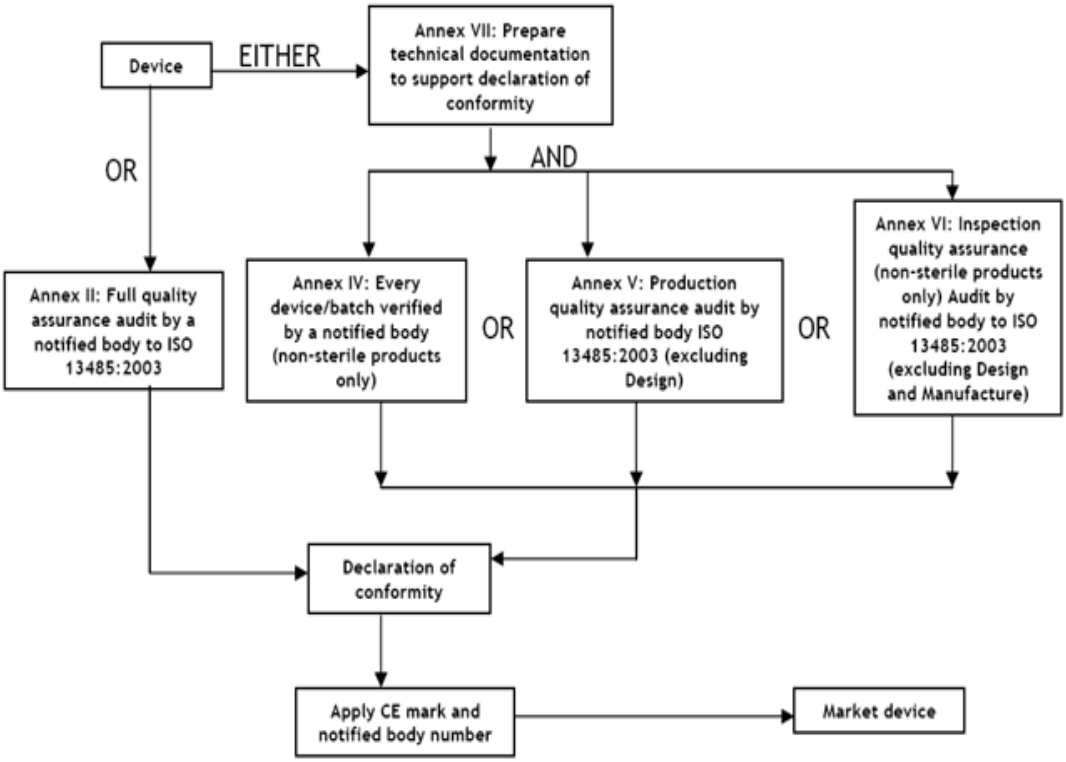
# Chapter 12 Appendix

Appendix 1: Conformance Assessment Routes. ..... 394
Appendix 2: Researcher Identity Memo ..... 396
Appendix 3: Survey Final Design ..... 398
Appendix 4: Survey Website Design ..... 405
Appendix 5: Recruitment Email ..... 406
Appendix 6: Participant Information Sheet ..... 407
Appendix 7: Linked In Recruitment Advertisement ..... 408
Appendix 8: Respondent Profiles ..... 409
Appendix 9: Pairwise Comparison Results (Drivers for Development) ..... 410
Appendix 10: Pairwise Comparison Results (Measures of Success) ..... 411
Appendix 11: Pairwise Comparison Results (Stages of User Involvement) ..... 412
Appendix 12: Participant Information Sheet (Interview Study) ..... 413
Appendix 13: Informed Consent Form (Interview Study) ..... 415
Appendix 14: Interview Protocol ..... 416
Appendix 15: Respondent Profiles (Interview Study) ..... 420

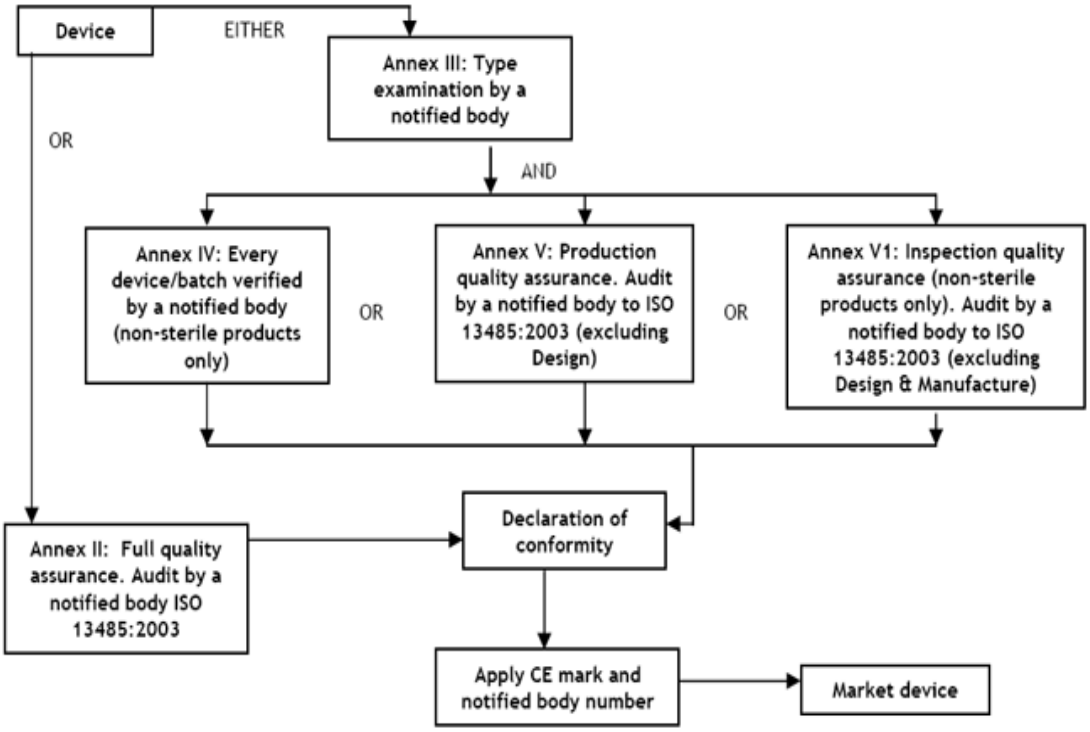
## Appendix 1: Conformance Assessment Routes.

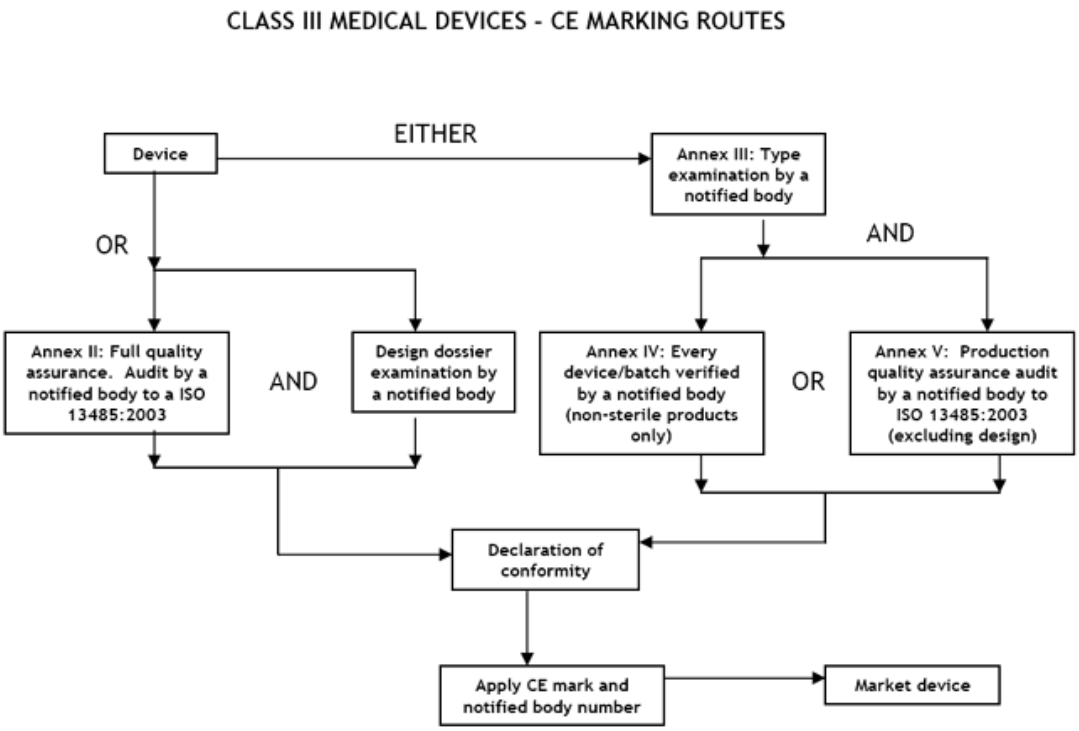


## CLASS IIa MEDICAL DEVICES - CE MARKING ROUTES




## CLASS IIB MEDICAL DEVICES - CE MARKING ROUTES






## Appendix 2: Researcher Identity Memo

Used as a method to explore your assumptions and experiential knowledge through writing down all of the expectations, beliefs and assumptions about the subject area. The method enables the researcher to recognise and identify the perspective he/she brings to the study. The following extract explores the researcher's background in medical device design.

| My Background, Expectations and Beliefs |
|---|
| My interest in user involvement in medical device design originates from my undergraduate degree studies, particularly my industrial placement with a medical device manufacturer. I was involved in the day-to-day issues, problems and solutions faced by both designers and end users. I gained valuable experience in the processes industry use to define their target population and their requirements, whilst also having the opportunity to speak with the product users in their environment of use.<br><br>The industrial experience increased my commercial awareness and understanding of how companies operate in the medical device industry. I was exposed to the |

challenges that companies face when attempting to deliver devices to market in conformance with the Medical Device Directive and supporting regulations whilst meeting strict budget requirements and time constraints.

Returning to Loughborough University gave me the opportunity to reflect and discuss with my supervisor the theoretical and academic knowledge about the role of the designer-user relationship. It became apparent that ergonomics could provide the bridge between industry and the end user to develop quality, safe and usable medical devices.

For my final year project at Loughborough University I was sponsored to work on a project in collaboration with my industrial placement employer. The project identified the usability issues involved with manual resuscitation and an upcoming change in CPR protocol. From the successes of this project, I applied to study for a PhD at Loughborough University to further explore the role of ergonomics in the design of medical devices.

The focus of home-use medical devices is important to me, not only for the changes in population demographics and the increasing elderly population, but due to my exposure from a young age of insulin pens and blood glucose meters used by my mother as a healthcare professional in diabetes care.

I began to recognise the diverse ways in which certain devices were prescribed and delivered, involving numerous teams of people leading to issues and breakdowns in communication. Problems with the use of the equipment within the home environment became increasingly evident, often requiring patients to seek assistance from proxies or experiencing challenges with the operation of such devices due to a mismatch of usability and their personal requirements.

This identity memo has been developed for the researcher to consider his background and stand point on medical device design. The memo demonstrates some personal opinions on current medical device design and it is evident that the researcher feels much more can be done in this field to support the transition of healthcare technology into the home environment.

The researcher’s current stance is one where usability and the real user’s needs are

often overlooked. In the researchers opinion the medical device industry sits on a continuum, between the delivery of quality medical devices for their end users and operating as a business, with the balance sometimes shifted towards operating profit.

As this bias has been recognised it is now vital that the literature reviewed in this report covers the range of design successes and failures within the field, as to not obstruct the researcher's view of the real problems. The researcher will reflect on the issues discussed in this memo throughout the research project to keep in mind the biases and focus of what the research is trying to achieve.

## Appendix 3: Survey Final Design

| **User Involvement in Medical Device Design**<br>**Survey Information** |
|---|
| My name is Thomas Grant and I am a PhD student at Loughborough University. My research is exploring user involvement in medical device design. At this stage of my research I want to explore current practice in incorporating the end user into design processes.<br><br>This short survey is the first part of a larger study to explore ways in which industry can be supported to increase user involvement and lead to safer, more usable and desirable medical devices.<br><br>The questionnaire is comprised of 15 questions only and should not take more than 5 minutes of your time to complete. All of the responses you provide in this questionnaire are completely confidential and we can assure you that your company will not be identifiable in any of the published results. I am more than willing to share any of the results from this survey with you when they are available and should you be interested to receive them.<br><br>On completion of the survey you will be asked to volunteer to take part in a further semi structured interview that will last no longer than 1 hour of your time. This interview is completely voluntary and you do not have to take part. If you do not |

wish to take part please tick the allocated box at the end of the survey. Otherwise please leave your contact details to enable me to get in contact with you directly.

You may withdraw from the survey at any time and will not be required to give a reason. The questionnaire is intended for anybody working within the medical device industry that is involved with the design and development of devices. If you feel you are unsuitable for this questionnaire but know or work with someone for whom this survey would be more appropriate please could you send this to them. Likewise if you feel there is someone else that this survey may be of interest to and they operate in the medical device sector, feel free to forward this on to them.

If you would prefer a paper based version of this survey please contact me at t.grant2@lboro.ac.uk and I will send as many copies as you
require together with a self-addressed envelope so that you will not be required to pay for postage.
I would like to thank you in advance for your time and support with this research and I very much hope you will be interested to take part in a further study.

Thank you.

Thomas Grant
Research Student
Loughborough Design School
Loughborough University
LE11 3TU
UK
t.grant2@lboro.ac.uk

## User Involvement in Medical Device Design

### Company Profile

**1. Please provide your company details**

**Company:**

**Address 1:**

**Address 2:**

**City/Town:**

**ZIP/Postal Code:**

**Country:**

**2. Approximate number of employees**

**3. Approximate turnover/annum (£)**

## User Involvement in Medical Device Design

**4. Which of the following best describes the area(s) of medical devices you have worked on? (Please tick as appropriate, you may provide more than one answer)**

- ☐ Drug Delivery
- ☐ Monitoring
- ☐ Assistive Technology
- ☐ Rehabilitation
- ☐ Emergency Care
- ☐ Post Acute Care
- ☐ Don't Know

Other (please specify)

## User Involvement in Medical Device Design

**5. If you were designing a medical device for the home environment, what would be the prime drivers for development? (If applicable, please rank your response in order of priority e.g. 1= Most important, 7 = Least important)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Don't know/Not applicable |
|---|---|---|---|---|---|---|---|---|
| Intellectual Property | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Cost | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Performance | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| User needs | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Sustainability | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Function | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Other | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Other (please specify)

## User Involvement in Medical Device Design

**6. What do you consider to be the barriers and or challenges to user involvement in your design process? (Please tick as appropriate, you may provide more than one answer)**

- ☐ Regulations – e.g Compliance with the Medical Device Directive
- ☐ Ethics – e.g Gaining Ethical approval to conduct user research
- ☐ Cost – e.g The cost involved to conduct user research
- ☐ Time – e.g The time involved to conduct user research
- ☐ Education/Training – e.g The training of research methods
- ☐ Access to the specialist knowledge required (in house or externally)
- ☐ Don't Know
- ☐ Not applicable

Other (please specify)

## User Involvement in Medical Device Design

**7. When designing a new medical device for your core business, who from the following list do you consider to be your users? (Please tick as appropriate, you may provide more than one answer)**

- ☐ Clinicians
- ☐ General Practitioners
- ☐ Patients
- ☐ Consultants
- ☐ Nurses
- ☐ Carers
- ☐ Buyers
- ☐ Standards agency
- ☐ All of the above
- ☐ Don't know
- ☐ Not applicable

Other (please specify)

## User Involvement in Medical Device Design

***8. Of the user groups mentioned in the previous question, whose needs do you consider to be the most important? (Please specify one answer)**

- ○ Clinicians
- ○ General Practitioners
- ○ Patients
- ○ Consultants
- ○ Nurses
- ○ Carers
- ○ Buyers
- ○ Standards agency
- ○ All of the above
- ○ Don't know
- ○ Not applicable

Other (please specify)

***9. What are your reasons for choosing this user group?**

## User Involvement in Medical Device Design

**10. What best describes the process you follow when designing or developing a new device for the market? (Please tick as appropriate)**

- ○ Standard Operating Procedure (SOP)
- ○ Prescribed Procedure
- ○ Detailed Design Process
- ○ User Centred Design Process
- ○ Don't know
- ○ Not applicable

Other (please specify)

## User Involvement in Medical Device Design

**11. Do you actively collect design feedback from your users once a product has been launched onto the market? (Please tick as appropriate)**

- ○ Yes
- ○ No
- ○ Don't know

## User Involvement in Medical Device Design

**12. How do you measure the success of a new device once it has been launched onto the market? (If applicable, please rank your response in order of priority e.g. 1= Most important, 8 = Least important)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | Don't know/Not applicable |
|---|---|---|---|---|---|---|---|---|---|
| Number of sales / market share | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Industrial awards | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Fewer / No product recalls / warranty claims | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Healthcare professional feedback | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Purchaser feedback | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| End user feedback | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| No product complaints | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Other | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Other (please specify)

## User Involvement in Medical Device Design

**13. At what stage(s) and to what extent during your design process do users become involved? (Please tick as appropriate)**

| | 0 = Don't know/Not applicable | 1 = Not involved | 2 = Rarely involved | 3 = Sometimes involved | 4 = Often involved | 5 = Highly involved |
|---|---|---|---|---|---|---|
| Initial Concept | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Design Stage | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Product Design Specification | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Product Development | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Product testing | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Post Launch | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

## User Involvement in Medical Device Design

### End of Questionnaire

Many thanks for completing this questionnaire. Your responses are greatly appreciated and highly valuable for this research.

Would you be willing to take part in a future study that will involve a short semi-structured interview and should not require more than 1hr of your time? If not then please tick the box below. Otherwise please provide your name and contact details in the fields provided below to allow me to contact you directly with more information. The follow up study is completely voluntary and you are not required to take part.

Once again thank you very much for your time.

**14. I would not be willing to take part in the follow up study**

☐ *

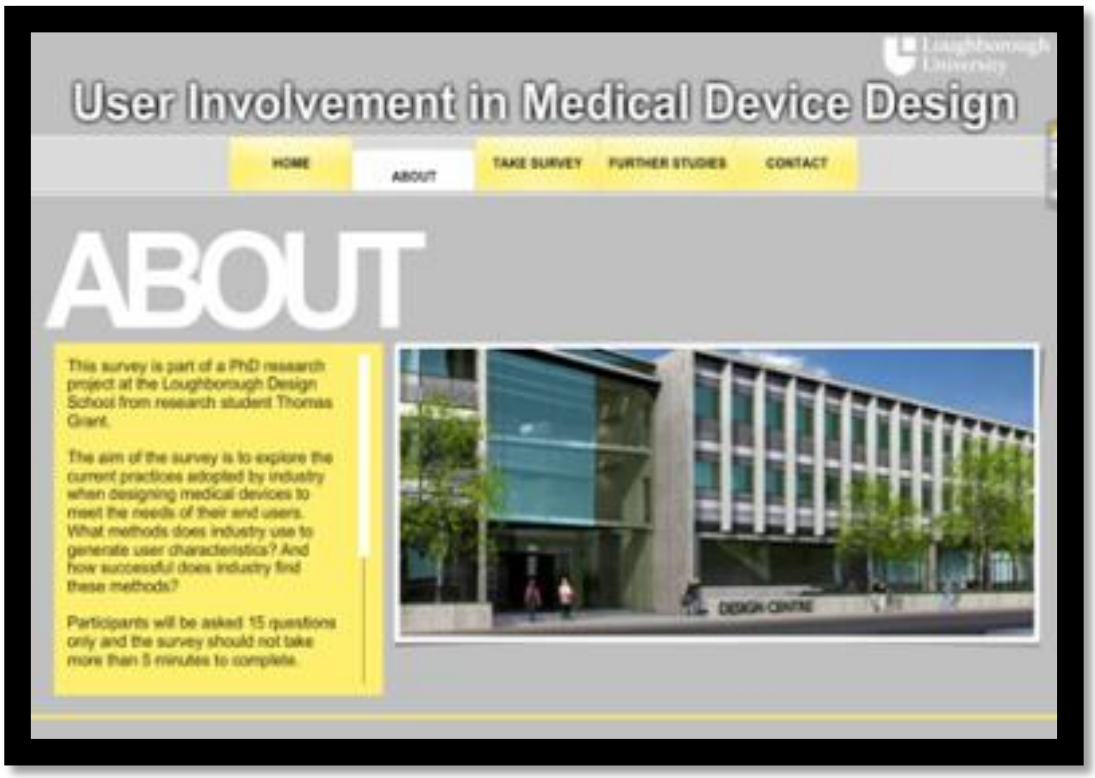
**15. Please provide your name, email and telephone number**

**Name:**

**Email Address:**

**Phone Number:**

## Appendix 4: Survey Website Design



## Appendix 5: Recruitment Email

My name is Thomas Grant and I am a PhD research student at Loughborough University. I am contacting you to ask if you would be interested in contributing to my research by completing a short online survey? The survey will take no longer than **5 minutes** to complete and your responses will be highly valuable to my research.

I have attached a short information sheet (below) that outlines the aims of the study and further details on the research if you are interested.

My research explores user involvement in medical device design and the methods industry use to meet the needs of their end users. I am particularly interested in home use medical device design as I believe this is a market that presents considerable challenges for the future and is an area that will continue to grow. The survey can be accessed at the following link;

www.wix.com/tgrantmail/medicaldevicedesign

I have developed the survey to establish the methods and processes used by industry to design for the needs of their end users. I would like to understand how company's design medical devices to be used in the home environment and the challenges faced throughout the design process.

I am interested to hear from anyone who is involved in the design and development of medical devices, particularly for home use. If you are aware of anyone else who may be interested in contributing to this research please feel free to forward this message onto them. I am keen to get as many responses as possible as this will really benefit my research.

I would like to thank you in advance for your support and I look forward to your response.

Kindest Regards,

Tom

Tom Grant
Research Student
Loughborough Design School, LDS.2.24
Loughborough University, LE11 3TU, UK

Tel +44 (0)1509 226969

**Loughborough Design School** - *Inspiring Design*

www.lboro.ac.uk/lds

## Appendix 6: Participant Information Sheet

Loughborough University

# Understanding the methods and processes used by industry to designing medical devices for the home market and the needs of device users.

**Primary researcher:** Thomas Grant

t.grant2@lboro.ac.uk, (Telephone: 01509 226969 Mobile: 07837942067)

**Supervisors:** Laurence Clift and Richard Bibb

**Introduction**

My name is Thomas Grant and I am postgraduate research student at Loughborough University based in the recently established Loughborough Design School. I am contacting you to ask if you would be interested in contributing to my research by completing a short online survey. The survey consists of 15 questions and will take no longer than 5 minutes to complete.

**Study Rationale**

The modern shift towards home healthcare is attributable to a myriad of factors that will continue to grow in the future. This study forms part of a research project exploring the role of user involvement in medical device design and the methods industry use to meet the needs of their end user's. This study aims to establish the methods and tools used to design for this complex user group and to identify the challenges faced by industry.

**Online Survey**

The online survey can be accessed at the following link:

www.wix.com/tgrantmail/medicaldevicedesign

This site has been developed solely for this study and all the information regarding the research together with the contact details can be accessed here.

**Follow up Interview (Voluntary)**

Once you have completed the survey you will be asked if you would like to take part in a follow up interview. It should be noted that this interview is voluntary but completion of the interview will greatly contribute towards my research. More information on the interviews can be found on the survey website under the 'further studies' tab. If you have any questions regarding any of the research please do not hesitate to contact me.

**Personal information and confidentiality**

All information and results from the survey and interview will be treated confidential. The interview is voluntary and completion of the interview will be taken as your informed consent for the data to be used anonymously – no personal details are required. The views you express in this interview will be documented as your own personal views, and not that of the organisation you work for. The data is confidential but as a participant, if you have any questions or are interested in the overall outcomes of the project, please contact me at t.grant2@lboro.ac.uk or 01509226969.

## Appendix 7: Linked In Recruitment Advertisement

**Thomas Grant** • How does industry design medical devices for the home environment? Survey from Loughborough University.

This survey forms part of a PhD study at Loughborough University that explores industry's approach to designing home use medical devices. The home use market continues to grow and is an area of product development that provides considerable challenges for design.

This survey is intended for anyone involved in the design and development process of medical devices, particularly home use and will take no longer than 5 minutes to complete. The survey can be accessed at the following link:

http://www.wix.com/tgrantmail/medicaldevicedesign

I have developed the survey to establish the methods and processes used by industry to design for the needs of their end users. I would like understand how companies design medical devices to be used in the home environment and the challenges faced throughout the process.

Please take time to visit the link which provides more information about the research. All responses are confidential but if you have any questions please do not hesitate to contact me via the contact page accessed at the same link.

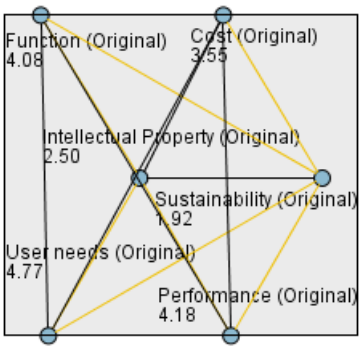
1 month ago

## Appendix 8: Respondent Profiles

| Respondent | Headcount | Turnover (£) | Company Size |
|---|---|---|---|
| 1 | 3000 | 200,000,000 | LARGE |
| 2 | 12 | 2,500,000 | SMALL |
| 3 | 70 | 6,000,000 | MEDIUM |
| 4 | 1 | 125,000 | MICRO |
| 5 | 12 | 1,000,000 | SMALL |
| 6 | 3 | UNKNOWN | MICRO |
| 7 | 8 | 1,000,000 | MICRO |
| 8 | 123 | 12,000,000 | MEDIUM |
| 9 | 2 | 80,000 | MICRO |
| 10 | 2 | 200,000 | MICRO |
| 11 | 3 | CONFIDENTIAL | MICRO |
| 12 | 40 | UNKNOWN | SMALL |
| 13 | 30 | 3,000,000 | SMALL |
| 14 | 9 | UNKNOWN | MICRO |
| 15 | <10 | UNKNOWN | MICRO |
| 16 | 5 | UNKNOWN | MICRO |
| 17 | 11 | 1,300,000 | SMALL |
| 18 | 1 | 40,000 | MICRO |
| 19 | 1 | 50,000 | MICRO |
| 20 | 7 | 250,000 | MICRO |
| 21 | 8 | 2,300,000 | MICRO |
| 22 | 9 | UNKNOWN | MICRO |
| 23 | 120 | 10,000,000 | MEDIUM |
| 24 | 1 | UNKNOWN | MICRO |
| 25 | 2 | 150,000 | MICRO |
| 26 | 120 | UNKNOWN | MEDIUM |
| 27 | 30 | CONFIDENTIAL | SMALL |
| 28 | 2 | 250,000 | MICRO |
| 29 | 1000 | UNKNOWN | LARGE |
| 30 | 30 | 3,000,000 | SMALL |
| 31 | 35-50 | UNKNOWN | SMALL |
| 32 | 10 | £1,500,00 | MICRO |
| 33 | 35 | £5,000,000 | SMALL |
| 34 | 2 | £250,000 | MICRO |
| 35 | 16 | £1,800,000 | SMALL |

## Appendix 9: Pairwise Comparison Results (Drivers for Development)

**Pairwise Comparisons**



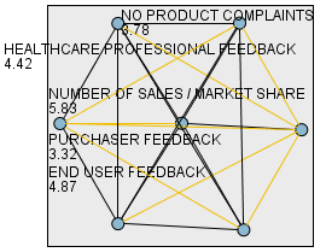

Each node shows the sample average rank.

| Sample1-Sample2 | Test Statistic | Std. Error | Std. Test Statistic | Sig. | Adj.Sig. |
|---|---|---|---|---|---|
| Sustainability (Original)-Performance (Original) | -2.258 | .475 | -4.752 | .000 | .000 |
| Sustainability (Original)-User needs (Original) | -2.855 | .475 | -6.008 | .000 | .000 |
| Sustainability (Original)-Function (Original) | -2.161 | .475 | -4.548 | .000 | .000 |
| Intellectual Property (Original)-User needs (Original) | -2.274 | .475 | -4.786 | .000 | .000 |
| Intellectual Property (Original)-Performance (Original) | -1.677 | .475 | -3.530 | .000 | .006 |
| Sustainability (Original)-Cost (Original) | -1.629 | .475 | -3.428 | .001 | .009 |
| Intellectual Property (Original)-Function (Original) | -1.581 | .475 | -3.326 | .001 | .013 |
| Cost (Original)-User needs (Original) | -1.226 | .475 | -2.580 | .010 | .148 |
| Intellectual Property (Original)-Cost (Original) | -1.048 | .475 | -2.206 | .027 | .411 |
| Cost (Original)-Performance (Original) | -.629 | .475 | -1.324 | .186 | 1.000 |
| Cost (Original)-Function (Original) | -.532 | .475 | -1.120 | .263 | 1.000 |
| Function (Original)-User needs (Original) | -.694 | .475 | -1.460 | .144 | 1.000 |
| Function (Original)-Performance (Original) | .097 | .475 | .204 | .839 | 1.000 |
| Performance (Original)-User needs (Original) | -.597 | .475 | -1.256 | .209 | 1.000 |
| Sustainability (Original)-Intellectual Property (Original) | -.581 | .475 | -1.222 | .222 | 1.000 |

Each row tests the null hypothesis that the Sample 1 and Sample 2 distributions are the same.
Asymptotic significances (2-sided tests) are displayed. The significance level is .05.

# Appendix 10: Pairwise Comparison Results (Measures of Success)

**Pairwise Comparisons**



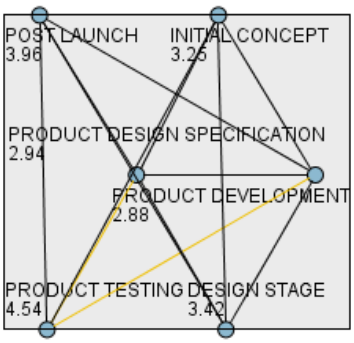

Each node shows the sample average rank.

| Sample1-Sample2 | Test Statistic | Std. Error | Std. Test Statistic | Sig. | Adj.Sig. |
|---|---|---|---|---|---|
| INDUSTRIAL AWARDS-NUMBER OF SALES / MARKET SHARE | -3.983 | .558 | -7.141 | .000 | .000 |
| INDUSTRIAL AWARDS-END USER FEEDBACK | -3.017 | .558 | -5.408 | .000 | .000 |
| PURCHASER FEEDBACK-NUMBER OF SALES / MARKET SHARE | -2.517 | .558 | -4.512 | .000 | .000 |
| INDUSTRIAL AWARDS-HEALTHCARE PROFESSIONAL FEEDBACK | -2.567 | .558 | -4.602 | .000 | .000 |
| INDUSTRIAL AWARDS-FEWER / NO PRODUCT RECALLs / WARRANTY CLAIMS | -2.083 | .558 | -3.735 | .000 | .004 |
| NO PRODUCT COMPLAINTS-NUMBER OF SALES / MARKET SHARE | -2.050 | .558 | -3.675 | .000 | .005 |
| INDUSTRIAL AWARDS-NO PRODUCT COMPLAINTS | -1.933 | .558 | -3.466 | .001 | .011 |
| FEWER / NO PRODUCT RECALLs / WARRANTY CLAIMS-NUMBER OF SALES / MARKET SHARE | -1.900 | .558 | -3.406 | .001 | .014 |
| PURCHASER FEEDBACK-END USER FEEDBACK | -1.550 | .558 | -2.779 | .005 | .115 |
| INDUSTRIAL AWARDS-PURCHASER FEEDBACK | -1.467 | .558 | -2.630 | .009 | .180 |
| HEALTHCARE PROFESSIONAL FEEDBACK-NUMBER OF SALES / MARKET SHARE | -1.417 | .558 | -2.540 | .011 | .233 |
| NO PRODUCT COMPLAINTS-END USER FEEDBACK | -1.083 | .558 | -1.942 | .052 | 1.000 |
| NO PRODUCT COMPLAINTS-HEALTHCARE PROFESSIONAL FEEDBACK | -.633 | .558 | -1.135 | .256 | 1.000 |
| PURCHASER FEEDBACK-FEWER / NO PRODUCT RECALLs / WARRANTY CLAIMS | -.617 | .558 | -1.106 | .269 | 1.000 |
| PURCHASER FEEDBACK-HEALTHCARE PROFESSIONAL FEEDBACK | -1.100 | .558 | -1.972 | .049 | 1.000 |
| END USER FEEDBACK-NUMBER OF SALES / MARKET SHARE | -.967 | .558 | -1.733 | .083 | 1.000 |
| FEWER / NO PRODUCT RECALLs / WARRANTY CLAIMS-END USER FEEDBACK | -.933 | .558 | -1.673 | .094 | 1.000 |
| FEWER / NO PRODUCT RECALLs / WARRANTY CLAIMS-HEALTHCARE PROFESSIONAL FEEDBACK | -.483 | .558 | -.867 | .386 | 1.000 |
| HEALTHCARE PROFESSIONAL FEEDBACK-END USER FEEDBACK | -.450 | .558 | -.807 | .420 | 1.000 |
| NO PRODUCT COMPLAINTS-FEWER / NO PRODUCT RECALLs / WARRANTY CLAIMS | -.150 | .558 | -.269 | .788 | 1.000 |
| PURCHASER FEEDBACK-NO PRODUCT COMPLAINTS | -.467 | .558 | -.837 | .403 | 1.000 |

Each row tests the null hypothesis that the Sample 1 and Sample 2 distributions are the same.
Asymptotic significances (2-sided tests) are displayed. The significance level is .05.

## Appendix 11: Pairwise Comparison Results (Stages of User Involvement)

**Pairwise Comparisons**




Each node shows the sample average rank.

| Sample1-Sample2 | Test Statistic | Std. Error | Std. Test Statistic | Sig. | Adj.Sig. |
|---|---|---|---|---|---|
| PRODUCT DEVELOPMENT-PRODUCT TESTING | -1.654 | .519 | -3.187 | .001 | .022 |
| PRODUCT DESIGN SPECIFICATION-PRODUCT TESTING | -1.596 | .519 | -3.076 | .002 | .031 |
| INITIAL CONCEPT-PRODUCT TESTING | -1.288 | .519 | -2.483 | .013 | .195 |
| DESIGN STAGE-PRODUCT TESTING | -1.115 | .519 | -2.150 | .032 | .474 |
| PRODUCT DEVELOPMENT-POST LAUNCH | -1.077 | .519 | -2.075 | .038 | .569 |
| PRODUCT DESIGN SPECIFICATION-POST LAUNCH | -1.019 | .519 | -1.964 | .049 | .742 |
| DESIGN STAGE-POST LAUNCH | -.538 | .519 | -1.038 | .299 | 1.000 |
| POST LAUNCH-PRODUCT TESTING | -.577 | .519 | -1.112 | .266 | 1.000 |
| PRODUCT DEVELOPMENT-INITIAL CONCEPT | -.365 | .519 | -.704 | .481 | 1.000 |
| PRODUCT DESIGN SPECIFICATION-INITIAL CONCEPT | -.308 | .519 | -.593 | .553 | 1.000 |
| INITIAL CONCEPT-POST LAUNCH | -.712 | .519 | -1.371 | .170 | 1.000 |
| PRODUCT DEVELOPMENT-PRODUCT DESIGN SPECIFICATION | -.058 | .519 | -.111 | .911 | 1.000 |
| PRODUCT DESIGN SPECIFICATION-DESIGN STAGE | -.481 | .519 | -.927 | .354 | 1.000 |
| INITIAL CONCEPT-DESIGN STAGE | -.173 | .519 | -.334 | .739 | 1.000 |
| PRODUCT DEVELOPMENT-DESIGN STAGE | -.538 | .519 | -1.038 | .299 | 1.000 |

Each row tests the null hypothesis that the Sample 1 and Sample 2 distributions are the same.
Asymptotic significances (2-sided tests) are displayed. The significance level is .05.

## Appendix 12: Participant Information Sheet (Interview Study)

# User Involvement in Home Use Medical Device Design. Interview Participant Information Sheet.

**Researcher**
Thomas Grant
Loughborough Design School
Loughborough University
Loughborough
LE11 3TU
T.Grant2@lboro.ac.uk
**Supervisors**
Laurence Clift and Dr Richard Bibb
L.Clift@lboro.ac.uk
R.J.Bibb@lboro.ac.uk

**What is the purpose of the study?**
The modern shift towards home healthcare is attributable to a myriad of factors that will continue to grow in the future. This study forms part of a research project exploring the role of user involvement in medical device design and the methods industry use to meet the needs of their end users'. This study aims to establish the methods and tools used to design for this complex user group and to identify the challenges faced by industry.

**Who is doing this research and why?**
This study is part of a student research project funded by Loughborough University. The research is being conducted by Thomas Grant a postgraduate research student at Loughborough University's Design School under the supervision of Laurence Clift and Richard Bibb.

**Once I take part, can I change my mind?**
Yes! After you have read this information and asked any questions you may have you will be asked to complete an Informed Consent Form, however if at any time, before, during or after the sessions you wish to withdraw from the study please just contact the main investigator. You can withdraw at any time, for any reason and you will not be asked to explain your reasons for withdrawing.

**Will I be required to attend any sessions and where will these be?**
The interview will be carried out at a time and place that is convenient for you. You may be asked if you would be willing to take part in a follow up interview at a later date, however you do not have to do this.

**How long will it take?**
The interview will take approximately 1 hour.

**Is there anything I need to do before the sessions?**
You are required to complete a short 5-10 minute questionnaire prior to the interview. The questionnaire is available online at www.wix.com/tgrantmail/medicaldevicedesign.

**Is there anything I need to bring with me?**
No. There isn't anything specific you are required to bring along with you. You may like to bring a pen and some paper if you would like to make any notes during the interview.

**What will I be asked to do?**
The topics and format of the interview will be explained to you prior to the start. The interview will begin with a few profiling questions about you and then move onto the previous answers you provided in the online survey.
Here the interviewer is just looking for more depth and explanations behind the responses you have already provided. You will be asked to sketch out and briefly described the design process you follow. This does not have to be a precise diagram it is just to identify the key stages involved in your design process.

**Are there any risks in participating?**
No. There are no further risks associated with your participation than can be expected in an office environment.

**Will my taking part in this study be kept confidential?**
Yes! All the information you provide in the interview will be kept confidential. No names, companies or places will be used in any reporting of the data. You data will be stored under a participant number which will be kept separate from any information or documents relating to personal identification.

**What will happen to the results of the study?**
Following the collection of all the data in this study transcriptions and thematic analysis of the data will begin. The data may then be presented anonymously at conferences, in journals and reported in the thesis of this research. As a participant I am happy to provide copies of these documents as and when they are available and if you are interested.

**I have some more questions who should I contact?**
If you have any questions regarding this research please feel free to contact Thomas Grant.

**What if I am not happy with how the research was conducted?**
The University has a policy relating to Research Misconduct and Whistle Blowing which is available online at
http://www.lboro.ac.uk/admin/committees/ethical/Whistleblowing(2).htm.

## Appendix 13: Informed Consent Form (Interview Study)

Loughborough University

# User Involvement in Home Use Medical Device Design

# INFORMED CONSENT FORM

**(To be completed after Participant Information Sheet has been read)**

The purpose and details of this study have been explained to me. I understand that this study is designed to further scientific knowledge and that all procedures have been approved by the Loughborough University Ethical Advisory Committee.

I have read and understood the information sheet and this consent form.

I have had an opportunity to ask questions about my participation.

I understand that I am under no obligation to take part in the study.

I understand that I have the right to withdraw from this study at any stage for any reason, and that I will not be required to explain my reasons for withdrawing.

I understand that all the information I provide will be treated in strict confidence and will be kept anonymous and confidential to the researchers unless (under the statutory obligations of the agencies which the researchers are working with), it is judged that confidentiality will have to be breached for the safety of the participant or others.

I agree to participate in this study.

**Your name** _____

**Your signature** _____

**Signature of investigator** _____

**Date** _____

## Appendix 14: Interview Protocol

# Home Use Medical Device Design Interview Protocol

| | |
|---|---|
| **Participant Number:** | |
| **Online Survey Completed:** | |

**Stage 1 – Interviewee Profile**

| Question | Response |
|---|---|
| **Date of Birth:** | |
| **Job Title:** | |
| **Experience in the position:** | |
| **Highest level of academic qualifications in this field:** | |
| **Any other experience you consider relevant:** | |

**Stage 2 – Survey Analysis**

| **Question 1: Prime drivers for development** | |
|---|---|
| **Response in Survey:** | • **Can you provide more detail?**<br>• **What do you understand by this term?**<br>• **When deciding which projects to go ahead with, who is responsible for that decision?**<br>• **If I can turn to user needs, how do they drive project selection?** |
| **Question 2: Barriers and Challenges** | |
| **Response in Survey:** | • **I'd like to go through each of your responses here and if you can explain to me why this is considered a barrier to user involvement?**<br>• **Can you provide an example of when these scenarios have restricted user involvement?**<br>• **How do you overcome such barriers within your design and** |

| | |
|---|---|
| | development process?<br>• Do you use any formal methods (focus groups, interviews etc.) to help you overcome these barriers?<br>• If you had to choose just 3 barriers from the list you provided what would be the most significant to increasing user involvement in your design process?<br>• What can practicably be done to help overcome these barriers? |
| **Question 3 – Who are your users?** | |
| **Response in Survey** | • How do you identify/create a profile for these users?<br>• What methods do you use to do this?<br>• How does the data/information collected come together to inform the design specification? |
| **Question 4 – Prioritising Users and Input** | |
| **Response in Survey** | • Elaborate further?<br>• At what stage of the process do you include these users?<br>• How are they included?<br>• Can you provide an example of this?<br>• Do they have equal influence on the final design? |
| **Question 5 – The Design Process** | |
| **Response in Survey** | • So to turn to the design process, could you possibly sketch out and briefly describe the stages involved?<br>• Here is an A3 sheet and I would like you to roughly sketch out the process you use from initial concepts to final product. I am not looking for an exact thorough process, rather an indication of the steps involved.<br>• Can you indicate on this process where the users are currently involved?<br>• Could you now indicate any other stages where you would like to involve them but are restricted by the barriers we described earlier? |
| **Question 6 – Design Feedback** | |
| **Response in Survey** | • So what feedback is actually collected from users?<br>• Is user satisfaction feedback |

| | |
|---|---|
| | **actively collected from users?**<br>• **How is this feedback collected?**<br>• **What happens with the feedback?**<br>• **Who collects this feedback?**<br>• **If a user provides insight that could benefit future designs, how does this iterate back into the design process?**<br>• **Do you have any formal methods to collect this data and how are user requirements implemented into design specifications?** |
| **Question 7 – Stage of User Involvement** | |
| **Response in Survey**<br><br>**Initial Concept:**<br><br>**Design Stage:**<br><br>**Product Design Specification:**<br><br>**Product Development:**<br><br>**Product Testing:**<br><br>**Post Launch:** | • **Are you familiar with participatory and co-design?**<br>• **Do you employ these methods in your process?**<br>• **Can you elaborate further?**<br>• **Who makes the decisions on when to involve users within the design process?**<br>• **Why do users become involved at this stage? Why is this different?**<br>• **Are there any formal methods used to include users in the design process?** |

**Stage 3 – Design Approach**

If we turn now to stage 3 of the interview I'd like to talk about some further topics of your design practice. I will apologise now as there will be some slight overlap with the responses you have already made but if you could just provide as much information as possible and any examples it would be much appreciated. So if we could start with the design guidance available. Can you tell me:

| **Topic 1: Design Approach and Guidance** |
|---|
| • Briefly describe the main methods you use to determine the needs of the user(s)?<br>• Do you refer to any guidance documents or material to help you with conducting such work?<br>• Why do you use this resource?<br>• Are you aware of any other resources that are available? If so, why do you not use these resources?<br>• Referring back to the survey responses, could any of these methods be practicably adapted to make the process of determining user requirements easier for you and your design process?<br>• Before we move onto the final section, do you believe there is a need for alternative methods or resources to help with user centred design? If yes, what can practically be done? |

| Topic 2: Design Tools |
| --- |
| • The final topic I want to discuss is design tools. Essentially supportive material that has been developed to make your role easier; be it IDEO method cards, Spidergrams or website resources.<br>• Do you use any design tools in your work?<br>• Can you tell me about the models you have considered and rejected?<br>• Which models have you considered and taken on board or implemented?<br>• Where do you go to find out about such tools?<br>• In your opinion, how could such tools practically be improved to be more effective?<br>• Is there a need for more tools to support user centred design in this field? |

**Stage 4 – Wrap up**

| |
| --- |
| • Thank you very much for your time and allowing me to come and visit you today. I really appreciate your support for my research and all the insights you have provided here today have been extremely valuable.<br>• Do you have any questions for me?<br>• I am still recruiting participants and at present I am short on numbers so can I ask if there is anyone else within your company that might be willing to take part? I would be happy to pay another visit in the future when the time is right.<br>• Do you have any comments in way of feedback that would help me improve my process when conducting future interviews? |

## Appendix 15: Respondent Profiles (Interview Study)

| Participant | Profile |
|---|---|
| **#1** | Gender: Male<br>Age: 30-39<br>Background: Ergonomics<br>Education Level: MSc or Above<br>Job Title: Industrial Designer<br>Experience: 6-10 Years |
| **#2** | Gender: Male<br>Age: 50-59<br>Background: Product Design<br>Education Level: BSc/BA Level<br>Job Title: Managing Director<br>Experience: 16-20 Years |
| **#3** | Gender: Male<br>Age: 50-59<br>Background: Industrial Design<br>Education Level: MSc or Above<br>Job Title: Managing Director<br>Experience: 11-15 Years |
| **#4** | Gender: Male<br>Age: 50-59<br>Background: Mechanical Engineering<br>Education Level: BSc/BA Level<br>Job Title: Director<br>Experience: 6-10 Years |
| **#5** | Gender: Male<br>Age: 50-59<br>Background: Sports Science<br>Education Level: BSc/BA Level<br>Job Title: Big Leader<br>Experience: 0-5 Years |
| **#6** | Gender: Male<br>Age: 40-49<br>Background: Product Design<br>Education Level: BSc/BA Level<br>Job Title: Director<br>Experience: 6-10 Years |
| **#7** | Gender: Male<br>Age: 50-59<br>Background: Biochemistry<br>Education Level: MSc or Above<br>Job Title: Director<br>Experience: 6-10 Years |

| | |
|---|---|
| **#8** | Gender: Male<br>Age: 40-49<br>Background: Ergonomics<br>Education Level: BSc/BA Level<br>Job Title: Director<br>Experience: 26-30 Years |
| **#9** | Gender: Male<br>Age: 50-59<br>Background: Industrial Design<br>Education Level: BSc/BA Level<br>Job Title: Group Leader<br>Experience: 16-20 Years |
| **#10** | Gender: Male<br>Age: 40-49<br>Background: Cognitive Psychologist<br>Education Level: MSc or Above<br>Job Title: President<br>Experience: 6-10 Years |
| **#11** | Gender: Male<br>Age: 40-49<br>Background: Mechanical Engineering<br>Education Level: BSc/BA Level<br>Job Title: Director<br>Experience: 6-10 Years |
| **#12** | Gender: Male<br>Age: 50-59<br>Background: Engineering<br>Education Level: BSc/BA Level<br>Job Title: Freelance<br>Experience: 26-30 Years |
| **#13** | Gender: Male<br>Age: 30-39<br>Background: Industrial Design<br>Education Level: MSc or Above<br>Job Title: Industrial Designer<br>Experience: 0-5 Years |