

**SYMBOLIC AND PRACTICAL FACETS IN THE USE AND
PRODUCTION OF HOME MEDICAL TECHNOLOGY:
THE EXAMPLE OF BLOOD PRESSURE MONITORING**

A thesis submitted for the degree of Doctor of Philosophy

by

Konstantina Vasileiou

Department of Computer Science, Brunel University London

February 2015

Abstract

The value to consider user needs throughout the development of medical devices has been acknowledged in the field of health technology assessment. Yet, user needs are narrowly conceptualised and are mainly examined from an ergonomic perspective. By focusing on the user-device interaction *per se* with a view to detect use errors and to create design solutions that promote intended use, the dominant approach to user needs research fails to adequately elaborate upon symbolic and practice-related dimensions¹ in the user-technology relationship. Moreover, whilst the examination of user needs from a User standpoint is clearly required, it is also crucial to investigate how the medical device industry understands and addresses this issue, since it is these understandings that will eventually be projected onto the technology.

The present research sought to provide a cross-actor account on the issue of user needs by examining the perspectives of two key stakeholders: the users and the medical device manufacturer. Using the example of home blood pressure (BP) monitoring, a qualitative programme of research explored, on the one hand, the process of integrating home blood pressure monitors (HBPMs) into daily life as well as the elements that are conducive to building trust in this technology, and on the other, the practices the medical device manufacturer adopts to capture its users and their needs.

The results suggest that people engage with home BP monitoring in an effort to develop an experiential understanding of their health condition reproducing the dominant discourse around the benefits of self-care. Nevertheless, communicating this practice outside the home was not always without tension since concerns around the ascription of undesired identities were expressed. Home measurements were occasionally performed to check the dependability of technology – arguably an unintended device use – indicating the importance of establishing trust in the artefact. Building trust in HBPMs appeared to be a multifaceted phenomenon that was not limited to the perceived trustworthiness of the technology but implicated a network of other trustworthy relationships with humans,

¹ The term ‘symbolic’ – also employed in the title of this thesis – signifies people’s representations, reasoning and meanings constructed around the *use* or *production* of home medical technology whilst the term ‘practical’ (or practice-related) refers to actions, activities, and routines pertaining to these two aspects .

institutions and technologies. Medium-to-large medical device manufacturers appear to appreciate the value of a user needs-informed approach to medical device development employing a series of routes, more or less direct and formalised, to reach their user. The challenge for the industry is to synthesise the evidential base deriving from individual user studies to create a higher order knowledge base.

Table of Contents

ABSTRACT	ii
TABLE OF CONTENTS.....	iv
LIST OF TABLES.....	x
LIST OF FIGURES.....	xi
LIST OF ABBREVIATIONS.....	xii
ACKNOWLEDGMENTS.....	xiii
PREFACE AND PUBLICATIONS	xv
CHAPTER 1 – INTRODUCTION	1
1.1 Overview.....	1
1.2 Introducing key concepts	1
1.3 Contextualising the problem	3
1.4 Statement of the problem.....	7
1.5 Research objectives and theoretical orientation.....	9
1.6 Using the example of home blood pressure monitoring.....	10
1.7 Overview of methodological approach	11
1.8 Key empirical contributions	13
1.9 Thesis roadmap.....	14
CHAPTER 2 – BACKGROUND LITERATURE REVIEW.....	18
2.1 Overview.....	18
2.2 Section I: Towards a technologically mediated self-care closer to home	19
<i>2.2.1 Conceptualising home and self-care</i>	<i>22</i>
<i>2.2.2 Policy context in the UK around home and self-care</i>	<i>24</i>
<i>2.2.3 On the empirics of home care.....</i>	<i>27</i>
<i>2.2.4 The landscape of technologically mediated self-care practices</i>	<i>28</i>

2.2.5 <i>In summary</i>	33
2.3 Section II: Placing the problem of ‘user needs’ under scrutiny.....	36
2.3.1 <i>Health Technology Assessment (HTA): the development of a policy-oriented research field</i>	36
2.3.2 <i>Users of medical devices: why and how to assess their needs</i>	39
2.3.3 <i>What user needs to assess: taking into account symbolic dimensions of user-device interaction</i>	44
2.3.4 <i>A note on theory in the field</i>	46
2.3.5 <i>Medical device manufacturers: attending to a poorly studied stakeholder</i> ...	48
2.4 Section III: The example of home blood pressure monitoring.....	50
2.4.1 <i>Justifying the choice of home blood pressure monitors</i>	50
2.4.2 <i>A brief history of blood pressure measurement</i>	52
2.4.3 <i>Types of blood pressure monitors</i>	54
2.4.4 <i>Prevalence of hypertension</i>	57
2.4.5 <i>Clinical guidelines, usefulness and prevalence of home blood pressure monitoring</i>	58
2.4.6 <i>Existing research on the experiences of users of home blood pressure monitors</i>	60
2.5 Research objectives and research questions	61
CHAPTER 3 – RESEARCH APPROACH.....	63
3.1 Overview.....	63
3.2 Selecting logic of enquiry and explicating ontological and epistemological commitments.....	63
3.2.1 <i>Situating the present research</i>	68
3.3 Methodological choices	70
3.3.1 <i>Qualitative interviewing</i>	72

3.3.2 <i>A text analytic study of naturally-occurring online discussions</i>	75
3.3.3 <i>Ethnographic case study research</i>	77
3.4 Quality criteria in qualitative research	79
3.5 Exposing the researcher’s ‘footing in the world’: notes on reflexivity	82
3.6 Ethical considerations in research with human participants	85
CHAPTER 4 – EMBEDDING HOME BLOOD PRESSURE MONITORS INTO	
DAILY LIFE: AN INTERVIEW STUDY	87
4.1 Overview	87
4.2 Introduction	87
4.2.1 <i>Domestication theory</i>	90
4.3 Methods	91
4.3.1 <i>Design, study population and sampling strategy</i>	91
4.3.2 <i>Recruitment strategy and data collection</i>	91
4.3.3 <i>Data analysis</i>	93
4.3.4 <i>Participants</i>	94
4.4 Results	95
4.4.1 <i>The phase of appropriation: turning health technology from a commodity to an object of ownership</i>	96
4.4.2 <i>The phase of objectification: displaying health technology within the domestic environment</i>	99
4.4.3 <i>The phase of incorporation: embedding health technology use into temporal structures</i>	101
4.4.4 <i>The phase of conversion: communicating the ownership and use of the health technology to the external world</i>	106
4.5 Discussion	112
5.5.1 <i>Limitations of the present study</i>	114

CHAPTER 5 – HOW DO PEOPLE BUILD TRUST IN HOME BLOOD PRESSURE MONITORS? A QUALITATIVE ANALYSIS OF ACCOUNTS WITHIN ONLINE COMMUNITIES	115
5.1 Overview.....	115
5.2 Introduction	115
5.3 Methods	118
<i>5.3.1 Generating context of the study.....</i>	<i>117</i>
<i>5.3.2 Study design.....</i>	<i>118</i>
<i>5.3.3 Data collection procedure.....</i>	<i>120</i>
<i>5.3.4 Data analysis.....</i>	<i>121</i>
<i>5.3.5 Ethical considerations in Internet-mediated research.....</i>	<i>122</i>
5.4 Results.....	137
<i>5.4.1 Overall positioning towards the trustworthiness of HBPMs.....</i>	<i>122</i>
<i>5.4.2 Shifting trust: from the field of professional care to the scene of home use health technologies</i>	<i>126</i>
<i>5.4.3 Trust in brand</i>	<i>130</i>
<i>5.4.4 Trust in consumer organisations.....</i>	<i>131</i>
<i>5.4.5 Trust in self.....</i>	<i>132</i>
<i>5.4.6 Trust in online community.....</i>	<i>133</i>
<i>5.4.7 Trust in technology.....</i>	<i>134</i>
5.5 Discussion	137
<i>5.5.1 Limitations of the present study</i>	<i>140</i>
CHAPTER 6 – INSIGHTS FROM THE MEDICAL DEVICE MANUFACTURING INDUSTRY: AN ETHNOGRAPHIC CASE STUDY	142
6.1 Overview.....	142

6.2 Medical device manufacturers and user needs: what does existing research tell us?	142
6.3 Methods	145
6.3.1 <i>Gaining insights from ‘inside’: an ethnographic case study design</i>	145
6.3.2 <i>Sources of data collection</i>	146
6.3.3 <i>Data analysis</i>	150
6.3.4 <i>Ethical aspects: balancing competing considerations</i>	151
6.3.5 <i>Describing the case and setting the scene: key features of the organisation</i>	152
6.4 Results	158
Section I: Ways to capture and understand the end-user	158
6.4.1 <i>The role of research</i>	158
6.4.2 <i>Online user reviews</i>	165
6.4.3 <i>Peripheral routes to the end user</i>	167
Section II: Challenges to accessing and understanding the end-users and to serving their needs	174
6.5 Discussion	177
6.5.1. <i>Strengths and limitations of the present study and recommendations for future research</i>	182
CHAPTER 7 – DISCUSSION AND CONCLUSIONS	185
7.1 Synopsis of empirical contributions	185
7.2 Theoretical contributions	189
7.3 Implications of the present findings	190
7.4 Limitations of the present research	189
7.5 Directions for future research	193
7.6 Epilogue: a few reflections on working across disciplinary boundaries	197

REFERENCES	199
APPENDICES	231
APPENDIX A.....	231
APPENDIX B.....	232
APPENDIX C.....	237
APPENDIX D.....	240
APPENDIX E.....	242
APPENDIX F.....	244
APPENDIX G.....	248
APPENDIX H.....	249
APPENDIX I.....	251
APPENDIX J.....	252
APPENDIX K.....	255
APPENDIX L.....	257
APPENDIX M.....	260

List of Tables

Table 2.1 Medical device classification.....	40
Table 2.2 Research questions of the present thesis.....	60
Table 3.1 Logics of enquiry in social sciences.....	69
Table 4.1 Recruitment sites.....	92
Table 4.2 Characteristics of participants (<i>N</i> = 18).....	94
Table 4.3 Device characteristics.....	95
Table 5.1 Classification of online communities.....	120
Table 6.1 Details of key informants participating in ethnographic interviews.....	145

List of Figures

<i>Figure 1.</i> Structure of the thesis.....	17
<i>Figure 2.</i> The landscape of healthcare from self to professional care.....	34
<i>Figure 3.</i> The landscape of self-care.....	35
<i>Figure 4.</i> Spectrum of medical device evaluation.....	39
<i>Figure 5.</i> User-centred design approach (from ISO 13407: 1999 and ISO 9241 210:2010).....	42
<i>Figure 6.</i> Capturing the user throughout the medical device development process (NPSA, 2010, p. 25).....	44
<i>Figure 7.</i> Stephen Hales (seated) measures the blood pressure of a horse (drawing by Cuzzo, 1944).....	52
<i>Figure 8.</i> Karl von Vierordt’s sphygmograph.....	53
<i>Figure 9.</i> Robert Ellis Dudgeon’s wrist sphygmograph.....	53
<i>Figure 10.</i> Riva-Rocci sphygmomanometer.....	54
<i>Figure 11.</i> Mercury (left) and aneroid (right) manual sphygmomanometers.....	55
<i>Figure 12.</i> Upper arm (a), wrist (b) and finger (c) automated, spot-check blood pressure monitors and ambulatory BP measuring device (d).....	56
<i>Figure 13.</i> Perceptual hierarchy of BPMs in terms of their perceived accuracy.....	125
<i>Figure 14.</i> Communication pathway to the end-user.....	166
<i>Figure 15.</i> Directness and formalisation of the routes to the end user.....	178

List of Abbreviations

BP: Blood Pressure
BMI: Body Mass Index
BHS: British Hypertension Society
DTC: Direct-to-consumer
EMEA: Europe, Middle East, Africa
EPO: European Patent Office
ESH: European Society of Hypertension
FDA: Food and Drug Administration
GDP: Gross Domestic Product
GP: General Practitioner
HTA: Health Technology Assessment
HBPM: Home blood pressure monitor
IT: Information Technology
IMDRF: International Medical Device Regulators Forum
ISO: International Organisation for Standardisation
MDD: Medical Device Development
MATCH: Multidisciplinary Assessment of Technology Centre for Healthcare
NHS: National Health Service
NICE: National Institute for Health and Care Excellence
BPSA: National Patient Safety Agency
OTA: Office of Technology Assessment
OTC: Over-the-counter
QA/RA: Quality Assurance & Regulatory Affairs
STD: Sexually Transmitted Disease
TAM: Technology Acceptance Model
UCD: User-centred Design
WHO: World Health Organisation

Acknowledgements

First and foremost, I would like to express my deep gratitude and thanks to my first PhD supervisor, Professor Julie Barnett, for her continuous support, apt advice, and valuable encouragement throughout my research. This project would not have been completed without her intellectual guidance, inspiration, and constructive comments and discussions. Moreover, and equally important, I would like to express my special appreciation to Prof Julie Barnett for being my mentor and for creating a fruitful space of professional socialisation. Her attitude and engagement with research have been stimulating and exemplary to me and I am greatly indebted for improving my skills, enriching my research experience, and above all, for gaining confidence in constructing an identity of researcher. Thank you very much Julie!

Further, I would like to express my sincere gratitude and thanks to Professor Terry Young, my second PhD supervisor, who made a significant contribution to my research. Prof Terry Young was always willing to support this research both intellectually and practically, offering his best suggestions and guidance. His insights and comments always provided novel angles and generated constructive dialogue. Thank you very much indeed Terry!

I also wish to thank the *Engineering and Physical Sciences Research Council* (EPSRC) which funded my doctoral studies through the *Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH)* programme (EP/F063822/1 and EP/G012393/1).

This research would not have been possible without the invaluable contribution of the people who willingly took part in my studies. I would like to specially thank all my participants who very kindly shared their thoughts and experiences with me. I am also deeply grateful to the medical device manufacturer who hosted me for four months and helped me to conduct my ethnographic work. I am particularly indebted to the marketing department of the organisation, and especially to my line Manager and the Manager of diagnostics and treatment, for offering a welcoming, comfortable, and professionally stimulating environment. Thank you very much!

My sincere thanks also go to Mr Peter Taylor whose guidance, advice and support during the process of negotiating my secondment to the medical device manufacturing organisation was invaluable. I also want to thank him for helping me pilot my interview study. I have also greatly benefited from the interactions with the academics, researchers and other PhD students belonging to *MATCH Project III: User needs*. Our regular meetings were particularly constructive through the exchange of ideas and the feedback I received.

I would also like to offer my special thanks to my friends and colleagues for their moral support throughout this process. Sharing common experiences with Dr Konstantina Spanaki, George Ioannou, George Xydopoulos, and Dr Anastasia Anagnostou made PhD life more enjoyable.

Last but not least, I would like to deeply thank my parents, Panagiotis and Eleni, and my sister, Maria, for their constant support and encouragement. Nothing would have been achieved if my family did not have faith in me.

Thank you so much!!

Preface and publications

This research was supported from the *Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH)* funded by the Engineering and Physical Sciences Research Council (EPSRC). MATCH conducted research in the field of health technology assessment (HTA) by bringing together expertise from various fields such as health economics, engineering and social sciences. The present research project was part of the MATCH subdivision that focused on user needs considerations throughout the medical device development process. By conducting primarily case studies the *User Needs* project aimed to advance our understanding of user considerations and to develop methods and tools that capture the user perspective in ways that could be fruitfully utilised by the medical device manufacturing industry.

Publication in peer-reviewed journals

Vasileiou, K., Barnett, J., & Young, T. (2013). Interpreting and acting upon home blood pressure readings: A qualitative study. *BMC Family Practice, 14*, 97.

Poster presentations

Vasileiou, K., Barnett, J., & Young, T. (2012, June). *Making sense of and acting upon home blood pressure readings: A qualitative study*. Poster session presented at the MATCH Conference, Birmingham, UK.

Vasileiou, K. Barnett, J., & Young, T. (2013, June). *Medical device manufacturers and general practitioners' perspectives on board: Progress on the case of home blood pressure monitors*. Poster session presented at the MATCH Conference, London, UK.

CHAPTER 1 – INTRODUCTION

1.1 Overview

Chapter 1 introduces the reader to the present research providing an overall picture of the thesis. Key concepts and a concise contextualisation of the set of problems that were investigated are initially presented followed by the identification of the research problem and the statement of research objectives. A succinct presentation of the methodological approach that was adopted is then outlined followed by a brief discussion of the main empirical contributions. Chapter 1 closes with a graphic depicting the structure of this thesis.

1.2 Introducing key concepts

Modern healthcare systems are inextricably linked with medical technologies. Technological developments have contributed considerably to improved diagnosis, monitoring and treatment of diseases offering medical competencies that were impossible or even inconceivable in the past; they have transformed, and indeed continue to transform, medical practice and patient outcomes in remarkable ways. According to an early definition provided by the US Office of Technology Assessment (OTA) (1976), medical technology is “the set of techniques, drugs, equipment, and procedures used by healthcare professionals in delivering medical care to individuals and the systems within which such care is delivered” and “includes all elements of medical practice that are knowledge-based, including hardware (e.g., equipment and facilities) and software (e.g., knowledge and skills) (p. 4).

Medical devices constitute an important category of health technologies which is characterised by an enormous degree of diversity, ranging from simple products such as wound dressings and contact lenses to highly sophisticated equipment such as MRI scanners, pacemakers and implantable defibrillators. According to the representative body of the European medical device manufacturing industry (Eucomed, 2013), the sector produces around 500,000 different medical technologies. Medical devices are also a product group that is intensely overseen and regulated at a national and international level

due to their safety-critical nature. At the same time, the medical device industry is a highly innovative sector that contributes to economies; in 2012, for example, more than 10,000 patent applications were filed with the European Patent Office (EPO) which amounts to approximately 7% of the total number of applications, a percentage that exceeded any other technical field (Eucomed, 2013).

Whilst a plethora of medical devices are commonly developed for, and used within, traditional clinical settings by experienced healthcare professionals, medical technologies for home use are increasingly gaining momentum (Bitterman, 2011) alongside broader shifts in healthcare organisation and provision (Cartier, 2003; Williams, 2002), clinical needs (e.g. rise of chronic, non-communicable diseases) (Daar et al., 2007; Yach, Hawkes, Gould, & Hofman 2004), and people's abilities and preferences concerning the management of health and illness. Indeed, the market of home medical devices is expected to grow considerably in the near future with some market research data suggesting an above average annual growth of around 7%². Home medical devices include a variety of technologies from the well-established pregnancy tests and thermometers, assistive equipment such as wheelchairs and walking aids, and self-testing kits such as glucose meters, to more complex artefacts such as oxygen cylinders. More recently, mobile healthcare applications (i.e. 'apps') have been added to the array of home health technologies (Carrera & Dalton, 2014) whilst if tele-health and tele-care equipment was additionally considered, the list expands even further.

In consideration of the rapid proliferation of home medical devices, regulatory responses have started to consolidate around this area in the past few years. For example, the US Food and Drug Administration (FDA) announced in April 2010 the *Medical Device Home Use Initiative* (FDA, 2010) whereby the rationale around the regulation of home medical equipment was outlined. A further regulatory response came the same year with the publication of the International Standard *Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment* (IEC 60601-1-11). To conform to this standard, manufacturers must provide evidence of risk assessment and

² Research and Markets (2010) [cited in UL, 2012]. *Home healthcare equipment: an overview*. Retrieved from: www.frost.com/prod/servlet/cpo/251073197

mitigation of identified risks, as the latter derive from the use of the device in uncontrollable settings – such as the home – by untrained users (i.e. lay persons).

The FDA (2010) defined home medical equipment “as a device intended for users in a non-clinical or transitory environment, which is managed partly or wholly by the user, requires adequate labelling for the user, and may require training for the user by a healthcare professional in order to be used safely and effectively” (p. 3). Clarification and expansion of the meaning of ‘home use’ was also provided to include “all environments [beyond home *per se*] in which a person plans to use his or her medical device in day-to-day life” (p. 4). The focus of the present thesis lies on home medical technologies and espouses the conceptualisation provided by the FDA to refer to health technologies used typically by non-experts in a non-clinical setting.

1.3 Contextualising the problem

Defining home medical technology is clearly an important task for purposes of delineating the object of interest. But it is also crucial to locate home use medical technologies within the broader landscape of shifts in healthcare organisation and related policy initiatives and to simultaneously shed light on people’s increasing engagement with technologically-mediated self-care practices.

The rapid spread of home health apparatus (Carrera & Dalton, 2014; Gibbons & Ward, 2011; Ryan, Wilson, Greenfield, Clifford, McManus, & Pattison, 2006) and the attendant rise of technologically-mediated home and self-care practices (Ronda, Portegijs, Dinant, Buntinx, Norg, & van der Weijden, 2009; Ryan, Wilson, & Greenfield, 2010; Wilson et al., 2008) are situated against a background of significant structural and operational shifts in healthcare organisation and care provision in advanced economies. From the 60s onwards, healthcare systems have gradually undergone a process of service decentralisation shifting care closer to home and community settings (Cartier, 2003; Williams, 2002). Driving forces, such as the considerable increase of an ageing population (Bloom, Boersch-Supan, McGee, & Seike, 2011; Christensen, Doblhammer, Rau, & Vaupel, 2009; Eurostat, 2013), the growth of chronic, non-communicable diseases (Daar et al., 2007; Yach et al., 2004), the push from constant technological developments in the field (Bitterman, 2011; Herman, 2001; Herman & Devey, 2011), the economic pressures that healthcare systems encounter

under tight public budgets (de la Maisonneuve & Martins, 2013), and the consolidation of individualistic notions such as autonomy, choice, and empowerment as values, have all been recursively implicated in the current healthcare system shifts.

Policy initiatives during the last few decades reflect, and simultaneously reinforce, the decentralisation of care provision and the rise of home and self-care. In the UK, explicit commitments and efforts to realise these visions appeared with the turn of the century (Department of Health [DoH], 2000). British governments started to place home and self-care at a prominent position within their healthcare agenda advocating both patient and cost-related benefits. But whilst for policy cycles the re-organisation of care closer to home presents several advantages as it is viewed to assign more power to patients and to achieve efficiency (e.g. DoH, 2005a; 2006a; 2008), some scholars adopt a more sceptical stance towards these transformations. First, it has been noted that the advocated ‘patient empowerment’ is part and parcel of greater individual responsibility and of hidden ‘health work’ gradually delegated from the healthcare system to patients, aspects that are less often explicated (Veinot, 2010; Wyatt, Harris, & Wathen, 2010). It has been further suggested that the focus on individual responsibility progressively weakens, in collective consciousness, the importance of the social contract that was agreed after the World War II for a universal, free at the point of care, healthcare service funded through taxation. Ultimately, scholars have raised the concern that the current shifts will gradually lead to the retreat of the state’s duty to provide universal, publicly-funded care (at least with regards to those countries, such as the UK, which historically have structured their healthcare service on such a financing model) (Pollock, Price, & Roderick, 2012; Pollock, Price, Roderick, & Treuherz, 2012; Pollock & Price, 2013).

Research evidence shows that an appreciable minority of the public does espouse the idea of self-care and engages with relevant activities entailing health technologies either proactively to prevent and diagnose health conditions or reactively to monitor and manage disease (Greenfield, Pattison, & Jolly, 2008; Ickenroth, Ronda, Grispen, Dinant, de Vries, & van der Weijden, 2010; Ronda et al., 2009; Ryan et al., 2010; Wilson et al., 2008). For some this might take place within an opportunistic context (e.g. ‘street corner tests’) but for others the acquisition of home medical equipment which will facilitate self-care activities is

purposive and actively planned and sought (Ickenroth, Grispen, Ronda, Tacken, Dinant, de Vries, & van der Weijden, 2011; Ryan, Ives, Wilson, & Greenfield, 2010).

The degree of connectedness of self-care practices to the healthcare provider varies; doctors might have recommended self-care in some instances and indeed provide the medical equipment, but also self-care might have been initiated by lay people themselves without reference to any medical advice and without necessarily communicating it back to the doctor. Indeed, qualitative research demonstrates that people sometimes perceive these practices as illegitimate and as something that should not be disclosed (Ryan et al., 2010). In terms of motivations, self-care is commonly embedded within a positive stance towards health maintenance and is seen to provide convenience, privacy and anonymity though occasionally it is enacted against feelings of discontent with healthcare professionals or the system more broadly (Ryan et al., 2010).

Finally, it has been argued that the engagement with home use health technologies is largely a reassuring experience for the lay person, though an occasional inertia to follow-up problematic results has been noted in the literature as a worrisome aspect (Ickenroth et al., 2011; Ickenroth et al., 2010). Faith and trust in the feedback provided by the medical equipment varies with some studies (Ickenroth et al., 2011) suggesting a high level of confidence and face value acceptance whilst others (Vasileiou, Barnett & Young, 2013) indicate a more complex picture involved in the meaningful interpretation of results that entails considerable ‘health work’ on the part of the lay user, characterised by high degrees of provisionality and tentativeness.

Alongside the rapid proliferation and omnipresence of medical technologies in modern times, there has been a corresponding increase in the control and surveillance of the process of technology production and implementation with a view to maximise the *value* of technology (Lehoux, Williams-Jones, Miller, Urbach, & Tailliez, 2008; Young & McClean, 2008) for implicated actors (e.g. patients, carers, healthcare professionals), healthcare systems, and society at large. Part of the societies’ response to the need for more surveillance and control was the development of a multidisciplinary policy research field around *Health Technology Assessment* (HTA) that aimed to “examine the short- and long-term social consequences (e.g. societal, economic, ethical, legal) of the application or use of technology” (Office of Technology Assessment, 1976, p. 45) in order to build the evidential

base that was needed for sound decision-making. It is interesting that the roots of the HTA can be traced back in the late 60s whereby discussions around the then newly developed – and very expensive at the time – computer tomography scanner were taking place concerning the extent to which the enthusiastic adoption of the technology by hospitals was justifiable from an evidential point of view (Lehoux & Blume, 2000).

Despite the fact that the programmatic objectives of the HTA were set up to evaluate medical technology from a multifaceted perspective, ranging from techno-scientific considerations, such as cost-effectiveness, to societal, ethical and user-related aspects, in practice the field largely concentrated its evaluative attempts on aspects of technology effectiveness and efficiency shrinking the other facets of valuation (Lehoux & Blume, 2000; Lehoux, Tailliez, Denis, & Hivon, 2004). Nevertheless, more recently this deficiency has been acknowledged and several efforts have been made to bring to the forefront both the societal-ethical angles more broadly (Lehoux & Williams-Jones, 2007) and the perspectives of the technology user more specifically (Facey, Boivin, Gracia, Hansen, Lo Scalzo, Mossman, & Single, 2010; Facey & Hansen, 2011; Grocott, Weir, & Ram, 2007; Shah, Robinson, & AlShawi, 2009).

Regarding the evaluation of medical technologies from a user standpoint, important steps have been taken to not only include these actors *after* the production of the technology – as routinely happens with HTA programmes in several countries – but also to incorporate their input *prior* to technology production. To that end, researchers in the *Multidisciplinary Assessment of Technology Centre for Healthcare*³ (MATCH) – a research collaboration based in the UK – have played a crucial role in advocating the incorporation of user needs from *early on* and *throughout* the medical device development (MDD) process (Martin, Murphy, Crowe, & Norris, 2006; Martin, Norris, Murphy, & Crowe, 2008; Shah & Robinson, 2007) whilst also developing tools to assist the medical device manufacturing industry to implement the principles of a user-centred design approach⁴.

Indeed, the necessity to account for user needs at certain stages of the MDD process is also recognised by regulatory bodies worldwide (e.g. FDA, 2011; Harmonised European Standards EN 62366:2008 & EN 60601-1-6:2010) and is reflected in International

³ <http://www.match.ac.uk/>

⁴The tools that MATCH has produced: http://www.match.ac.uk/tools_and_guides.php

Standards (IEC 62366: 2007; IEC 60601-1-6: 2010). From a regulator's point of view, the accommodation of user needs is understandably framed in relation to use-related risk minimisation, a focus which is of course very important given the safety-critical nature of medical devices. Nevertheless, producing medical devices that will be acceptable, satisfying and will provoke sustainable use necessitates a more encompassing conception of the User that takes into account socio-psychological needs and lay reasoning.

1.4 Statement of the problem

Undoubtedly, *usability considerations* within the MDD process have now acquired not simply a legitimate position but one that is increasingly seen to create value (Lehoux et al., 2008) for both the user and the medical device manufacturer as the chances for commercially successful products increase. Nevertheless, usability and related user needs research have been primarily conceived and conducted from an ergonomic approach (Martin et al., 2006; Martin et al., 2008). Ergonomists mainly concentrate their efforts on improving the device use-related safety and effectiveness and on reducing potential use errors. The primary objective is thus to contribute to the creation of design solutions that promote proper and intended device use by accommodating user preferences and needs.

Clearly, the development of medical devices from an ergonomic point of view is crucial. However, this approach is poorly placed to articulate and account for socio-psychological 'user needs' that extend beyond the immediate and focused user-device interaction to include the symbolic content that is implicated, recursively constructed, and constantly evolved around and beyond this interaction. In other words, the human factors approach fails to consider what the meaning of using a medical device is, how this might shape identity, and how technology is incorporated within the routines of daily life, might transform them and be shaped by them. In this sense, the needs of user within the ergonomic field are narrowly conceived despite the existence of evidence suggesting that the 'interpretative work' the user does in relation to medical technology, attendant practices, and the self are important components for understanding processes of technology acceptance, rejection, use, misuse and transformation alongside configurations of the user, delineation of responsibilities and construction of identities (Money, Barnett, Kuljis, & Lucas, 2013; Lehoux, Saint-Arnaud, & Richard, 2004; Thomson, Martin, & Sharples,

2013; Timmons, Harrison-Paul, & Crosbie, 2008). Building on this body of literature, the present research sought then to attend more closely to these socio-psychological aspects. Specifically, it examined how home use medical technologies become part of daily life and what meanings are ascribed, what sort of identities are claimed and enacted or potentially threatened (Breakwell, 1983), and how trust in medical equipment is built (Siegrist, 2000; Timmons et al., 2008).

The need to widening the scope of ‘user needs’ to encompass socio-psychological aspects is evident if our understanding of the user perspective was to be improved. Indeed, the value of such an approach might become even more salient for the field of home use medical equipment whereby this sort of user considerations have been little addressed. Nevertheless, an exclusive focus on end-users alone limits our ability to better conceive and understand the *user perspective* from a point of view that takes into account the ways other key actors in the arena understand ‘user needs’. Indeed, the perspective of the medical device manufacturing industry around user needs considerations is a critical one (Privitera & Murray, 2009) since the user conceptions held by manufacturers are eventually inscribed into the technological artefacts to a greater or lesser extent. Madeleine Akrich (1992) expressed this point when she suggested that “we cannot be satisfied methodologically with the designer’s or user’s point of view alone. Instead we have to go back and forth continually between the designer and the user, between the designer’s projected users and the real users, between the world inscribed in the object and the world described by its displacement” (pp. 208 - 209). Therefore, the present research, noting the often one-sided treatment of the phenomenon of interest from the perspective of a single stakeholder – either the user or the manufacturer – attempted instead to explore simultaneously both stakeholders in order to provide an enriched, *cross-actor* account that might eventually enable a widening of the lens deployed to comprehend the issue of ‘user needs’. In other words, the present work sought to enhance our understanding of ‘user needs’ at two levels: a. by examining socio-psychological aspects implicated in the user-device relationship as these are experienced and articulated by users themselves and b. by incorporating the construction of user and user needs from the point of view of the medical device manufacturer.

The exploration of the manufacturer perspective, as it was conducted in the present thesis, comes to fill some important deficits in our existing knowledge. Specifically, though the existing research with medical device manufacturers is not particularly extensive, the few empirical studies that have been conducted in the field focus on Small and Medium size Enterprises (SMEs) (e.g. Money, Barnett, Kuljis, Craven, Martin, & Young, 2011) and academic spin-offs (e.g. Lehoux, Daudelin, Williams-Jones, Denis, & Longo, 2014; Martin & Barnett, 2012). By contrast larger medical device manufacturers, who have more resources and organisational experience, have hardly been approached. Further, most empirical work is based on cross-sectional interview studies (for a few exceptions see Miller, Sanders, & Lehoux, 2009; Ram, Grocott, & Weir, 2007) which preclude an examination of the details of the routines the industry has developed to capture the end-user. Thus the present research endeavour, recognising the importance for a closer and longer-term exploration, adopted an ethnographic case study approach to document ‘from inside’ the manufacturer’s attempts to account for user needs during the MDD process.

In summary, the present thesis examined user needs considerations from the perspectives of two key actors: the users themselves and the manufacturer. It did so in order to provide a multi-sided account around the subject matter, and focused on angles that are less satisfactorily attended to in the literature. In the next section, the research objectives are stated and the theoretical orientation and assumptions of this work are also explicated.

1.5 Research objectives and theoretical orientation

With regards to the *user* perspective, this research had two objectives: (1) to examine how lay users integrate into their daily life, and make sense of, home medical devices and what challenges (if any) they encounter and (2) to investigate how people come to trust home medical equipment. In terms of the *manufacturer* standpoint, the present work aimed to observe and document the details of the activities and approaches that the medical device manufacturer employs to understand the user and to examine the potential challenges the industry faces along this way. Three empirical investigations were conducted to pursue these objectives, two implicating the user and one the manufacturer.

Broadly, the present programme of research was informed theoretically from insights offered by a stream of social scientific perspectives that have attempted to overcome, on the

one hand, technological determinism, and on the other, essentialist conceptions of the user (Oudshoorn & Pinch, 2003). Specifically, insights from semiotic approaches to users (Woolgar, 1990; Akrich, 1992), cultural and media studies (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992) and the approach of social construction of technology (Pinch & Bijker, 1984) shaped much of the theoretical thinking that is present in this thesis. A basic axiomatic assumption that runs across this work as a common thread is that the relationship between users and technology is deeply dialectical (Timmermans & Berg, 2003) and always immersed within a broader network of social relationships with other people and objects. Users and technologies are seen to be co-constituted through an ongoing process of interaction whereby users have the potential to define and use technologies in multiple ways (i.e. interpretive flexibility) beyond those envisioned or intended, but simultaneously the technologies have the power to configure users in certain ways. In essence, both technology use and production – the two sides of the same coin as these were studied in this research across the two key actors – are viewed as practices that are inherently social (Shove, Pantzar, & Watson, 2012) and cannot be isolated from their immediate and broader context (Greenhalgh & Swinglehurst, 2011).

1.6 Using the example of home blood pressure monitoring

Home blood pressure monitors (HBPMs) were selected as an example of home use medical technology around which the issues of interest were investigated. Home blood pressure (BP) monitoring is predominantly used to detect and diagnose hypertension and to monitor the progress of the condition in patients under treatment. Research shows that home BP monitoring is clinically useful (Agarwal, Bills, Hecht, Light, 2011; Cappuccio, Kerry, Forbes, & Donald, 2004; Verberk, Kroon, Kessels, & de Leeuw, 2005) leading medical professional organisations to recommend its official adoption in clinical practice (e.g. National Institute for Health and Care Excellence [NICE], 2011). Home BP monitoring also appears to be well accepted by patients (Aylett, Marples, & Jones, 1999; Little, Barnett, Barnsley, Marjoram, Fitzgerald-Barron, & Mant, 2002) whilst an appreciable minority of the general public have self-tested their blood pressure (McManus, Ryan, Greenfield, Pattison, Clifford, Marriott, & Wilson, 2007) suggesting that lay people do occasionally engage with this self-care activity.

Two main reasons prompted the choice of this technology. First, HBPMs typify a medical technology that gradually migrates from the clinical setting to the home environment, reflecting in this way the shift of care closer to home. Though the value of home BP measurements started to be explored in 1940 (Ayman & Goldshine, 1940), it is only recently in the UK that home BP monitoring is officially considered as a legitimate and necessary adjunct to office measurements (NICE, 2011). Against the background of this recognition, it is likely that the use of HBPMs will increase in the future.

Second, home blood pressure monitoring has wide relevance since the condition with which it is most strongly associated, namely hypertension, affects a significant percentage of the population which is likely to further increase in the future as the epidemiological evidence suggests (Kearney, Whelton, Reynolds, Muntner, Whelton, & He, 2005). Therefore, it is expected that the results of the present research will be useful and applicable to a considerable number of people.

1.7 Overview of methodological approach

A qualitative programme of research was designed and conducted for the purposes of the present work. Investigating the phenomena of interest using qualitative approaches was in line, on the one hand, with the nature of the research questions (i.e. questions of *how* and *what* focusing on people's experiences and activities from their own standpoint) (Willig, 2013), and on the other, with the broader ontological and epistemological commitments characterising this research endeavour (Coyle, 2007).

The empirical investigations presented in this thesis are part of an *abductive logic of enquiry* which according to Blaikie (2000) characterises distinctively the social sciences. In the abductive logic of enquiry the focus is on the accounts, meanings and experiences that people provide in relation to their social world and in this sense this mode of scientific investigation is closely aligned with *interpretivism* (Bhattacharya, 2008). Within an interpretivist paradigm, the research efforts concentrate on the detailed, in-depth and context-sensitive examination of the phenomena and seek to generate *plausible* explanations deriving from, and grounded in, people's accounts and their meaning-making processes as they engage with their day-to-day affairs. Therefore, in terms of ontological assumptions, the present research accepts axiomatically that people's experiences, views

and activities are meaningful and legitimate elements of social reality warranting scientific examination on their own.

To examine the *user* perspective and to pursue the research objectives 1 and 2, two qualitative investigations were undertaken: one interview-based study with users of HBPMs and one observational study of naturally-occurring discussions around this medical technology as generated within the context of online communities. Qualitative, semi-structured interviews allowed the researcher to gain an in-depth understanding of the processes of acquiring, using, and communicating the ownership and deployment of home use medical technology as these were articulated in users' accounts. The study was informed theoretically by the domestication framework (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992), yet attention was also paid to any themes that might derive inductively from the data, being thus sensitive to any material the users themselves might bring into the discussion. Qualitative interviewing as a method of data collection was conceived to be a way of learning about the phenomenon of interest. Nevertheless, the phenomenon was not considered to be precisely reflected since the performative function of language (Burr, 1995) and the interactive and situated nature of the interview context are acknowledged to play a role in shaping the versions of reality produced in people's accounts (Miller & Glassner, 2004).

The qualitative analysis of the online discussions around HBPMs was conducted to complement the qualitative interviews and augment our understanding of the *user* perspective. Fuelled by a consideration of the nature of the topics that people might spontaneously discuss around the technology when there is no research intervention, and thus no research agenda imposed, the analysis of online forums revealed the range of elements which contribute to the construction of trust in medical technology. Utilising the capabilities afforded by the Internet for communication and extension of human interactions (Hewson, Yule, Laurent, & Vogel, 2003), this study principally conceptualised this medium as a *tool* through which potentially useful research material can be accessed (Markham, 2004).

The final empirical study reported in this thesis, which sought to address the third research objective, sheds light on the perspective of *the medical device manufacturer*, an important stakeholder implicated in the medical device development and the attendant

evaluation of user needs. To this end, a 4-month ethnographic case study was conducted within a leading manufacturer in the field of blood pressure monitoring devices. The ethnographic approach enabled the researcher to gain an understanding ‘from inside’ (Hammersley & Atkinson, 2007; Bloor & Wood, 2006; Emerson, Fretz, & Shaw, 2011) around the activities with which a medium-to-large manufacturer engages in order to account for user needs considerations during the development of a new HBPM. By deploying multiple methods of data collection such as participant observation, ethnographic interviews and analysis of documentary material, this study aimed to achieve a detailed and plausible insight, yet rounded and sensitive to the singularities of the case and its context.

1.8 Key empirical contributions

The studies that examined the user perspective revealed useful insights around how people integrate HBPMs into their daily life and how they come to trust this home use medical technology. The findings from the interview study with users of HBPMs suggest that people were motivated to acquire a HBPM in order to gain a first-hand and experiential understanding of their health condition that increased their sense of self-efficacy and control over their health. Importantly, whilst home BP monitoring was mostly seen to assist and complement the role of healthcare professionals, in a few instances the decision to buy the monitor came to replace or to ‘audit’ professional care against a background of lost trust and scepticism towards healthcare professionals.

The duration and frequency of device use primarily depended on the health condition and its progress, but there was also some evidence that the practice of monitoring failed to be sustained – despite the existence of clinical need – due to distrust towards the dependability of technology or doubts around the practical ability to capture blood pressure accurately within the routines of real life. Alongside the routine monitoring schedule that users had progressively developed and established, an unstructured pattern of device use was also reported when people sought to examine whether certain somatic sensations related to their BP variations. Interestingly, an additional device use was articulated when people took measurements to check the dependability of the technology and the accuracy of their readings, especially during the early stages of owning and interacting with the technology, indicating that users did not accept the technology at face value. Indeed, and as

the analysis of the online forums showed, building trust in HBPMs was a multifaceted, dynamic and contingent phenomenon that did not merely implicate the usage and perception of the technology but also a series of other trustworthy relationships with other humans (e.g. health professionals), one's self and abilities, other technologies, organisations, and abstract systems of expertise.

Finally, whilst the acquisition of the home health technology endorsed, at a private level, a self-image of a responsible person who takes control over his/her health, this identity had to be negotiated when the ownership of the device and the practice of home monitoring were communicated outside the domestic environment. Users sometimes expressed concerns that they would be ascribed with undesirable identities, such as 'hypochondriac' or 'paranoid' if they drew much attention to the practice of self-monitoring and occasionally they felt that they had to negotiate the legitimacy of this practice with their doctor.

Turning to the findings from the ethnographic case study that was conducted within a medium-to-large medical device manufacturer, this research suggests that there was a clear appreciation of the value of a user needs-informed approach to the MDD process. User needs research throughout the MDD played a central role in the manufacturer's efforts to capture and understand its user. Apart from user needs research, the manufacturer deployed additional routes to reach and understand its user, such as product reviews on the Internet, aggregate reports of user complaints, or information about the user coming from other actors in the field (e.g. product distributors; doctors). All these pathways helped the organisation to concretise the user in order to come closer to the 'man on the street'. On the basis of the degree of directness and formalisation that characterised the various pathways to the user, an analytical framework of 'user embodiments' was developed suggesting a *reflected, represented, mediated*, and an *imagined user*. The user thus came into being in various forms and shapes and in one form or another was a constant presence in the MDD process.

1.9 Thesis roadmap

The present thesis consists of seven chapters.

Chapter 1 introduced the reader to the present research providing an overall picture of the thesis.

Chapter 2 aims to provide a solid base for the conduct of the present research by critically reviewing the relevant literature. Initially, the broader context within which the phenomena of interest unfold is illustrated by discussing the shift of care closer to home and the rise of technologically mediated self-care practices. Then, the area of medical technology evaluation is developed with a particular focus on user needs considerations. Relevant research is presented and poorly-attended aspects are highlighted. Chapter 2 closes with the introduction and discussion of the home medical device that was selected as an exemplar in this work, namely, home blood pressure monitors (HBPMs). The (re)statement of the research objectives and questions concludes the chapter.

Chapter 3 describes the methodological approach that was employed to pursue the research objectives. The broader ontological and epistemological commitments are initially explicated and justified followed by an overall introduction to the particular methodological choices that were made. Then, the issue of evaluating qualitative research is discussed and linked to the present work and some reflections on the researcher's positioning are noted. Chapter 3 concludes with a discussion of the broader ethical stance that was espoused in the conduct, management and presentation of this research.

Chapter 4 presents the first empirical study that was undertaken with users of HBPMs in order to address the first research objective. Existing research on the experiences and perspectives of users of HBPMs is initially examined and the theoretical framework that informed the reported work is then presented. The chapter then proceeds with a detailed presentation of the methods and results of the study and concludes with a critical discussion of the findings.

Chapter 5 moves to the second piece of empirical work which again focused on the user perspective and aimed to address the second research objective. The literature around the issue of trust in medical technologies is first reviewed followed by a detailed description of the methods of the study. The results of the analysis of the naturally-occurring discussions around HBPMs within online communities are then presented and the chapter closes with the interpretation and discussion of the findings.

Chapter 6 turns to the second key stakeholder, namely the medical device manufacturer, and describes the empirical investigation that sought to address the third research objective. In the beginning, the existing evidence around the ways the medical device industry tries to understand the user is reviewed and the gaps in our knowledge are identified. Then the methods employed are reported along with a detailed presentation of the case that was studied. A presentation and critical discussion of the findings then follow and conclude the chapter.

Chapter 7 summarises and synthesises the empirical contributions of the present research and provides a discussion of their theoretical significance. The chapter concludes with identifying the limitations of the present work and with suggesting avenues for future research.

Figure 1 provides a pictorial illustration of the structure of the thesis and maps the research objectives to the respective empirical chapters.

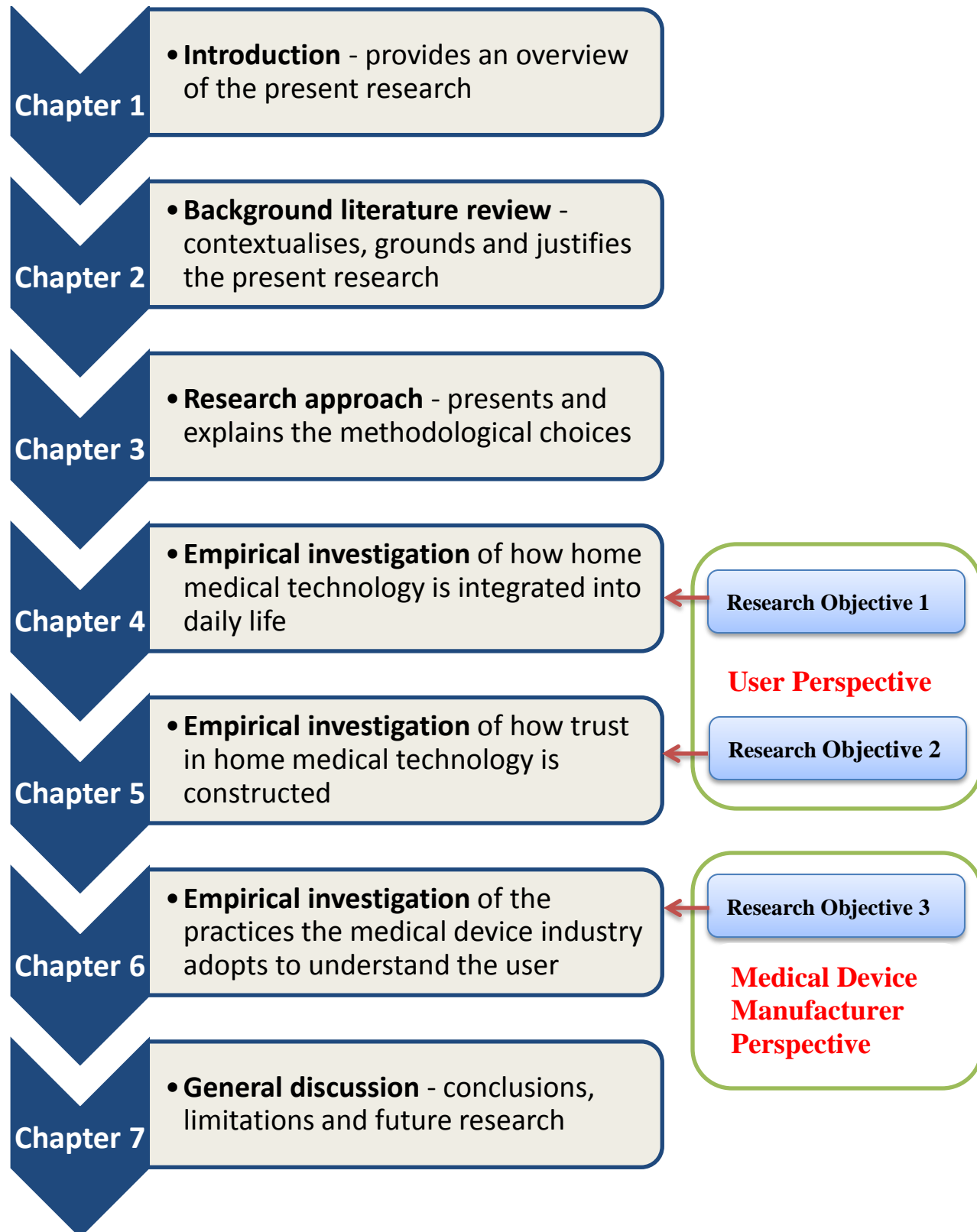


Figure 1. Structure of the thesis.

CHAPTER 2 – BACKGROUND LITERATURE REVIEW

2.1 Overview

Chapter 2 seeks to build a solid foundation for the conduct of the present research. It does this by locating the present work within the context of previous literature in order to highlight the main areas of interest, identify the gaps in existing research and justify the necessity of the work undertaken in this thesis.

This chapter consists of three main sections. *Section I* sets the broader scene within which the topics of interest are situated and unfold. Specifically, the gradual transition of contemporary healthcare systems towards a decentralised model of care provision that takes place closer to home and emphasises the importance of self-care is outlined and the underlying driving factors are presented. A conceptualisation of home and self-care is then provided and the policy context within the UK is reviewed. Section I closes with some empirical evidence around the nature and ‘epidemiology’ of home and self-care practices that are mediated by technology.

Section II introduces and develops the set of problems surrounding the needs of users of medical technologies. Specifically, it outlines the development of the field of *Health Technology Assessment* (HTA) within which the examination of medical devices user needs is embedded. Then, it introduces the legal context regulating the development and application of medical devices, and explains why user needs should be taken into account throughout the medical device development process and how user needs research has been primarily conceptualised within existing literature. The angles of user needs that have attracted less attention are then highlighted and their importance is stressed. A note on theoretical considerations is also provided. Finally, section II seeks to incorporate in the discussion the perspective of a key stakeholder who is less well-voiced, namely the medical device manufacturer. The insufficiencies in existing evidence regarding the activities that medical device manufacturers perform in order to understand their user are determined.

Section III proceeds to justify the selection of home blood pressure monitors (HBPMs) as an example of medical technology on the basis of which the topics of interest were

investigated. A short history of blood pressure monitoring is offered along with a presentation of the major types of this technology. Epidemiological evidence of hypertension is then outlined and the usefulness, prevalence and related clinical guidelines on home BP monitoring are presented. Finally, the literature that examines the user perspective and experiences is reviewed.

Following the aforementioned contextualisation, chapter 2 concludes with the statement of the research objectives and concomitant research questions that orchestrated the development and conduct of the present investigation.

2.2 Section I: Towards a technologically mediated self-care closer to home

Healthcare organisation has undergone major structural changes during the last decades, reshaping substantially the landscape of care provision as this was configured, established and became known in advanced industrialised countries throughout the 20th century. The gradual decentralisation of services and the concomitant shifting of care from hospital closer to home (Cartier, 2003; Williams, 2002) along with the emphasis on self-care and the rise of relevant movements and initiatives (e.g. Expert Patient Programme in the UK) are among the most profound transitions. Although self, home and community care are not new phenomena since they constituted the main care models till the end of 19th century (Herman, 2001), the current shift has taken place against the background of a unique constellation of material capabilities, demographic changes, healthcare needs, economic demands, and discursive resources. More specifically, the interconnected factors that are commonly associated with the aforementioned transitions are as follows:

- *Demographic changes:* Most developed countries around the world encounter the reality, but also the challenge, of an increasingly ageing population. The striking increase in life-expectancy over the course of the previous century, the declining birth rates, and the ageing of the post Second World War ‘baby boom’ generations, which now reach retirement, have all been considered to account for this demographic shift (Bloom et al., 2011; Christensen et al., 2009; Eurostat, 2013).
- *Growth of chronic diseases:* Epidemiological evidence documents the epidemic growth of chronic and/or non-communicable diseases around the world (Daar et

al., 2007; Yach et al., 2004). According to the World Health Organisation (2011), 63% of global deaths in 2008 were the result of chronic diseases such as cardiovascular disease, diabetes, chronic respiratory diseases, and cancer. Indeed, the burden of chronic disease does not any longer afflict only high-income countries (Anderson & Horvath, 2004; Busse, Blümel, Scheller-Kreinsen, & Zentner, 2010), whereby a shift from infectious and communicable diseases to chronic pathologies has been marked, but it also increasingly affects low and middle-income countries (Dans, Ng, Varghese, Shyong Tai, Firestone, & Bonita, 2011). Since many chronic conditions are related to life-style and other modifiable risk factors, such as high blood pressure, smoking, unhealthy diet, sedentary lifestyle and physical inactivity, the efforts to tackle this health challenge are largely oriented towards raising public awareness, prevention and early detection (Daar et al., 2007; Busse et al., 2010). Simultaneously, the necessity of realigning and adjusting healthcare systems, traditionally structured around acute care, so as to be responsive to the needs of chronic care is also highlighted (Yach et al., 2004). As a result, the emphasis is gradually placed on the strengthening of primary care services, whilst secondary care is seen to play an auxiliary role (Hunter, 2008).

- *Economic pressures:* The rising costs of healthcare spending, combined with a tight fiscal climate more broadly, pose severe pressures on national economies and public budgets. Across developed countries, the public care and long-term care expenditure has increased on average by 3.5 percentage points of gross domestic product (GDP) during the last four decades, and is estimated to further increase by 3.3 to 7.7 percentage points between 2010 and 2060 (de la Maisonneuve & Martins, 2013). Under these economic strains and scarcity of resources healthcare systems worldwide are called to operate more efficiently to ensure viability.
- *Technological advances:* Technological developments have allowed the emergence of a plethora of medical innovations that contribute to the expansion of home and self-care capabilities now available to people (Herman, 2001). Medical devices for lay use, usually within the home environment, hold a prominent position enabling people in an unprecedented manner to detect,

monitor and manage their health status (Lewis, 2001). The FDA, using the results of an expert-based study, forecasted that decentralised care technologies, with primary examples those of home and self-care devices, as well as detection, diagnostic and monitoring technologies, are among those areas of technological development that are more likely to lead to innovation in the future (Herman & Devey, 2011). Despite the challenges that the particularities of both the lay user and the non-clinical environment of device use pose (Bitterman, 2011), home and self-medical equipment is commonly thought to confer certain advantages for the lay person such as convenience, privacy, independence and control.

- *Patient autonomy, self-determination and empowerment:* The notions of autonomy, self-determination, control, choice, independence and empowerment often dominate the public discourse around health and emerge as important elements of care provision and organisation. Home and self-care are commonly located within, and linked to these discourses, and simultaneously are seen to constitute a primary scene for the realisation of these aspirations (Tarricone & Tsouros, 2008). The value of patient empowerment and engagement is further intensified when it comes to people who suffer from chronic health conditions allowing for self-management programmes and initiatives to be advocated and develop extensively (Bodenheimer, Lorig, Holman, & Grumbach, 2002). Though the aforementioned notions are often promoted as self-evident values to be celebrated and sought, scholars have questioned whether individual choice and autonomy are necessarily translated to ‘healthy’ decisions (Wyatt et al., 2010). To what extent and how people want to be ‘empowered’ is also an empirical question. Ultimately, what is less often articulated within the rhetoric of choice, autonomy and empowerment is the greater responsibility that is gradually assigned to individuals, away from collectives, (Veinot, 2010; Wyatt et al., 2010) and the considerable but often hidden ‘health work’ (e.g. seeking for health information, taking care of family members early discharged from hospitals etc.) that people are required increasingly to perform (Bella, 2010).

Arguably, the health reforms in developed countries are not independent from broader societal, economic and political arrangements. The healthcare changes that favour

decentralised care models, foster market-oriented principles such as competition and privatisation, and privilege the discourses of individual choice and autonomy have been seen as expressions of the prevalence, in the arena of social policy, of a set of ideas known as neoliberalism. Neoliberalism is based on the three basic principles of *individualism*, *free market* - via privatisation and deregulation - and *decentralisation* (McGregor, 2001) and assumes that free markets are able to “regulate themselves in order to create social justice” (McGregor, 2001, p. 85). State intervention should be minimal and should primarily ensure that the market works the way it is assumed to work.

Healthcare policies reflecting neoliberal ideals were forcefully implemented in several European countries after the 2007 banking crisis in an effort to reduce national debts and public spending. This has led to what some scholars called ‘healthconomic crises’ due to adverse public health consequences resulting from the implementation of austerity measures and public budget cuts (Callum & Mahiben, 2013). In England, the recent Health and Social Care Act 2012 has paved the way for a radical restructuring of the National Health Service (NHS) which, according to some views, opens the door to marketisation (i.e. through decentralisation and privatisation of services) and to the retreat of the state-funded, universally-provided healthcare service (Pollock, Price, & Roderick, 2012; Pollock, Price, Roderick, & Treuherz, 2012; Pollock & Price, 2013). Though an efficiency-focused rationale commonly lies behind the changes, scholars argue that these justifications are not always sufficient and that the reform primarily stems from a political choice (Pollock & Price, 2013).

2.2.1 Conceptualising home and self-care

Self-care: Self-care is certainly not a new phenomenon but one that characterises human conduct across all of human history (Levin, 1976). People have always taken some form of action to combat illness and maintain health. What seems to be new though, during the last decades, is a growing interest in self-care emerging within research, practice and governmental health policy cycles.

Self-care has been referred to as ‘a movement, concept, framework, model, theory, process or phenomenon’ (Gantz, 1990, p. 2) revealing the complexity of the notion. Though there is no widely accepted definition of self-care in academic literature (Godfrey,

Harrison, Lysaght, Lamb, Graham, & Oakley, 2011), as conceptualisations are often tied to different disciplines and theoretical approaches and are simultaneously shaped by social, political and economic forces (Wilkinson & Whitehead, 2009), the concept has been broadened considerably in its evolution over the last 40 years (Godfrey et al., 2011). According to a recent definition provided by the World Health Organisation (WHO, 2009), ‘self-care is the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a healthcare provider’ (p. 17).

This definition encompasses both proactive, that is preventive, health-maintaining and health-enhancing behaviours and reactive forms of self-care, the latter aiming to restore health or to manage chronic health conditions (Ziguras, 2004). It is also noteworthy in the aforementioned definition that self-care practices are not only restricted to the individual level, but they can also extend to include the family and community levels. In corroboration of this point, a recent content analysis of the definitions of self-care which were proposed the last four decades showed that current conceptualisations tend to embrace facets of *care by others* (e.g. self-care assisted by others) and *care of others* (e.g. parents taking care of their ill child) in addition to the commonly enunciated *care of self* (Godfrey et al., 2011). Finally, according to the aforementioned definition, self-care does not necessarily imply non-involvement from healthcare professionals and distancing from the formal healthcare delivery systems, but it can be seen as a set of actions that can be performed in a collaborative manner under professional support. Though this is true, at least at a rhetorical level, it has been argued that the current state-funded promotion of self-care increasingly cultivates the idea of individual responsibility and weakens the expectation that healthcare is a collective good to be secured and provided universally by states (Wyatt et al., 2010).

Home care: Home care, commonly provided by family members in an informal way, was traditionally the dominant care model before the institutionalisation of healthcare and the advent of large-scale organisations, such as hospitals, during the 20th century. Yet with the emergence of opposing forces supporting the de-institutionalisation and decentralisation of care from the 60s onwards, home care once again came to the forefront, this time under new terms (Tarricone & Tsouros, 2008). Given these historical pathways, it is perhaps not surprising that home care is often defined in contradistinction to institutional care;

according to a definition provided in the dictionary of public health (Last, 2007), home care is “the medical, nursing, or other health-related care of ill, infirm, or disabled persons in their own homes as contrasted with care that is provided in an institutional setting, such as a hospital or nursing home”.

Though home care is largely conceived to be bound to people’s private dwellings, an expansion of the term that would allow the inclusion of settings (e.g. related to work, leisure) - other than home - in the larger community where people normally reside and function in their daily life has been advocated (Kane, 1995). This broadening of the concept would respectively enable the expansion of home care services that are likely to be offered by formal healthcare delivery systems (e.g. assistance with shopping).

Home care encompasses a wide variety of care activities that can range from primary prevention and satisfaction of individual needs (e.g. physical, psychosocial) to palliative care in terminal conditions. For this reason, it has been suggested that home care is better understood as an umbrella term under which diverse care practices are entailed (Thomé, Dykes & Hallberg, 2003). Formal home care may involve a broad spectrum of health and allied professionals such as doctors, nurses, therapists, home care assistants, and social workers who are either state or privately funded. Informal home care, that is unpaid care provided primarily by family members, continues to be the pillar of home care provision (Tarricone & Tsouros, 2008).

2.2.2 Policy context in the UK around home and self-care

In the UK, the emphasis on self-care and on the necessity to shift the balance towards a re-organisation of healthcare provision that takes place closer to home started to become concrete in governments’ visions and policy makers’ healthcare reform plans at the turn of the 21st century. In 2000, the Department of Health (DoH) published *The NHS plan: a plan for investment, a plan for reform*, in which the vision and commitment to design a health service that places the patient at the centre was declared. Self-care, supported by the NHS, constituted one of the core priorities in this reform plan as “most healthcare starts with people looking after themselves and their families at home” (DoH, 2000, p.18). At the same time, a focus on strengthening intermediate care that would “build a bridge between

hospital and home” was highlighted so as people can “recover and resume independent living more quickly” (DoH, 2000, p.20).

The Wanless report *Securing our future health: taking a long-term view*, which was published in 2002, explicitly stated the importance of self-care in contributing to the achievement of a sustainable and high-quality healthcare system that will respond to the changing health needs of current and future generations. Self-care was seen to epitomise the kind of partnership which the public should be encouraged to develop with the healthcare system in the effort to promote and maintain health and well-being and to manage health conditions. Considerable cost benefits were also estimated to arise from the increased engagement of the public with self-care activities. In parallel, the Wanless report (2002) emphasised the need to provide care, especially for older people, at community-based settings such as health centres, intermediate care facilities and people’s own homes. Immediately after the publication of the Wanless report, the British government at the time announced its plans for health reform in the *Delivering the NHS plan: next steps on investment, next steps on reform* (DoH, 2002).

A further commitment to home and self-care was expressed in *The NHS improvement plan: putting people at the heart of public services* (DoH, 2004a). A move towards a more personalised care that will take place closer to home was declared, along with a focus on prevention that would “transform [the NHS] from a sickness service to a health service” (p. 10). Information Technology (IT) was also acknowledged as an important tool for the realisation of decentralised care (i.e. telecare, telehealth) especially for people with chronic conditions. The White paper *Choosing health: making healthy choices easier* (DoH, 2004b) further emphasised the significance of self-care not only in the management of chronic conditions but also in prevention so as people are enabled to develop their “own personal health guides” (p. 112).

Policy documents that exclusively addressed self-care started to being promulgated by the DoH in 2005. *Self-care - a real choice; self-care support - a practical option* (DoH, 2005a) was the first document to explain in detail the rationale behind the propulsion and support of self-care and proposed practical steps towards the attainment of this vision. Indeed, the same year a baseline survey was published documenting how the public feels and thinks about self-care and to what extent people engage with self-care practices (DoH,

2005b). This survey suggested that although the public shows a generally high awareness about, and positive attitudes towards, self-care, this did not always coincide with actual engagement (DoH, 2005b). One year later a best practice guidance was published that applied self-care specifically to the needs of people managing chronic health conditions (*Supporting people with long term conditions to self-care – A guide to developing local strategies and good practice*; DoH, 2006a). An “integrated package” of self-care was seen to materialise through the provision of four basic elements which would bring benefits not only to the patient but also to the healthcare system. These elements were the following:

- Self-care information,
- self-monitoring and diagnostic devices,
- self-care skills, education and training, and
- self-care support networks.

The shift towards a decentralised care model grounded on self-care and care closer to home was also evident in the White paper *Our health, our care, our say: a new direction for community services* (DoH, 2006b) whereby the British government restated its commitment to these policies. In the process of working on the actualisation of the commitments declared in the aforementioned command paper, a best practice guidance document was then published to share the most promising ways through which the *Care Closer to Home Framework* could be applied (*Delivering Care Closer to Home: Meeting the Challenge*; DoH, 2008).

A further wave of transformations in the English healthcare system came with the formation of the Coalition Government assuming its duties in May 2010. Two months later, the White paper *Equity and excellence: liberating the NHS* (DoH, 2010) announced the reforms which were needed in the NHS in order to place “patients at the heart of everything we do” (p. 1). An extensive restructuring of the care organisation was laid out in this document that aimed to help patients and the public have more choice and control over their health and to empower NHS staff – primarily frontline healthcare professionals - to act more autonomously in the performance of their duties. Eventually, the arguably controversial *Health and Social Care Act 2012* passed to the primary legislation of the country many of the NHS reforms presented in the 2010 White paper. Much of the spirit of

these latest reforms continues to reflect and reproduce the foundational shifting – already taking place during the last 15 years – towards a decentralised care model, grounded on the notions of individual choice, autonomy, and control.

2.2.3 On the empirics of home care

In Europe, most of home care is provided informally by family, relatives and friends (Suanet, Van Groenou, & Van Tilburg, 2012) and there is considerable variation across countries around the organisation of formal home care provision depending on the extent of welfare state (Genet, Boerma, Kringos, Bouman, Francke, Fagerström, Melchiorre, et al. 2011). In the UK, home care is provided either by state funded local authorities, the independent sector (i.e. private and voluntary sector) or by hiring a home care assistant deploying personal resources⁵. In the last 25 years, the provision of state funded home care has declined and has been progressively limited to critical cases, whilst the provision by the independent sector has grown considerably (Humphries, 2013). At the same time, an incremental number of people self-fund their own home care, with some estimates suggesting that around 70,000 older people arrange home care using their own means (Humphries, 2013). In England, 485,000 adults of all ages received publicly funded home care in 2012-2013 while the respective numbers in 2011-2012 were 517,000 and 543,000 in 2010-2011 (Health and Social Care Information Centre, 2013a & 2013b; UK Home Care Association, 2013).

Similarly, in North American countries home and community care have gained momentum. In Canada, for example, healthcare is increasingly being provided in a series of settings away from hospitals (Coyte & McKeever, 2001). Home healthcare has risen during the last three decades and its role is anticipated to become even more important in the future (Canadian Healthcare Association, 2009). Data from the 2009 Canadian Community Health Survey show that 1 in 4 people over 65 years old – which equates to just over 1 million individuals – have used some sort of formal or informal (i.e. family, friends, neighbours) home care services (Hoover & Rotermann, 2012). In US, an estimate of 12 million people currently receives formal community-based care from home health and

⁵ NHS Choices (former NHS Direct) - <http://www.nhs.uk/CarersDirect/guide/practicalsupport/Pages/Homecare.aspx>

hospice care providers (National Association for Home Care & Hospice, 2010). This estimate presents a considerable increase in homecare recipients compared to 2000 when the respective number was 7.2 million patients. The majority of these patients is aged over 65 years old and often suffers from a multitude of chronic conditions (Caffrey, Sengupta, Moss, Harris-Kojetin, & Valverde, 2011).

The concept of home care commonly connotes the care of older people who suffer from chronic or terminal conditions. Though private dwellings are the main scene of home care, the same notion is sometimes used to refer to care taking place at community settings (e.g. nursing homes, residential care homes). In this thesis, the term home care is used more loosely to signal caring activities performed by lay people themselves outside clinical settings. Their purpose can range from maintenance of health and prevention of illness to the management and cure of health conditions. In this sense, home care overlaps conceptually with self-care and therefore the two terms are used interchangeably.

2.2.4 The landscape of technologically medicated self-care practices

One facet of proactive and reactive self-care, performed outside traditional clinical settings and usually within the home environment, entails the usage of diagnostic, monitoring and therapeutic devices, kits, tests and tools by lay people themselves (DoH, 2005a). Some well-established examples of home health technologies include:

- thermometers
- pregnancy tests kits
- cholesterol test kits
- nebulisers
- home blood pressure monitors
- blood glucose measuring devices
- home oxygen cylinders
- self-testing devices of oral anticoagulation, and
- medical equipment used by people with disabilities such as hearing aids, walking aids, and wheelchairs (Medicines and Healthcare Products Regulatory Agency [MHRA], 2014).

The technologies might have been provided by the formal healthcare system or alternatively purchased by people themselves with or without prior professional advice. A systematic search of self-testing kits on the Internet, available to citizens in the UK, identified 104 unique tests that claimed to diagnose or screen 24 health conditions such as cancers, cardiovascular disease, acute or chronic infections. These self-testing technologies required bodily material from users while their purchase and use did not necessitate the participation of a healthcare professional (Ryan et al., 2006). Gibbons and Ward (2011), examining the availability in the UK of online tests for Sexually Transmitted Diseases (STDs) – including HIV – identified 92 unique websites which offered 221 products testing for 12 STDs. Tests for chlamydia were the commonest, followed by HIV tests. It should be noted here that most of these direct-to-consumer tests were not marketed as having any regulatory approval.

Direct-to-consumer (DTC) or over-the-counter (OTC) genetic testing is an additional health technology that has recently proliferated, despite the surrounding debate about the extent and the nature of regulation that should be put in place (Hauskeller, 2011; Hogarth, Javitt, & Melzer, 2008; Prainsack, Reardon, Hindmarsh, Gottweis, Naue & Lunshof, 2008; Direct-to-consumer genetic testing, 2012). These tests can be used to diagnose or predict heritable diseases, assess the risk of disease recurrence and guide treatment decisions based on individual genetic profiles (Hogarth et al., 2008). Twenty-six companies were identified in 2008 advertising DTC genetic testing (Hogarth et al., 2008) and around half of them – with parallel appearance of new companies – continued to operate in 2012 (Saukko, 2013). As far as the general public is concerned, increasing levels of awareness around DTC genetic testing have been observed. A nationally representative survey in US, for example, found a statistically significant growth in the public awareness between 2008 (29% of the population) and 2011 (37%) (Finney-Rutten, Gollust, Naveed, & Moser, 2012). General practitioners in the UK are also alert to the possibility of increasingly encountering patients who are willing to perform or have already performed DTC genetic testing (Rafi et al. 2009).

A further set of technological advancements that has been recently added to the array of home health technologies are the so-called mobile health (mHealth) tools. mHealth tools leverage contemporary mobile communication and information technologies, such as

smartphones and tablets, and consist of medical applications (widely known as ‘apps’) and smartphone plug-in and add-on devices (Carrera & Dalton, 2014). Some market research data indicate that at the moment there are more than 100,000 mHealth apps available, most of which target people with chronic conditions and people interested in health and fitness (Research2guidance, 2014). The market revenue in 2013 was 2.4bn USD and the projected revenue by the end of 2017 was estimated to reach 26bn USD (Research2guidance, 2014). Amid of the vast expansion of mHealth tools, the FDA issued, in 2013, a guidance document to industry communicating the regulator’s thinking around which of those technologies meet the definition of a medical device and how accordingly they will be overseen and regulated (FDA, 2013).

The range of self and home medical equipment would not be complete if tele-health and tele-care innovations were not mentioned briefly. *Tele-health* equipment enables remote exchange of health-related information between the patient who is located at home and the healthcare professional for diagnostic, monitoring and management purposes. *Tele-care* refers to the remote monitoring of people in order to manage the risks of independent living (e.g. falls) (Goodwin, 2010; Sanders, Rogers, Bowen, Bower, Hirani, Cartwright, Fitzpatrick, et al. 2011). Tele-health and tele-care technologies are provided by the formal healthcare system in the effort to redesign the health service in consideration of the challenges posed by current healthcare needs. In the UK, the implementation of tele-health and tele-care has been at a pilot and small-scale level thus far (Goodwin, 2010). Nevertheless, a recently conducted large-scale trial (i.e. Whole System Demonstrator programme) is expected to inform decisions about the widespread roll-out of these technologies (Steventon, Bardsley, Billings, Dixon, Doll, Hirani, Cartwright, et al. 2012).

Clearly, the range of self-care technologies available to the public is constantly increasing. But how many people are actually using these technologies and what are their characteristics, motivations and experiences? A recent survey in the UK demonstrated that about 1 in 11 women and 1 in 19 men have used a self-testing kit after excluding pregnancy tests and blood pressure monitoring devices (Ryan et al., 2010). The most frequently reported self-test was for diabetes, followed by tests for urine infection and cholesterol. When self-testing for high blood pressure was analysed separately, it was found that 1 in 8 women and 1 in 9 men have used a blood pressure monitor (Ryan et al., 2010). The self-

testing devices had either been purchased by users themselves or had been accessed to through their working or social environment, whilst the purchase and/or the use of the self-test did not require any involvement from healthcare professionals, though the latter had sometimes recommended it.

Similarly, a cross-sectional survey in the Netherlands that examined the prevalence of self-tests, which required sample of body material, found that 16% of respondents had used at least one self-test. Self-testing kits for diabetes and cholesterol were again the most commonly used and the average number of the technologies used across self-testers was 2.1. Self-testers were more likely to be older, to have higher Body Mass Index (BMI) and to suffer from a chronic condition or to perceive their health as being poor compared to non-testers. At the same time, self-testers were more likely to embrace a health-oriented lifestyle such as eating more healthily (e.g. avoid fat, use supplements) or adopting homeopathic medicine (Ronda et al., 2009). The same survey was repeated two years later showing a slightly raised percentage of self-testers, that is 18.1%. Self-tests for diabetes, kidney disease, cholesterol, urinary tract infection, chlamydia and HIV/AIDS were the most popular (Ickenroth et al., 2010).

Moreover, a community survey in England revealed that around 1% of the population have used a cancer-related self-testing technology while 36% of participants declared that they would consider to use one in the future (Wilson et al., 2008). Among coronary heart disease patients, a questionnaire study in the UK demonstrated that 23% had used a self-testing device, with HBPMs being the commonest. A belief in individual responsibility and in the importance of adopting a holistic stance towards health significantly predicted the use of technologies (Greenfield et al., 2008).

Research shows that people who engage with self-care practices are likely to have a specific socio-demographic profile. A systematic review of the factors that are associated with several forms of self-care activities among adults in the UK – such as the use of OTC medicine, complementary and alternative medicine and self-testing devices – showed that being a female, middle aged, with higher socio-economic and/or educational status, and facing some sort of health problem were all linked to self-care (Ryan, Wilson, Taylor, & Greenfield, 2009). Other research has shed light on the psychosocial determinants of self-test use. A cross-sectional, internet survey among Dutch self-testers and non self-testers

showed that the perceived benefits of self-tests and increased levels of self-efficacy predicted the use of health kits testing for glucose, cholesterol and HIV (Grispen, Ronda, Dinant, de Vries, & van der Weijden, 2011).

Qualitative research (Ickenroth et al., 2011; Ryan et al., 2010) has sought to enrich our understanding on why and how people decide to perform a self-test and to clarify the nuances of the lay experience. An interview-based study among self-testers in the UK revealed a rather complex picture. Concerning motivations, people engaged with self-tests either speculatively and out of curiosity, usually within an opportunistic framework, or because they wanted to check and diagnose a specific condition, in which case they had actively acquired the technology. For some participants performing a self-test was embedded within a broader positive attitude towards health, but importantly for others self-testing was linked to negative experiences with healthcare professionals. The benefits of performing a self-test were convenience, privacy, anonymity and avoidance of, or justification for, booking a GP consultation. Finally, whilst self-tests were experienced as empowering tools, in other instances they were perceived as illegitimate and as something that should not be communicated to the doctor (Ryan et al., 2010). Similarly, a qualitative study among self-testers in the Netherlands showed, on the one hand, the opportunistic character of self-testing (e.g. ‘street-corner tests’ offered to people for free) and, on the other, the more active and targeted involvement with the test purchase and performance. People generally reported high levels of confidence in the validity of tests and few problems with usage (though this depended on the specific test, sometimes in conjunction with environmental factors). Interestingly, whilst people felt reassured when obtaining a negative result, they did not appear particularly alarmed or anxious when they had got a positive result, with some mentioning that they had not taken any follow-up action (Ickenroth et al., 2011). The high levels of faith in the test results and the existence of a minority of people (i.e. around 10%) who did not act upon positive test results have also been identified in quantitative research (Ickenroth et al., 2010).

Undoubtedly, the market of home and self-care technologies continues to expand offering a plethora of diagnostic, monitoring and therapeutic tools. Some of these technologies are well-established and accepted, such as thermometers and pregnancy tests, whilst others, such as genetic testing, provoke heated debate across stakeholders.

Healthcare professionals and researchers warn that some self-care technologies, such as self-testing devices, are hardly suitable for well people (Freedman et al., 2008) and that failure to communicate self-care activities to the doctor or lack of sufficient information around both the technology and the health condition entail risks for the patients (Ryan, Greenfield, McManus, & Wilson, 2006).

2.2.5 In summary

Self-care that takes place outside the traditional healthcare settings and usually within the home environment is certainly a core element of the current healthcare agenda. Self-care activities may be employed to prevent and diagnose diseases or to monitor and manage health conditions and can be linked – though not necessarily – to healthcare professionals, in the sense that the latter may have prompted these activities or are being aware of them when initiated by people themselves. Health technologies facilitate self-care, and in many cases have considerably expanded the range of self-care practices, offering new capabilities but also rearranging ‘geographies of responsibility’ (Akrich, 1992).

Figure 2 aims to illustrate in a simplified way the healthcare arena, as it ranges from self-care in non-clinical settings to professional care in traditional clinical settings, and to indicate where the focus of the present thesis lies. The dashed arrows suggest that the boundaries are not rigid and always clear-cut; for example, professional care might be provided in a non-clinical setting, such as the home, whilst self-care can take place within institutional settings (e.g. parents assist with the care of their ill child).

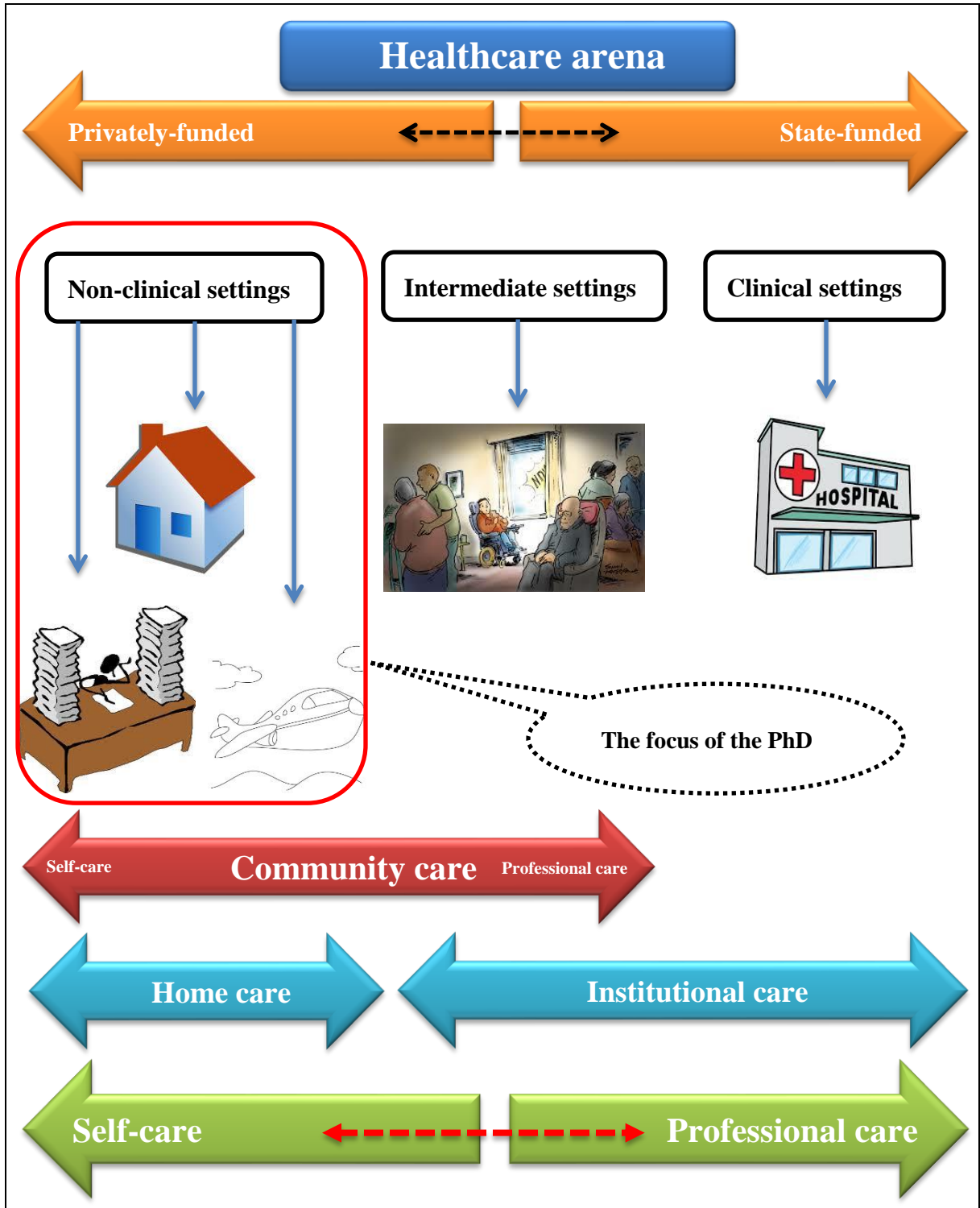


Figure 2. The landscape of healthcare from self to professional care

Moreover, Figure 3 seeks to map the landscape of self-care by indicating the purposes of self-care and the sort of medical equipment that can be deployed. Figure 3 also pinpoints

the focus of the present thesis regarding the type of health technology that was selected to examine the issues of interest. The dashed arrows indicate that self-care activities might be linked or not to healthcare professionals.

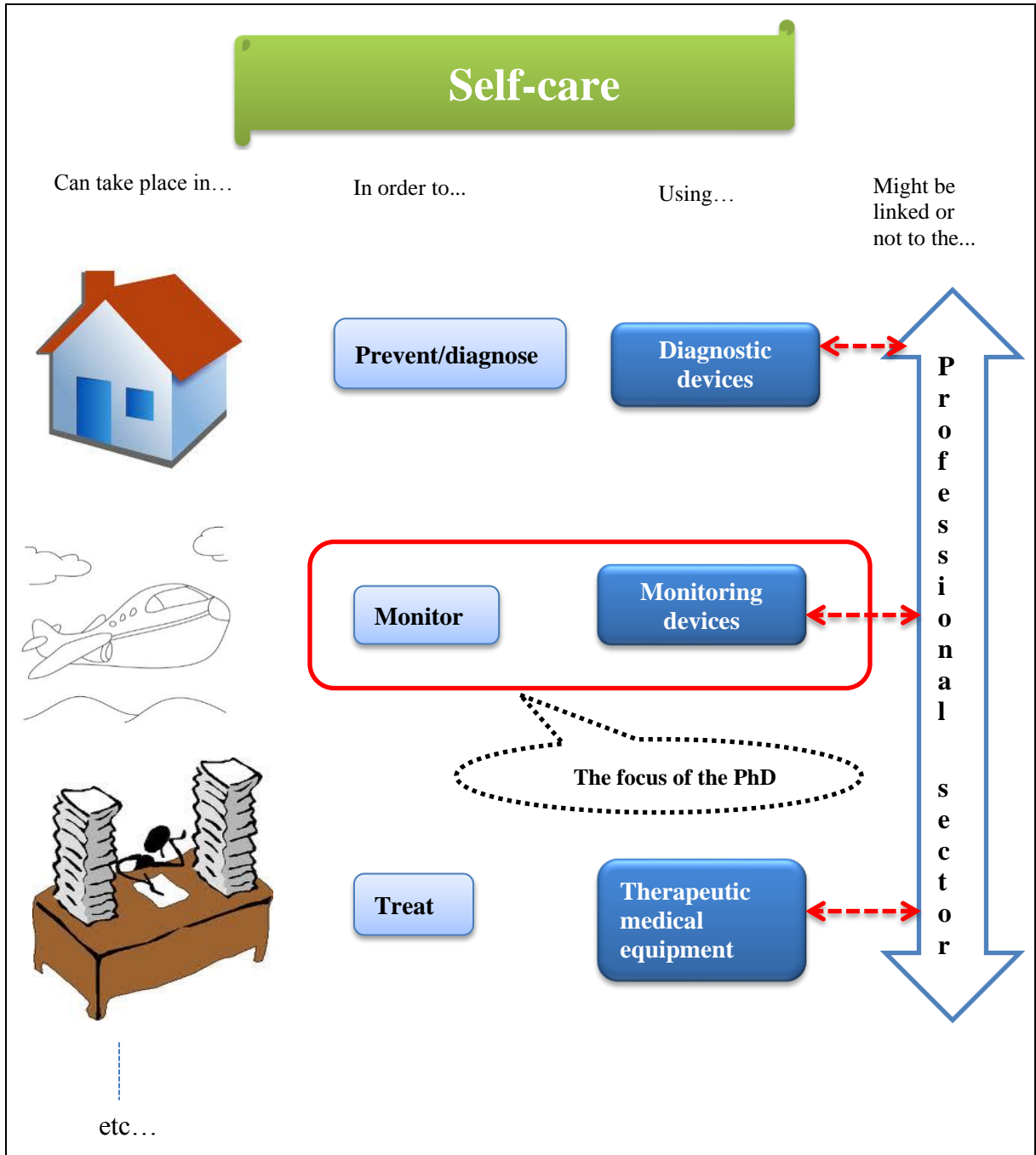


Figure 3. The landscape of self-care

2.3 Section II: Placing the problem of ‘user needs’ under scrutiny

2.3.1 Health Technology Assessment (HTA): the development of a policy-oriented research field

The in-principle contribution of health technologies to advances in medical practice is hardly questioned. But how can societies discern which health innovations are more valuable than others – let alone which ones have the potential to cause harm – especially under conditions of limited healthcare resources, fast-developing innovations and constantly changing healthcare needs? An attempt to answer these questions was born in August 1976 from the then newly established US Office of Technology Assessment (OTA) with the publication of a report entitled *Development of Medical Technology: Opportunities for Assessment* (Office of Technology Assessment, 1976). In this document the foundations of the field of *Health Technology Assessment* (HTA) were laid out with a view to better manage the production, adoption and implementation of healthcare technologies. Health technology assessment was defined as “a comprehensive form of policy research that examines the short- and long-term social consequences (e.g. societal, economic, ethical, legal) of the application or use of technology” (Office of Technology Assessment, 1976, p. 45). Medical technology was considered to be “the set of techniques, drugs, equipment, and procedures used by health-care professionals in delivering medical care to individuals and the systems within which such care is delivered” (Office of Technology Assessment, 1976, p. 4).

Thereafter several HTA programmes and organisations were set up in developed countries in recognition of the value of the field. Indeed, international organisations were also founded, such as the *Health Technology Assessment International*⁶ and the *International Network of Agencies for Health Technology Assessment*⁷ to assist with promoting the HTA work and collaboration among relevant groups. In the UK, the HTA programme was established in 1993 and until 2013 it had produced more than 700 assessment reports of which 56 concerned medical devices (Raftery & Powell, 2013). The emphasis of the British HTA programme is primarily on the effectiveness of healthcare

⁶ <http://www.htai.org/index.php?id=428>

⁷ <http://www.inahta.org/>

technologies – and not on their mere efficacy – but cost-effectiveness and patient-related considerations are also investigated (Raftery & Powell, 2013).

Despite the initial conception of HTA as a multidisciplinary research field that seeks to examine a wide spectrum of considerations ranging from techno-scientific aspects to broader societal, legal and ethical angles, scholars have argued that in practice HTA has narrowly focused on technology clinical effectiveness, safety and costs while little attention has been paid to more generic societal concerns (Lehoux & Blume, 2000; Lehoux et al., 2004) and to the perspectives of patients who receive or directly interact with the technology and live with a certain health condition (Facey et al., 2010). The inherently socio-political nature of health technology, in the sense that it constructs and consolidates particular issues within communities and societies at large, configures users and healthcare systems in certain ways (and not in others) and involves a diversity of stakeholders (e.g. users, healthcare professionals, industry, policy-makers), has not been sufficiently recognised, partly due to the strong influence of the evidence-based movement in medicine and beyond and to the ‘awkward’ position of the HTA field between policy and science (Lehoux & Blume, 2000). Yet, the necessity to explicate the socio-political dimensions of health technology and the concomitant normative assumptions that this raises becomes even more intensive when controversial health technologies are to be assessed (e.g. genetic screening; xenotransplantation) and recommendations to exclude certain technologies (*vs* others, due to limited resources or due to small number of people benefited from the technology) have to be justified (Johri & Lehoux, 2003).

It has been argued that a multilateral articulation of the value of health technology that goes beyond techno-scientific evidence would also assist HTA programmes to better disseminate their products to several stakeholders who often hold different, sometimes even conflicting, views about which technologies are ‘good’ or ‘better’, for whom, and why (Lehoux, Denis, Tailliez, & Hivon, 2005). The task to disseminate HTA knowledge becomes even more challenging when it comes to certain stakeholders, namely user and patient organisations, which may not always be well-equipped (e.g. organisationally, resource-wise) to translate and use HTA knowledge effectively (Hivon, Lehoux, Denis, & Tailliez, 2005). At the same time, user and patient organisations by definition are well

placed to broaden the public debate around health technologies since they represent and are commonly concerned with ethical, social and end-user matters (Fattal & Lehoux, 2008).

Frameworks (Abelson, Giacomini, Lehoux, & Gauvin, 2007) or guidance (Facey et al., 2010) to involve the public into HTA processes and respective policy decision-making have been proposed and certain HTA programmes – such as the British one – have been quite proactive in that respect since the public (e.g. patients) is routinely engaged in the processes of research identification and prioritisation (Raftery & Powell, 2013) (though less so in other phases of research management such as commissioning, monitoring and dissemination; see Moran & Davidson, 2011). In parallel, analytical frameworks and ‘roadmaps’ have been developed to assist HTA communities to encompass societal, ethical (Lehoux & Williams-Jones, 2007) and user-related perspectives (Grocott et al., 2007; Shah et al., 2009) into their technology assessments *per se* and recommendations have been made as to how this effort should also be supported by suitable organisational structures and processes (Lehoux & Williams-Jones, 2007). More systemic approaches to the understanding and examination of user-technology interaction which take into account the role of context have also been suggested (Sharples, Martin, Lang, Craven, O’Neill, & Barnett, 2012). Under these persistent calls for ‘patient-focused’ HTAs (Facey & Hansen, 2011), the perspectives and experiences of users and recipients of health technologies have started to be incorporated more systematically into the assessments.

Whilst HTA programmes primarily assess health technologies once they have been developed and are under consideration for large-scale adoption by healthcare systems, attention has been increasingly paid to the necessity of assessing health technologies *throughout* their development process. In the UK, the recognition of the need to assess the value of health technologies *while* they are being developed was reflected in the work of the *Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH)*. MATCH was a research collaboration focusing on medical devices that aimed to inform the assessment of medical equipment from concept phase all way through to final product. Several streams of research were undertaken to reflect the various angles of assessment from economic and user needs evaluation to consideration of organisational elements. In the following section, it will be examined why the needs of users of medical devices should be assessed and how this has been primarily conceived and performed. Moreover, Figure 4

illustrates the spectrum of medical device evaluation; it indicates where HTA programmes' remit commonly lies as well as the assessment that can be performed up to the point of product development.

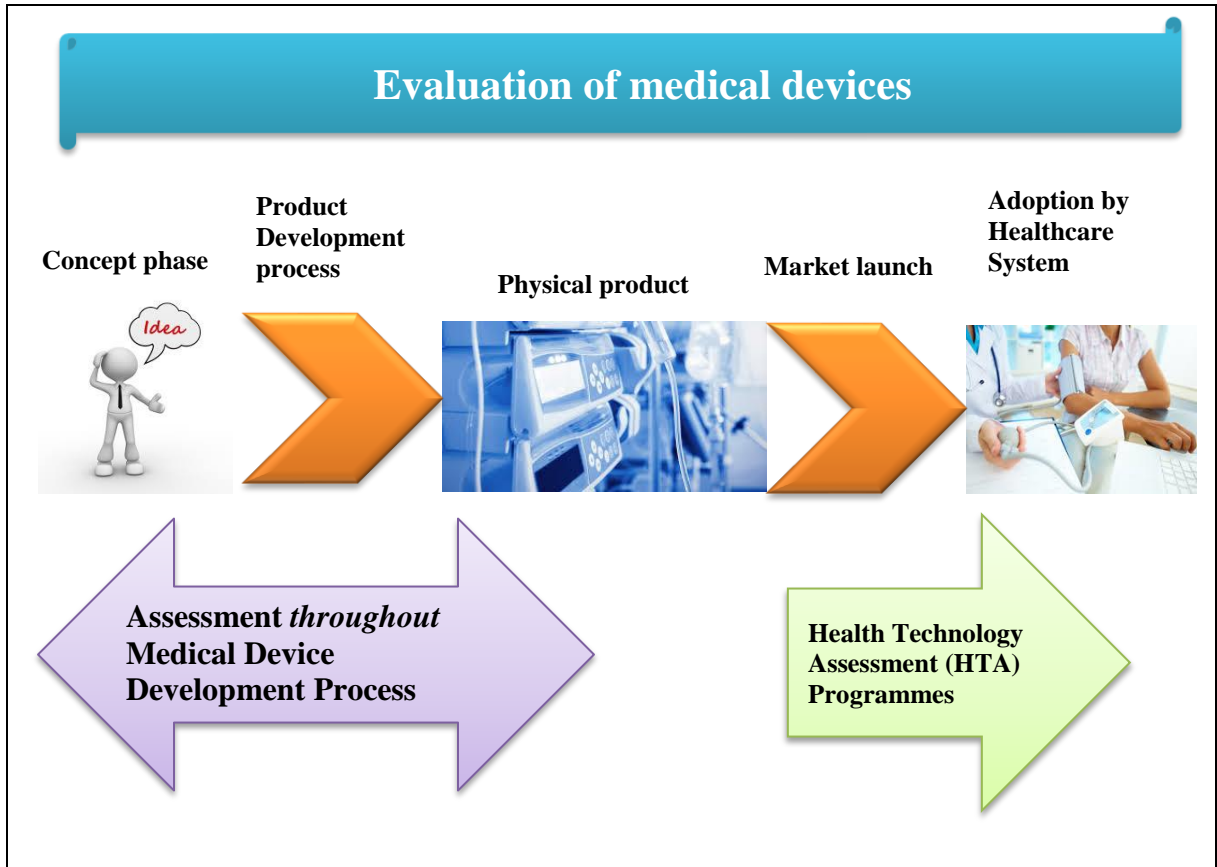


Figure 4. Spectrum of medical device evaluation

2.3.2 Users of medical devices: *why* and *how* to assess their needs

Medical devices constitute a significant category of health technologies that is subjected to particular regulations and legal oversight due to their safety-critical nature. According to the European Medical Device Directive 93/42/EEC, medical device is defined as “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software 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 handicap,

- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means” (1993, p. 169/3 – 169/4).

The regulators around the world have developed systems of classification of medical devices depending on their inherent risk. Within the European Union for example, and under the Medical Device Directive, medical products are organised into four classes (I, IIa, IIb, & III) with higher classes indicating greater risk. In broad terms, the factors that are considered when a medical device is to be ascribed to one of those classes are the following:


- The duration of the contact of the device with the patient
- The degree of invasiveness, and
- The part of the body that is affected by the device use (MEDDEV 2. 4/1 Rev. 9., 2010).

Similar systems of classification on the basis of the device riskiness have been developed in US and Canada and by the *International Medical Device Regulators Forum*⁸ (IMDRF) (see Table 2.1). The device classification determines the regulatory procedures that should be followed, with stricter regulations being applied to higher classes.

Table 2.1
Medical device classification

Medical Device Classification				
European Union	United States	Canada	International Medical Device Regulators Forum (IMDRF)	Device Riskiness
Class I	Class I	Class I	Class A	Low hazard

⁸ The former *Global Harmonization Task Force* (see <http://www.imdrf.org/>)

Class IIa	Class II	Class II	Class B	 High hazard
Class IIb	Class III	Class III	Class C	
Class III		Class IIII	Class D	

Device hazards can be conceptualised as falling into two broad categories (Food and Drug Administration, 2011):

1. **the use-related hazards** (i.e. failures or errors to use the device as expected or intended to), and
2. **the device failure hazards** (e.g. chemical, mechanical, thermal, electrical, radiation, biological hazards)

Taking into account the needs of users while developing and testing a medical device aims exactly to mitigate the first group of hazards. Indeed, this is massively important since use-related errors and failures are responsible for adverse events implicating medical devices which result either in major injuries or even fatalities. The latest report published from the regulator in the UK, for example, indicates that 3.7% of the adverse events reported in 2013 were due to use errors (Medicines and Healthcare Products Regulatory Agency [MHRA], 2014). For this reason, a human factors engineering process⁹ has been recommended by International Standards (e.g. IEC 62366: 2007; IEC 60601-1-6: 2010) which in turn have been embedded into regulatory frameworks both in Europe and North America (e.g. Food and Drug Administration Human Factors Guidance, 2011; Harmonised European Standards EN 62366:2008 & EN 60601-1-6: 2010). An iterative design approach that involves the user throughout the medical device development (MDD) process is proposed with a view to mitigate as much as possible the use-related hazards. Figure 5 shows the iterative nature of a user-centred design approach as this has been proposed for interactive systems by the International Organisation for Standardisation (ISO).

⁹ Also called *usability engineering*, *user-centred design*, or *ergonomic approach*.

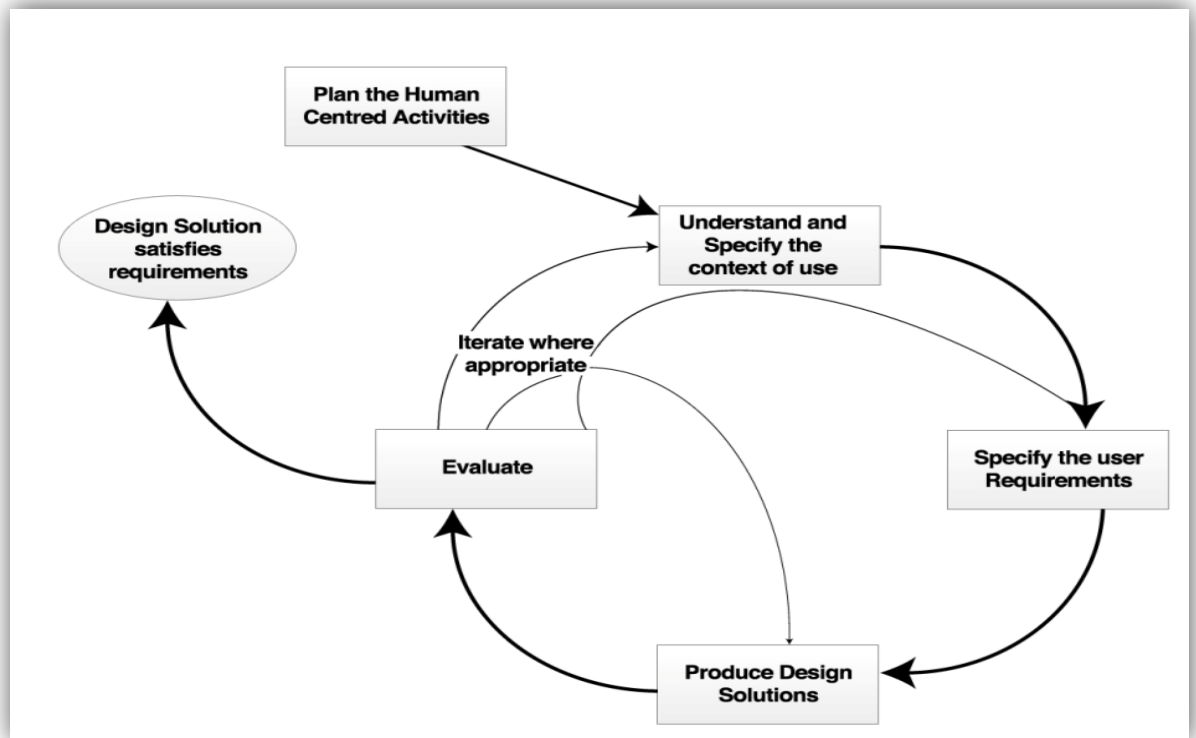


Figure 5. User-centred design approach¹⁰ (from ISO 13407: 1999 and ISO 9241 210:2010).

Considering user needs during the MDD process becomes even more crucial when it comes to technologies that are intended for home use by non-experts. The FDA responding to the increasing availability and use of home medical equipment issued a guidance document in 2012 highlighting the challenges of designing medical devices for home use (FDA, 2012). These challenges relate on the one hand to the lay user who has a wide variety of characteristics (e.g. physical, cognitive, emotional) and on the other to the home environment which is less controlled and predictable (e.g. environmental risks, power outages) than the traditional clinical setting (FDA, 2012).

From a regulatory point of view, adopting a user-centred design approach aims principally to ensure the (use-related) safety and effectiveness of the device. Nevertheless,

¹⁰ Adapted figure from ISO 13407:1999 and ISO 9241-210:2010 on Human-centred design processes for interactive systems

Source of figure: Martin, J., Murphy, E., Crowe, J.A., & Norris, B.J. (2006). Capturing user requirements in medical device development: the role of ergonomics. *Physiological Measurement*, 27, R49–R62.

usability is a broader concept; according to Rubin and Chisnell (2008, p.4-5) a product is considered to be usable when it is:

- *accessible* to a diversity of potential users (i.e. accommodates the widest range of abilities of diverse users),
- *useful* (i.e. enables users to achieve their goals),
- *efficient* (i.e. allows users to perform their tasks as quickly as possible),
- *effective* (i.e. users achieve their goals in the ways they expect and with ease),
- *learnable* (i.e. enables users to use the product with a good level of competence after a period of training) and,
- *satisfying* (i.e. accommodates users' perceptions, beliefs and emotional aspects).

Therefore, the examination of user needs throughout the MDD process should take into account all the aforementioned aspects in order to create truly usable medical equipment.

But how and when is the user being involved in the MDD process? Research in the area shows that users are more likely to be engaged in the design and testing of medical devices but less so during the ideation and deployment stages (Shah & Robinson, 2006). This finding is particularly applicable to Small and Medium Enterprises (SMEs) which are more constrained in terms of resources. Limited resources is a significant challenge for adopting a user-centred design approach (Shah & Robinson, 2007), yet SMEs are more likely to develop new device categories compared to large medical device manufacturers who most typically develop consecutive iterations of existing devices (Kaplan, Baim, Smith, Feigal, Simons, Jefferys, Fogarty, et al., 2004). In an effort to assist industries to adopt a user-centred design approach during the MDD process, a detailed framework of user research has been developed by researchers in the UK (The *Multidisciplinary Assessment of Technology Centre for Healthcare*) and has been adopted by the National Patient Safety Agency (NPSA) in 2010 as guidance. Figure 6 displays this framework indicating the stages whereby user research can be conducted, the purposes it can achieve, and the methods to be employed at every stage.

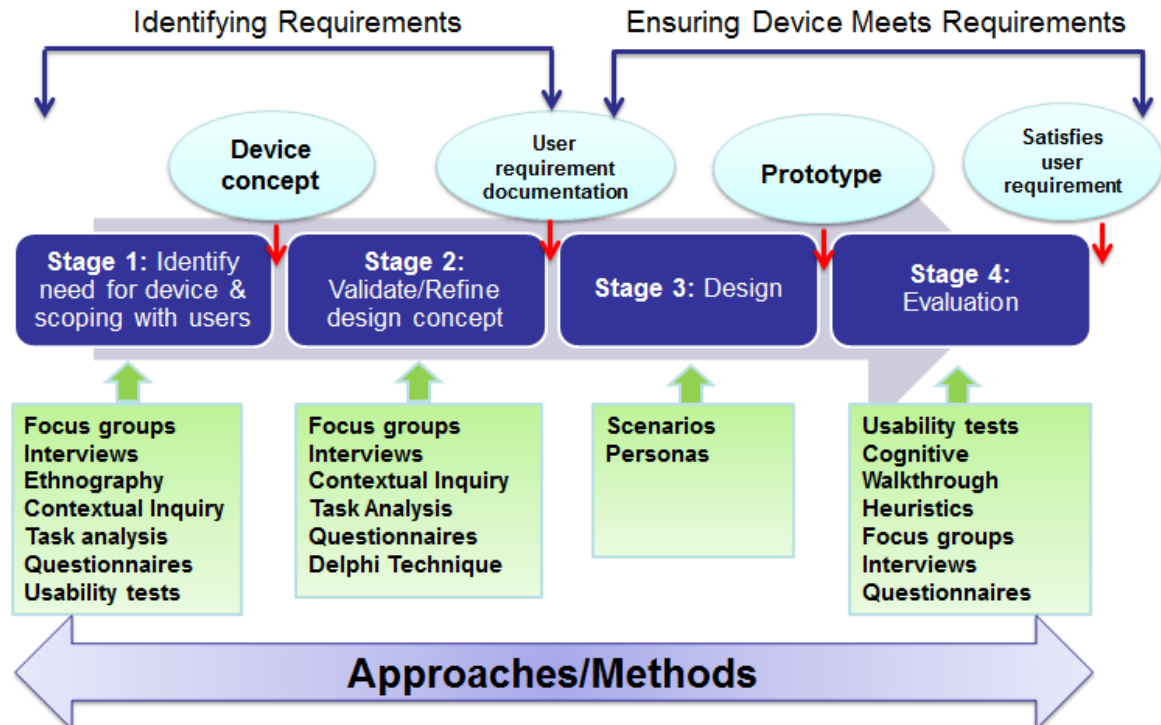


Figure 6. Capturing the user throughout the medical device development process¹¹ (NPSA, 2010, p. 25).

2.3.3 What user needs to assess: taking into account symbolic dimensions of user-device interaction.

User needs research in the MDD process has been primarily conceived and conducted from an ergonomic or human-factors approach (Martin et al., 2006; Martin et al., 2008) which aims principally to improve, through usability, the device safety and effectiveness and therefore reduce post-market recalls and modifications and increase the likelihood for successful and satisfying products. Consequently, the focus has been concentrated on reducing use errors during the interaction with the device and on creating design solutions that promote proper and intended device use.

Nevertheless, the symbolic content of the user's interaction with the technology is less well-attended to, though its role appears to be important for the acceptance, adoption and sustainable engagement with the technology. For example, a qualitative study with people

¹¹ Source of figure: National Patient Safety Agency (2010). *Design for patient safety: user testing in the development of medical devices*. Reference Number: 1184. Retrieved from: <http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=74946>

who were prescribed with an epinephrine auto-injector device due to severe allergy revealed that participants were reluctant to carry or use in public a device that looked like a weapon. The findings also suggested that users were further concerned with the stigma that might be attached to them (Money et al., 2013). These concerns made participants to avoid carrying with them the technology despite their life-threatening condition.

Another qualitative investigation (Lehoux et al., 2004) of patients using specialised medical equipment at home (i.e. antibiotic intravenous therapy, parenteral nutrition, peritoneal dialysis and oxygen therapy) indicated that the real-life experience of interacting with these technologies was heavily imbued with ambivalence. The technologies simultaneously enabled (e.g. being at home and not in hospital) but also constrained users (e.g. accessing their social world) in several ways (the so-called *dual function* of technology; Lehoux, 2008), and this was in opposition to a technical user representation promoted in patient manuals, brochures and leaflets whereby an almost healthy user was depicted to engage with the device without problems and to achieve autonomy and empowerment (Lehoux et al., 2004). The acceptance of the technologies was contingent on users' competence, indicating how medical technologies are recursively implicated with illness (Lehoux, 2004). The connectedness of technology with illness and the dual function of home medical equipment have also been empirically supported in research with older people (Thomson et al., 2013).

Moreover, longitudinal qualitative research (Peel et al., 2007) with people who self-monitored their blood glucose suggests that continuing engagement with self-monitoring depended on the quality of patient-doctor relationship. To the extent that patients perceived a lack of interest, on the part of their doctor, in their self-care activity, the engagement with self-monitoring declined over time. This finding suggests that sustainable device use is often influenced by parameters outside the narrowly focused user-device duo, such as the nature of relationship with other people (e.g. healthcare professionals, carers). It is perhaps then not surprising that a recent systematic review around the benefits of blood glucose self-monitoring concluded that the clinical usefulness of this technology could be considerably enhanced if both patients and healthcare professionals were receiving education about how to deal more effectively with the challenges that the self-monitoring

of blood glucose provokes (e.g. interpretation of readings, lifestyle and medication alterations) (Clar, Barnard, Cummins, Royle, & Waugh, 2010).

Finally, developing trust in medical technology is another important aspect of the symbolic processing that takes place in the user-device interaction. It is argued that trust in medical technology has an indirect effect on the acceptance of health technologies (Siegrist, 2000) and influences the ways technologies are used or misused (Montague, Kleiner, & Winchester, 2009). Some recent work in the area has started to emerge indicating that trust development follows different paths for different user groups (e.g. healthcare professionals *vs* patients) (Montague et al., 2010) and that trust in health technology is deeply interwoven – and perhaps only analytically separable – with other trustworthy relationships (Timmons et al., 2008). This work has focused on medical technologies used in clinical settings (e.g. in obstetric work systems) or technologies used in public spaces (e.g. automatic external defibrillators) by lay people (e.g. staff working at airports). Nevertheless, little is known about how lay users of home use technologies develop trust (or not) in their equipment.

The present research sought to enrich our understanding around user needs considerations by examining in more depth some of the symbolic and meaning-making dimensions of the user-device interaction which have attracted less attention within the field of user needs research. Specifically, two aspects were studied: first, how people integrate into their daily life home use technologies, from the point of consumption to the articulation of certain identities, and second how people come to trust home use medical technologies.

2.3.4 A note on theory in the field

Arguably, much of the research that examines how people come to accept and use health technologies is largely inductive and infrequently informed by theory. The studies focus primarily on mapping and describing the phenomena of interest at a first level, and then on identifying the factors that either facilitate or obstruct the ‘desired’ behaviour which is commonly considered to be the adoption and use of the technology as intended and prescribed by experts (i.e. designers). Attempts to theoretically articulate and explain the research findings are not regularly observed, whilst empirical investigations around cases where people resist adopting a technology or abandon it along the way are even less

common. The largely a-theoretical character of the field might be partly explained by its nature which is heavily applied. From this quality a second reason perhaps stems that concerns the high degree of complexity that characterises the phenomena and behaviours under investigation. Despite the challenges to theorisation, some efforts in this direction have been made from several disciplines.

The *Technology Acceptance Model* (TAM) (Davis, 1989; Bagozzi, Davis, & Warshaw, 1992) constitutes one of the most popular theoretical propositions that has been used to explain and predict the adoption of technology, including health technologies (e.g. health Information Technologies, see Holden & Karsh, 2010; self-testing medical devices, Shah, Barnett, Kuljis, Hone, & Kaczmarek, 2013). Based on the propositions of two social-psychological theories – the Theory of Reasoned Action (Ajzen & Fishbein, 1980) and the Theory of Planned Behaviour (Ajzen, 1985) – TAM, in its simplest form, predicts that the actual use of the technology is influenced by its perceived usefulness and perceived ease of use, which in turn both shape the users’ attitude towards the technology and by extension their behavioural intentions. Although the parsimony of the model is arguably attractive and seems to account for its widespread uptake by the scientific community, this very same quality constitutes perhaps one of the greatest weaknesses of the model in the sense that it cannot easily accommodate the complexity of real life. Connected to this point is the observation that TAM focuses on the individual level of analysis and does not consider the broader context (e.g. group, cultural and social factors) that influences the user-technology interaction (Bagozzi, 2007).

More sophisticated perspectives to the understanding of the relationship between users and technology have been proposed including work from several theoretical approaches such as the semiotic approaches to user (Woolgar, 1990; Akrich, 1992), cultural and media studies (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992) and the approach of social construction of technology (Pinch & Bijker, 1984). This stream of thought has made three important contributions:

1. First, the *User* has been brought to the forefront of the processes of technological innovation, adoption and transformation and has been assigned with an agentive status that was often missing from the literature of technological innovation and adoption (Rogers, 1983). The diversity of users has also been highlighted including

those stakeholders who might not use the technology but are affected by it (i.e. implicated actors).

2. Second, the scope of the phenomena that are subjected into scrutiny has expanded considerably. For example, the ways with which users appropriate technologies in manners that were not envisioned or anticipated by designers or how user resistance might transform technologies have been added to the research agenda. These aspects go well beyond the mere user acceptance – often the critical end point in TAM – to explore the nuances of the user-technology dialectic as well as the network of relationships surrounding users and technological artefacts.
3. Finally, different lens of enquiry that tries to overcome, on the one hand, technological determinism and, on the other, an essentialist view of the user have been offered within these approaches (Oudshoorn & Pinch, 2003).

The present thesis is broadly informed by this stream of scientific work espousing as an axiomatic assumption that the relationship between users and technology is deeply dialectical and immersed within a broader network of relationships with other people and objects. This means that users and technologies are co-constructed through an on-going process of interaction whereby users have the potential to define and use technologies in multiple ways (i.e. interpretive flexibility), but simultaneously the technologies have the power to configure the users in certain ways.

2.3.5 Medical device manufacturers: attending to a poorly studied stakeholder

Medical device manufacturers are a critical stakeholder in ensuring that the medical products satisfy user needs and preferences (Privitera & Murray, 2009). In principle, the industry has a strong motive to incorporate user needs considerations during the MDD process as their products are more likely to be commercially successful. Testing assumptions and identifying problems early on in the process can potentially save valuable resources (e.g. time, money) from future costly product modifications or even recalls (see Rajanen, 2003 for usability cost-benefit analysis). But what is that status of our current knowledge about the ways the industry tries to incorporate user needs considerations into their products?

Research in the field indicates that medical device manufacturers do not always espouse, materialise and sustain user-centred design practices. For example, a recent study (Money et al., 2011) revealed a discrepancy between the user that would actually operate/use the device and the stakeholders whom the medical device manufacturers consulted in order to inform their design processes. The same study also showed that in most of the cases, the medical device manufacturers did not have in place formal procedures that would embed early and systematic user research in the product development cycle and that user research was mainly conducted within the context of meeting regulatory requirements (Money et al., 2011).

Several barriers have been identified in the literature that might prevent medical device manufacturers from investigating and taking into account user needs considerations. One is related to the limited resources; this is more applicable to Small and Medium Enterprises (SMEs) that comprise the vast majority of companies in the UK in the field of medical device manufacturing (Association of British Healthcare Industries, 2009; Martin, Craven, & Norris, 2005). These organisations do not often have the necessary resources (i.e. money, time, personnel) to invest in expensive user needs research (Martin et al., 2012). Therefore, although the small size of these companies allows them to be flexible and enter the markets quickly, the resource constraints are likely to compromise this competitive advantage as their innovations are less likely to capture user needs sufficiently.

An additional barrier to incorporate effectively user-centred design approaches relates to poor communication both across different teams within the organisation and between the organisation and the intended users (Vincent, Li, & Blandford, 2014). The cumbersome and time-consuming procedures that the manufacturers need to follow in order to gain relevant ethical approvals (Mihoc & Walters, 2013; Money et al. 2011) for conducting user research has also been reported as a discouraging factor since this requirement creates significant delays in launching the products into the market.

The structure of the MDD projects as well as their management can also hinder sometimes timely and suitable user needs research. This can happen due to loose ties or even lack of contingencies between several phases and elements of the project. For instance, it has been documented that in this kind of projects engineering aspects of the

technology tend to be prioritised without necessarily being linked to user considerations (Martin & Barnett, 2012).

Finally, the broader economic landscape within which the medical device manufacturer operates can also discourage or discount the perceived value of user needs research. A recent interview-based study showed that the strong emphasis of markets on costs, and the prioritisation of cost reductions from those making purchasing decisions (e.g. NHS procurement services in the UK) de-incentivise medical device manufacturers to concentrate on user research and instead are heavily pre-occupied with producing low cost products that may compromise quality (Mihoc & Walters, 2013). Similarly, the little attention of the funding bodies, which provide economic support to development of medical innovations, to user needs considerations discourages the adoption of relevant practices, or at least does not highlight the value of this (Martin & Barnett, 2012).

Thus far most of the research in this field has been conducted with SMEs (Money et al. 2011) and academic spin-offs (Lehoux et al., 2014; Martin & Barnett, 2012) while large medical device manufacturers, who have more resources and organisational experience, have hardly been approached. Moreover, most research is based on cross-sectional interview studies which preclude an examination of the daily activities of the organisations in their effort to capture the user. Thus, the present research sought to fill this gap in our knowledge by adopting an ethnographic case study approach which aimed to examine the details of the practices the manufacturer engages with in order to approach and understand their end-user.

2.4 Section III: The example of home blood pressure monitoring

2.4.1 Justifying the choice of home blood pressure monitors

Home blood pressure monitors (HBPMs) were selected as an example of home health technology around which the research questions of the present thesis were examined. There are three reasons that led to the choice of this particular technology. First, HBPMs exemplify a medical device that is gradually migrating from the clinical setting to the home environment. Though the first study that reported the effects of home blood pressure measurements compared to clinical measurements is dated back to 1940 (Ayman &

Goldshine, 1940), it is only recently in the UK that home BP monitoring is officially considered as a legitimate and necessary adjunct to office measurements (National Institute for Health and Clinical Excellence [NICE], 2011). This clinical guideline is likely to increase the use of HBPMs in the future.

Second, home BP monitoring has wide relevance due to the fact that the condition with which it is most strongly associated, namely hypertension, affects a significant percentage of the population and is likely to further increase in the future as the epidemiological evidence suggests (Kearney et al., 2005). Thus, it is anticipated that the results of the present research will be useful and applicable to a considerable number of people.

Finally, contemporary BPMs for home use are relatively simple and easy-to-use devices that do not require any special skills on the part of the user, though it should not be ignored the fact that the level of ease is a function of the user-device interaction rather than an intrinsic quality of the technology. Nevertheless, if HBPMs were thought comparatively to other home medical equipment, they would be seen as a relatively simple and straightforward technology (Rickerby & Woodward, 2003), that is relatively well accepted by people (Aylett et al., 1999; Little et al., 2002) and is also recommended by the medical profession (NICE, 2011). Consequently, any user-related challenges that might be identified in the present research could potentially inform by analogy respective aspects that are implicated in the usage of more complex medical equipment (e.g. oxygen cylinders) and/or more controversial technologies (e.g. genetic testing).

In the following sub-sections, home BP monitoring is contextualised by presenting a brief history of blood pressure measurement along with the major types of monitors that are currently available on the market. Then, the prevalence of hypertension for which HBPMs are primarily used is introduced and the evidence on the uptake and usefulness of home BP monitoring is reviewed along with the clinical guidelines that have been issued by professional medical organisations. The existing research on the perspectives of users of HBPMs is then examined concluding this section.

2.4.2 A brief history of blood pressure measurement

The discovery of blood pressure along with the first blood pressure measurement are attributed to Stephen Hales (1677 – 1761) an English scientist and clergyman who measured invasively the blood pressure of a horse in 1733 (Booth, 1977; Manley, 2000; Roguin, 2006) (see Figure 7). Almost one century later, in 1828, John Leonard Marie Poisseuille (1799–1869), a French physicist and physiologist, improved significantly the existing blood pressure measurement apparatus. He created the mercury haemodynamometer and introduced the manometric unit of pressure, that is mmHg (i.e. millimetre of mercury), which is still being used with mercury manometers (Booth, 1977; Roguin, 2006). It was not until 1855 that it was made possible to measure the blood pressure by non-invasive methods thanks to the sphygmograph invented by Karl von Vierordt (1818–1884) (see Figure 8) and his idea that blood pressure can be recorded indirectly by measuring the counter pressure that suppresses the pulse (Booth, 1977; Roguin, 2006).



Figure 7. Stephen Hales (seated) measures the blood pressure of a horse (drawing by Cuzzo, 1944).

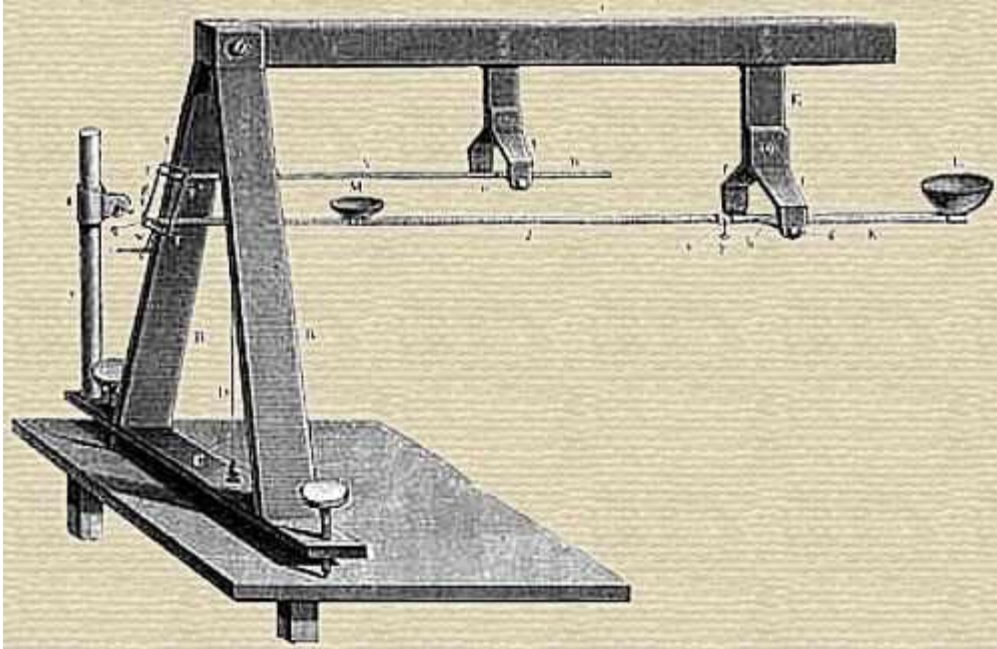


Figure 8. Karl von Vierordt's sphygmograph.

In 1860, the French scientist Etienne-Jules Marey (1830–1904) improved considerably Vierordt's cumbersome equipment making it more usable for clinical practice while the Scottish homeopathic doctor Robert Ellis Dudgeon (1820–1904) introduced a portable sphygmograph in 1881 measuring the blood pressure on the wrist (Figure 9). Further technological improvements were made later by the Austrian physician Samuel Siegfried Karl Ritter von Basch (1837–1905) though many doctors at the time were sceptical about the technology and the clinical usefulness of blood pressure measurement (Booth, 1977).

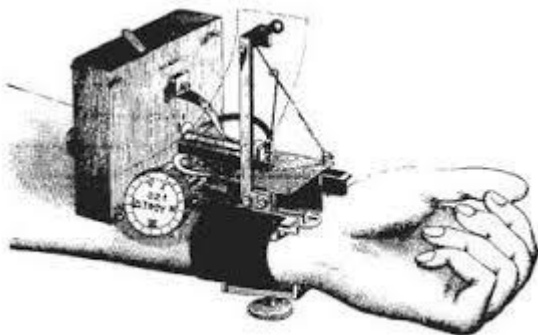


Figure 9. Robert Ellis Dudgeon's wrist sphygmograph.

In 1896, an Italian doctor, Scipione Riva-Rocci (1863-1937), developed further the mercury sphygmomanometer upon which present-day instruments are based (Figure 10) and almost a decade later, in 1905, the Russian surgeon Korotkoff made an important observation when he noticed the sounds produced by the constriction of the artery. Korotkoff, using a stethoscope and the Riva-Rocci apparatus, invented ultimately the auscultatory method of arterial blood pressure measurement which constituted a more accurate and easier way to determine the blood pressure (Booth, 1977; Manley, 2000; Roguin, 2006).



Figure 10. Riva-Rocci sphygmomanometer.

2.4.3 Types of blood pressure monitors

There are two techniques through which blood pressure can be measured and on which several types of blood pressure monitors are based: the auscultatory and the oscillometric technique. The first is based on listening through a stethoscope the co-called Korotkoff sounds while an upper arm cuff is gradually deflated. The oscillometric method detects variations in pressure oscillations due to arterial wall movement beneath an occluding cuff (Medicines and Healthcare Products Regulatory Agency, 2013)

The types of blood pressure monitors that use the auscultatory technique are the mercury sphygmomanometers and the aneroid sphygmomanometers both of which require manual inflation of the cuff (Figure 11). The mercury BPM is considered the ‘gold standard’ for measurement and has been used widely in clinical settings. However due to environmental concerns about the mercury, this type of monitor has started to be banned in several countries while its supply in the UK has been limited only to clinical settings (Medicines and Healthcare Products Regulatory Agency, 2013). The aneroid manometer is considered

less accurate especially under the demands of heavy clinical use. Both types of BPMs have been used predominantly by experienced healthcare professionals.



Figure 11. Mercury (left) and aneroid (right) manual sphygmomanometers.

The oscillometric technique of measurement is employed by the majority of automated BPMs that are currently available on the market. There are four main types of automated devices:

- the upper arm (spot-check) type
- the wrist type,
- the finger type,
- and the ambulatory type which measures the person's blood pressure at pre-specified intervals over a 24-hour period and stores the data automatically (Figure 12).



Figure 12. Upper arm (a), wrist (b) and finger (c) automated, spot-check blood pressure monitors and ambulatory BP measuring device (d).

The upper arm, wrist and finger automated devices are well placed for home use by lay people due to their ease of use and portability, though the latter two types are not as accurate as the upper arm models and thus they are hardly recommended. Finally, ambulatory blood pressure monitors are offered by healthcare professionals to patients for diagnostic purposes and the information they provide is routinely used in conjunction with measurements taken at the doctor's office (Medicines and Healthcare Products Regulatory Agency, 2013).

2.4.4 Prevalence of hypertension

Blood pressure monitors are predominantly used to detect and diagnose hypertension which is sometimes called ‘the silent killer’ due to its asymptomatic character. Hypertension constitutes an important public health challenge since it is strongly associated, as one of the leading risk factors, with cardiovascular and renal disease (Lim, Vos, Flaxman, Danaei, Shibuya, Adair-Rohani, Amann, et al., 2012) and affects a significant number of people worldwide. World-scale epidemiological research has shown that 26.4% of the world’s adult population, or 972 million people, had hypertension in 2000. This number is estimated to increase to 29.2% by 2025 which equates to 1.56 billion people (Kearney et al., 2005). While the prevalence of hypertension appears to have been stabilised in some western countries, such as the US (Ong, Cheung, Man, Lau, & Lam, 2007) or the UK (Falaschetti, Chaudhury, Mindell, & Poulter, 2009), with parallel improvements in patients’ awareness, condition treatment and control, in other parts of the world, such as in China, there appears to be an increase in the prevalence of hypertension with low levels of awareness, treatment and control (Gu, Reynolds, Wu, Chen, Duan, Muntner, et al. 2002). In Europe, hypertension seems to be a particularly significant problem as it affects 44.2% of the adult population, a much higher percentage than that reported for North American countries where the respective percentage is 27.6% (Wolf-Maier et al., 2003). Moreover, in Europe there is evidence that only 8% of hypertensive patients control their condition, while in US and Canada control was found to have been achieved for 23% of the patients (Wolf-Maier et al., 2003).

Despite the fact that the timely detection of hypertension is often hindered by its asymptomatic character and an accurate diagnosis is challenged by the inherently variable nature of blood pressure and the susceptibility of blood pressure measurement to the influence of several exogenous factors (e.g. observer’s bias) (O'Brien et al., 2003), determining the condition precisely is crucial for appropriate management. The process of measurement and the necessity for accurate and reliable technologies are fundamental to this end.

2.4.5 Clinical guidelines, usefulness and prevalence of home blood pressure monitoring

Traditionally, blood pressure measurements are taken in doctors' surgeries using a mercury or aneroid sphygmomanometer. Nevertheless out-of-office measurements, with primary example being that of home BP monitoring, have gained popularity allowing lay people to measure this vital sign on their own. The uptake of home BP monitoring is partly fuelled by technological advancements and the manufacturing of easy-to-use automated devices which do not require any special skills or expertise. But also the recognition of the medical community that this alternative mode of measurement is clinically necessary due to the singularities that the blood pressure measurement presents – such as the “white-coat hypertension” and the “white coat effect” whereby normotensive and hypertensive individuals respectively have higher blood pressure readings in the clinical environment (O’Brien et al., 2003) – has promulgated further adoption of HBPMs.

In the UK, the *National Institute for Health and Care Excellence* (NICE) in cooperation with the *British Hypertension Society* (BHS) released, in 2011, an updated guidance for the clinical management of adult hypertension, whereby primary care practitioners are instructed for the first time to offer ambulatory or home blood pressure monitoring in certain patient categories for purposes of diagnosis or monitoring when people are under antihypertensive treatment (NICE, 2011). Other medical organisations have also promoted HBPM; the *European Society of Hypertension* (ESH) for example published recommendations for conventional, ambulatory and home blood pressure measurement in 2003 (O’Brien et al., 2003) and a practice guideline exclusively on home BP monitoring in 2008 (Parati et al., 2008). The ESH suggests that home BP monitoring is most suitable for hypertensive patients who want to contribute to the self-management of their condition and for the long-term follow-up of patients with ‘white coat effect’ (i.e. hypertensive patients present higher BP in the clinical environment) and recommends it in almost all patients with *treated* hypertension. Finally, professional organisations in the US, such as the *American Heart Association*, the *American Society of Hypertension*, and the *Preventive Cardiovascular Nurses Association* have issued detailed recommendations on the utilisation of home BP monitoring (Pickering, Miller, Ogedegbe, Krakoff, Artinian, & Goff, 2008).

Concerning the usefulness of home BP monitoring, the research evidence appears encouraging. Specifically, home BP monitoring has a positive effect in terms of blood pressure management and control, patient acceptance and cost-effectiveness. A meta-analysis of 18 randomised clinical trials that compared patients who followed either conventional or home BP monitoring showed a significant improvement of blood pressure levels and control in self-testing patients (Cappuccio et al., 2004). Similarly, systematic reviews concluded that home monitoring demonstrates several clinical advantages, such as improved hypertension control (Agarwal et al., 2011; Verberk et al., 2005), strong correlation with target organ damage and cardiovascular mortality (Verberk et al., 2005), and the potential to reduce therapeutic inertia (i.e. unchanged medication in hypertensive patients despite uncontrolled BP) (Agarwal et al., 2011). There is also some evidence that home monitoring has better predictive value than office monitoring for subsequent morbidity and mortality linked to hypertension (Yarows, Julius, & Pickering, 2000). Despite the clinical advantages of home BP monitoring that allow the method to be incorporated to routine clinical practice, there are researchers who emphasize that home BP monitoring should always be used in conjunction with clinical assessment and cannot replace the conventional clinical evaluation (Celis, Hond, & Staessen, 2005).

Other research has examined the extent to which home BP monitoring is accepted by patients and has demonstrated that people consider home monitoring as the most acceptable and satisfactory method of measurement compared to clinical or ambulatory monitoring, that causes little inconvenience and is easy in use (Aylett et al., 1999; Little et al., 2002). There is also some evidence suggesting that home BP monitoring contributes to cost savings, through a reduction of patients' visits to, and usage of, the healthcare services (Soghikian, Casper, Fireman, Hunkeler, Hurley, Tekawa, & Vogt, 1992).

With regard to the prevalence of home BP monitoring among lay people, research indicates that it is increasingly adopted, often without prior medical advice since a wide variety of HBPMs can be reached in the free market and bought 'over-the-counter' or via the Internet (see Graves, 2005 for a list of automated blood pressure monitors available on the Internet). A UK survey among a randomly selected sample showed that 9% of participants had self-tested their blood pressure (McManus et al., 2007). The percentage of people who self-monitor increases considerably among hypertensive adults; 31%, 43% and

75% of the respondents in cross-sectional studies in the UK (Baral-Grant, Haque, Nouwen, Greenfield, & McManus, 2011), US (Viera, Cohen, Mitchell, & Sloane, 2008) and Italy (Cuspidi, Meani, Lonati, Fusi, Magnaghi, Garavelli, Palumbo et al., 2005), respectively, reported to having measured their own BP. The growing interest that people show in monitoring and controlling their health state in general is often considered as one of the main drivers behind the spread of home BP monitoring (O'Brien et al., 2003; Parati et al., 2008).

2.4.6 Existing research on the experiences of users of home blood pressure monitors

Though the research in the field has been predominantly quantitative seeking to map the prevalence of usage and the characteristics of users, there are a few qualitative studies conducted with users of HBPMs which examined the nuances of experience of engaging with home BP monitoring (Abdullah & Othman, 2011; Jones, Greenfield, Bray, Baral-Grant, Hobbs, Holder, Little, et al. 2012; Ovaisi, Ibison, Leontowitsch, Cloud, Oakeshott, & Kerry, 2011; Rickerby & Woodward, 2003). An interview-based study with 13 hypertensive adults showed that people were generally satisfied with the practice of self-monitoring as they were feeling that they had more control over the management of their condition; they considered the use of the device easy and self-evident and some of them demonstrated a high level of knowledge around hypertension, the health risks it entails and the target values for blood pressure. Nevertheless, there was some variation across individuals in terms of the enthusiasm they showed towards self-monitoring (Rickerby & Woodward, 2003).

Similarly, a study with 23 hypertensive patients who participated in a trial that assessed the effectiveness of self-monitoring combined with self-titration showed that people were generally contented and confident with home monitoring, though less so with altering their medication (i.e. self-titration) without consulting first their doctor. Many participants expressed a willingness to continue home BP monitoring after the trial as they felt that multiple home readings had greater informational value than single office readings (Jones et al., 2012).

Another qualitative study with 26 stroke patients who were offered HBPMs by their healthcare professional arrived at similar observations; people generally had positive

attitudes towards self-monitoring as they felt more empowered and were strongly motivated to avoid another stroke. However, a degree of anxiety was expressed by some regarding their blood pressure levels and the attitudes were becoming less favourable among those participants with higher levels of impairment as a result of their stroke (Ovaisi et al., 2011).

Finally, individual interviews and focus group research with 24 hypertensive patients who had self-initiated home BP monitoring showed a mixed picture of positive and negative experiences (Abdullah & Othman, 2011). In terms of positive influences, participants reported that the home readings helped them to adapt their lifestyle routines (e.g. diet, exercise) in order to control better their blood pressure and reassured them that the blood pressure was checked between visits to the doctor. They also felt that their relationship with their doctor was strengthened as a result of discussing the home readings and many showed increased awareness of, and motivation to manage, their condition. Regarding the negative aspects, many participants expressed uncertainty and mistrust as to whether their blood pressure monitor was accurate and some showed confusion concerning the targeted blood pressure levels or the proper frequency of taking the readings. Importantly, some participants reported that they altered their treatment (frequency, dosage, or medication) on the basis of the home readings and their own judgments and interpretation of them. This latter finding challenges the assumption that greater patient involvement in the management of health conditions fosters necessarily greater adherence to medication and disease management plans. Perhaps this depends more on the nature and strength of the patient-doctor relationship rather than simply on greater patient involvement *per se*.

Overall, the results from qualitative research are suggestive of the duality of medical technology in the sense that it both solves and creates problems and is recursively embedded in the health condition (Lehoux, 2008). Even in the case of HBPMs which constitute a relatively simple and straightforward technology, users might experience both positive (e.g. reassurance) and negative effects (e.g. uncertainty, anxiety).

2.5 Research objectives and research questions

The present research sought to examine the perspectives of two key stakeholders, namely users of HBPMs and medical device manufacturers. Concerning the user

perspective, this work focused on aspects of user needs which are less well-developed in the relevant literature and relate to the meaning-making and symbolic processing of device use. Specifically, using the example of HBPMs two research objectives were set out:

- To examine how lay users integrate into their daily life, and make sense of, home medical devices and what challenges (if any) they encounter
- To investigate how people come to trust home medical equipment

With regard to the medical device manufacturer, the present research aimed to augment the evidential base around the user needs research activities the industry adopts. The research objective was:

- To observe ‘from inside’ and document the details of the activities and approaches the medical device manufacturer uses to understand the end-user and to examine the potential challenges the industry faces in this effort.

The research questions that derive from the aforementioned objectives are presented in Table 2.2.

Table 2.2

Research questions of the present thesis

Stakeholder	Research Question
User	<ul style="list-style-type: none"> • How do users of HBPMs integrate the technology into their daily life, how do they make sense of it, and what challenges (if any) do they encounter? • How do lay people develop trust in HBPMs?
Manufacturer	<ul style="list-style-type: none"> • In what ways do medical device manufacturers try to approach and understand the end-user and what are the challenges they might face?

CHAPTER 3 – RESEARCH APPROACH

3.1 Overview

According to Blaikie (2000, p. 42), every research venture should satisfactorily answer three main questions:

1. *What* will be studied?
2. *Why* will it be studied? and
3. *How* will it be studied?

Chapter 2 attempted to answer the first two questions of *what* and *why* whilst locating the present research within existing literature. Chapter 3 aims to answer the question of *how* by describing the methodological approach that was adopted to pursue the research objectives and to answer the research questions as these were formulated in chapter 2.

A research design refers to ‘the process that links the research questions, empirical data, and research conclusions’ (Blaikie, 2000, p. 39) and includes ‘the plans and the procedures that span the decisions from broad assumptions to detailed methods of data collection and analysis’ (Creswell, 2009, p.3). This chapter presents the logic of enquiry - or research strategy - that was selected for this research endeavour and explicates the broader ontological and epistemological assumptions that are entailed in this decision. In doing so, the selected research strategy is situated against the wider canvas of logics of investigation that have been developed in the social sciences and its appropriateness is justified. Then the methodological approaches and techniques that were employed for the conduct of the individual empirical studies are introduced and a discussion of the criteria for assessing the quality in qualitative research follows. Finally, a reflexive account of the role of the researcher which was espoused from the author of this thesis is provided and the ethical framework that guided the present research closes this chapter.

3.2 Selecting logic of enquiry and explicating ontological and epistemological commitments

Clearly, designing a suitable research approach and selecting appropriate methods of data collection and analysis is of paramount importance for achieving adequate answers to

the research questions. Nevertheless, these decisions are not made in a philosophical vacuum but they are influenced by, and sometimes delineate, the researcher's orientation and commitments to certain premises around ontology and epistemology.

Ontology, which literally means the *speech about being* (from the Greek words 'ov' = being and 'λόγος' = speech), is that branch of philosophy that studies the nature of being, existence and reality (Klein, 1966). When we talk about ontological assumptions in research, we refer to the axiomatic claims that are being made about the nature of reality that is studied. In parallel, an interconnected set of assumptions concerns the nature of knowledge as such. The term epistemology (from the Greek words 'επιστήμη' = science and 'λόγος' = speech) literally refers to the *speech about knowledge* (Klein, 1966) and as a field of philosophical inquiry investigates the nature, origins, scope and justifications of knowledge seeking to answer questions of what can be known and how (Stone, 2008; Willig, 2013).

Ontological and epistemological assumptions are embedded in the broader logic of enquiry that is adopted in a research approach. Blaikie (2000) suggests that there are four major logics of investigation that can be identified in social scientific research, each carrying its own philosophical and historical load: the *inductive*, *deductive*, *retroductive* and *abductive* research strategies. Though it should be noted that these research strategies constitute rather abstract typologies since in real research practice the boundaries are not rigid or always clear-cut and different strategies may be combined (Blaikie, 2000), their typical characteristics are presented below:

Inductive logic of enquiry: Inductivism was seen as the paradigmatic scientific reasoning by the British philosophers Francis Bacon (1561 – 1626) and later by John Stuart Mill (1806 – 1873) (Hammersley, 2006). The inductive logic attempts to provide generalisations proceeding from a particularity towards a more generic statement or theoretical proposition (Fox, 2008). Therefore, the inductive logic of inquiry starts with empirical observations and data collection, data are then analysed and generalisations are progressively built to develop law-like propositions that explain the phenomenon of interest. One basic prerequisite of this logic is that the collection of observations should be as systematic, objective and unbiased as possible (Blaikie, 2000; Willig, 2013).

Inductivism is closely tied to a set of philosophical ideas known as positivism. As a result of this philosophical commitment, in terms of ontological assumptions the inductive logic presumes that there is an ordered reality ‘out there’ to be discovered that is governed by laws and is external to, or independent from, human beings. Its epistemological premises accept that scientific knowledge can be produced through the use of senses (i.e. empiricism) and the goal each time is to provide objective and uncontaminated observations which can faithfully document the reality. The components that characterise the inductive logic of investigation are the progressive accumulation of empirical observations, the inductive inference of generalisations (i.e. from the particular to the universal), and the instance confirmation of these generalisations (Blaikie, 2000). Though the inductive research strategy is traditionally tied to quantitative methods, such as surveys that seek to record and establish patterns and associations, this logic of inference has also been adopted by some qualitative approaches to data analyses such as the ‘grounded theory’ developed by Glaser & Strauss in the 60s which aims to develop or extend theory (Bloor & Wood, 2006, pp. 95-98; Fox, 2006; Hammersley, 2006). Finally, the main scientific objectives of the inductive logic are to *explore*, *describe* and possibly *explain* through the law-like propositions the observed regularities (Blaikie, 2000).

Deductive logic of enquiry: Deduction as a form of syllogism has its roots in ancient Greek philosophy (Shank, 2008a) and follows a reverse-from-induction pattern of logical reasoning that starts from the generalities to arrive at the particularities. As a logic of scientific investigation, deduction became dominant during the 20th century with Karl Popper’s (1902 – 1992) work which developed and advanced what is now commonly known as the *hypothetico-deductive method* (Willig, 2013).

The deductive logic was developed on the assumption that observations are necessarily selective and cannot be collected without presuppositions. That was one of the main criticisms and limitations of inductivism that the deductive logic tried to overcome. Given this premise, and in order to collect useful observations, one should first have or form a set of ideas about what to investigate and some tentative answers, that is hypotheses derived from a theory, about why the phenomenon of interest unfolds in particular ways. Data are then collected to test the theory and the aim of science is to progressively eliminate false theories and to accept, for the time being, those that stand the empirical test (Blaikie, 2000).

Thus, within the deductive logic of enquiry, the scientific endeavour shifts from efforts of verification of theoretical propositions - as happens in inductivism - to efforts of falsification that will enable to keep only those theories that are closer to truth (Willig, 2013).

The hypothetico-deductive method is located within the philosophical tradition of Critical Rationalism. Critical rationalism has some common ontological assumptions with positivism as it accepts the existence of an ordered and objective reality that should be discovered, but it differs in its epistemological premises. Specifically, critical rationalism challenges the absolute primacy of senses as a secure source of knowledge and gives prominence to Reason (Blaikie, 2000). Finally, with regard to methods the deductive logic has been strongly aligned with quantitative approaches, primarily experimental, and the basic scientific aim is to provide *explanations* of why reality unfolds in certain ways.

Retroductive logic of enquiry: The retroductive logic of enquiry is closely tied to the philosophical tradition of Scientific or Critical Realism which is founded on the work of the British philosopher Roy Bhaskar (2008). Critical Realism disputes the assumption that the *real* is purely *empirical* (Smith, 2006), as being accepted by positivists and post-positivists, and proposes instead a stratified view of social reality that consists of three domains: the *empirical*, the *actual* and the *real*. The actual realm of reality consists of all those events and outcomes that happen and are observed in the social world whilst the real domain consists of latent, unobserved forces, structures and mechanisms that have the potential to cause the events unfolding in the actual domain under certain conditions. Finally, the *empirical* realm encompasses the perspectives of humans (Clark, 2008; Elger, 2010).

In a retroductive research strategy one primary aim is to discover and establish the existence of the structures and mechanisms that are responsible for, and explain, the observable events (Blaikie, 2000). At the same time, the social character of knowledge generation is recognised and sufficient emphasis is placed on the importance of human experience, meaning, and interpretation with regards to their potential to influence human conduct (Clark, 2008). Within critical realism, social regularities are not considered to be universal laws but they are seen as historically and context-dependent tendencies. Moreover, unlike deductive reasoning, prediction is not easily accommodated in the

retroductive logic due to the premise that the social systems are open systems (Smith, 2006).

In a simplified form, the retroductive research strategy proceeds by proposing a theoretically-driven hypothetical model of the possible structure or mechanism that gives rise to the phenomenon of interest, followed by data collection that aims to document the existence of this underlying force. Retroduction emphasises the value of a theoretically informed research whilst also recognising its open-ended character since the ‘objects’ of study constantly evolve and are susceptible to new arrangements (Elger, 2010). With respect to the methods that are adopted, critical realism tends to accommodate both quantitative and qualitative techniques (Clark, 2008) and the purpose of science is primarily *explanatory*.

Abductive logic of enquiry: Abduction as a form of logical reasoning is oriented towards meaning and explanation and its importance as a distinct syllogistic was stressed by the American philosopher Charles Pierce (1839 –1914). According to Locke (2010) ‘it is a practical reasoning mode whose purpose is to invent and propose ideas and explanations that account for surprises and unmet expectations’ (p. 1). Unlike deductive reasoning that results in *certain* or *necessary* inferences - provided that the premises are true - and inductive reasoning that results in *probable* inferences, abduction can only produce *plausible* inferences and in this sense it is a suppositional reasoning (Locke, 2010; Shank, 2008b). Though the plausibility of inferences can be seen as an inherent weakness of abductive reasoning compared to the other two, it is exactly this quality that creates the space for novel scientific insights and alternative explanations.

Blaikie (2000) suggests that the abductive logic of investigation characterises distinctively the social scientific research. It encompasses a variety of philosophical traditions and research paradigms within social sciences, from ethnomethodology, phenomenology, hermeneutics, and social constructionism to critical approaches, which are all often come under the more generic term of *interpretivism* (Bhattacharya, 2008). Interpretivism focuses on the accounts that people provide around the phenomenon of interest, such as their knowledge, interpretations, reasoning, experiences, values and so on. Human meaning and sense-making occupy a central position within interpretive approaches and the value of detailed, in-depth and contextualised research is emphasised. As a result,

idiographic approaches are often privileged, such as case studies, whilst reductionist investigations are overtly rejected (Bakker, 2010). The aim is to produce scientific accounts from, and grounded in, lay accounts and to examine the social world as this is experienced and interpreted by people providing an understanding from ‘the inside’ (Blaikie, 2000).

In terms of ontological assumptions, the abductive logic of enquiry in essence accepts that the reality does not exist independently from humans but it is socially constructed by social actors through language. It is those social constructions of reality that should be studied, producing scientific knowledge that describes and interprets them (Blaikie, 2000). Given that the central preoccupation of interpretivism and abduction is the meanings and interpretations that people articulate around their actions and experiences, qualitative methods offer a particular advantage for their study. However, at this point it should be noted that not all qualitative research is tied necessarily to a purely relativist epistemological position, as it happens for instance in radical social constructionist and post-structuralist approaches but there are positions that accept some degree of external reality. Qualitative research is rather pluralistic and embraces positions and practices that can range from purely realist to purely relativist stances (Willig, 2013).

Table 3.1 presents succinctly the four logics of enquiry that have been generated in the social sciences along with their typical features.

3.2.1 Situating the present research

Broadly, the present research is subsumed under the abductive logic of investigation and adopts an interpretive approach which seeks to give prominence to peoples’ experiences, meanings, interpretations and everyday practices in relation to the topics of interest. Consequently, ontologically this research accepts that these experiences, views, and interpretations are legitimate and meaningful components of the social reality. With regards to the possibility of a reality existing beyond people’s immediate experiences and accounts, a moderate position is espoused that can be located between the two poles of positivism and radical social constructionism, which is in line with the premises of critical realism (Bhaskar, 1989; 2008). Specifically, it is accepted that social reality is not exclusively confined to people’s intersubjective experiences and meanings - which constituted the

principal focus of this research - but it is also consisted of entities and mechanisms, discursive and structural, that may surpass human experience. If the terminology of

Table 3.1
*Logics of enquiry in social sciences*¹²

Logics of Enquiry Typical characteristics	Induction	Deduction	Retroduction	Abduction
Aim	To develop law-like generalisations from empirical data	To test theories	To discover underlying generative mechanisms	To understand the phenomenon in terms of people's accounts
Scientific objectives	Exploratory Descriptive Explanatory Predictive	Explanatory Predictive	Explanatory	Exploratory Descriptive Understanding
Philosophical tradition	Positivism	Critical Rationalism	Scientific or Critical Realism	Interpretivism
Ontological assumptions	There is an objective reality external to human beings	There is an objective reality external to human beings	There is a domain of reality that is external to human beings (<i>i.e. real</i>)	Social reality is the symbolic world(s) of human meaning and interpretations
Epistemological assumptions <i>Scientific knowledge can be produced...</i>	...through the use of senses (i.e. empiricism)	...through the use of Reason (i.e. rationalism)	...through the use of rational abstractions	...from lay, everyday concepts, meanings and interpretations
Research Methods	Quantitative	Quantitative	Quantitative & Qualitative	Qualitative

the stratified view of reality proposed by critical realists was to be adopted, it is the *empirical realm* of reality that was subjected to scrutiny within the context of the present research.

¹² This table is based on Blaikie's (2000) typology (p. 101) but has also been extended to include additional features of the four logics of inquiry.

Epistemologically, the present research assumes that knowledge about aspects of the social world is possibly to be produced from the accounts and practices of people. At a first level, this knowledge is phenomenological in the sense that it attempts to describe in detail and convey the content and texture of the experiences that people articulate (Willig, 2013). Secondly, it is accepted that through the interpretation of the empirical data a window to the ‘real’ world opens and plausible explanations about the phenomena under investigation are possible to be provided. Finally, this research also recognises the socially constructed character of scientific knowledge since its production is historically and contextually bounded and the ‘knower’ or the observer cannot be easily separated from the ‘known’ or the observed.

3.3 Methodological choices

In line with the broader ontological and epistemological commitments and driven from the nature of the research questions, a qualitative methodological approach was selected for the empirical investigation of the topics of interest in the present thesis.

Any attempt to define qualitative research is particularly arduous due to the fact that it does not constitute a homogenous field (Yin, 2011). Rather, it is a diverse and quite fragmented terrain that is often characterised by contradictions and tensions (Denzin & Lincoln, 2005). Qualitative research encompasses a community of researchers who spread over the whole spectrum of disciplines in social sciences from sociology and anthropology, to psychology and communication studies, each with its own history, norms and research practices. Moreover, qualitative research emerges from, and is practiced within, multiple ‘paradigms’, that is sets of ontological, epistemological and theoretical commitments, that range from positivist and post-positivist philosophies to post-modern and critical approaches. These multiple disciplinary, philosophical, and theoretical influences make qualitative research diverse (Denzin & Lincoln, 2005; Mason, 2002). If the historical evolution and critical turning points of qualitative research as such throughout the 20th century was to be added, the picture becomes even more complex (for a historical overview of the field, see Denzin & Lincoln, 2005).

Despite the polyphonic and polymorphic character of qualitative research, there are some elements that characterise distinctively the field, often in contradistinction to

quantitative research. A first feature concerns the principal preoccupation of qualitative research with human meaning from the perspectives of the people who are studied. Qualitative research seeks to explore and understand how people make sense of, experience, interpret and construct their social realities from their own standpoint. Providing an account ‘from inside’ that captures the content and texture of people’s experiences is prioritised in opposition to quantitative research which primarily attempts to identify causal relationships between predetermined states that take the form of variables (Mason, 2002; Willig, 2013; Yin, 2011).

Secondly, qualitative research tends to be naturalistic, meaning that the phenomena of interest are studied in their own settings as they are naturally occurring rather than in artificial environments (Willig, 2013). As a result, context becomes highly important in qualitative researchers’ effort to understand the social world (Yin, 2011). For this reason, qualitative methods tend to be malleable and accommodating of the particularities of the situation within which data are generated as opposed to quantitative techniques which are highly structured and detached from real-life contexts (Mason, 2002). Finally, qualitative research is concerned with providing a rich, detailed, nuanced, and attentive-to-the-context account of the phenomenon of interest. To achieve this comprehensive and rounded examination, multiple sources of evidence are often used (Yin, 2011).

Flick, von Kardorff and Steinke (2004) suggest that qualitative research is appealing for one more reason; it creates a particularly fruitful space for the exploration and understanding of “an ever-increasing number of new modes and forms of living” in an era “when fixed social life-worlds and lifestyles are disintegrating and social life is being restructured” (p. 5). The open-ended character of qualitative research and its emphasis on the perspectives of the social actors allow a detailed examination of the experiences and everyday practices that come to the fore out of the constant “processes of pluralisation and dissolution” that are taking place in the modern world (Flick, von Kardorff & Steinke, 2004, p. 5).

In the present research, three qualitative approaches were employed to investigate the research questions; qualitative interviewing, a text analytic study of naturally-occurring online discussions, and an ethnographic case study. These qualitative methods and/or approaches are introduced in the following sections.

3.3.1 Qualitative interviewing

Qualitative interviewing is one of the most commonly employed methods of data collection in social sciences, making it a prevailing tool for knowledge acquisition (Brinkmann, 2008). In fact, interviewing has become so pervasive and ubiquitous in contemporary world that some scholars talk about ‘the interview society’ (Atkinson & Silverman, 1997) whereby interviewing has developed into ‘a routine and nearly unnoticed part of everyday life’ (Fontana & Frey, 2005, p. 698). Qualitative interviewing was favoured as a data-gathering method by different disciplinary fields and areas of study during the first half of the 20th century. The Chicago School of Sociology, for example, relied substantially on qualitative interviews, as well as several fields of psychological research, such as psychoanalysis and developmental psychology, and early industrial psychology (Brinkmann, 2008; Fontana & Frey, 2005).

Research interviews vary in their level of pre-imposed structure, ranging from highly structured formats, such as those used in surveys, where a predetermined set of closed questions with specific answer choices are designed and administered to all research participants, to semi-structured or unstructured formats (Britten, 1995). Though it is argued that qualitative interviews can never be completely unstructured as they are motivated by a specific research agenda (DiCicco-Bloom & Crabtree, 2006; Mason, 2002) qualitative interviewing pertains to this latter category of loosely structured conversations, which are also called in-depth interviews (Britten, 1995; DiCicco-Bloom & Crabtree, 2006).

Qualitative interviews are characterised by a relatively informal style of conversation where the respondents are encouraged to freely express their thinking in their own words (Yin, 2011). They are also open and flexible enough to allow for emerging, and possibly unexpected, themes to be discussed (Mason, 2002). As a result the sort of questions that are normally used are open-ended whilst follow-up questions are not uncommon as they aim to instigate further discussion on the basis of the material that the respondent brings into the conversation (Yin, 2011). Building and establishing a positive relationship between the interviewee and the interviewer have also been stressed in qualitative interviewing. Though this might be challenging because interviewer and interviewee are normally strangers to each other and convene for a short period of time to discuss sometimes personal matters, a

trustworthy rapport contributes to the creation of a comfortable space for respondents to narrate their thoughts and experiences (DiCicco-Bloom & Crabtree, 2006).

Despite the features that commonly characterise qualitative interviews, such as their open and flexible character or their focus on people's perspectives, qualitative interviews differ in the ways they are used by researchers depending on their broader epistemological and theoretical commitments. Roulston (2010) examined how qualitative interviews are used and theorised in various research reports and developed a typology of qualitative interviews based on their *theoretical conception*. Her classification identified the following six types:

- *The 'neo-positivist' interview*: The neo-positivist interview assumes that the research participant has an 'inner' self, consisting of thoughts, experiences, beliefs, opinions, and so on which can be revealed through careful and systematic interviewing. The role of the interviewer should be as neutral and distanced as possible.
- *The 'romantic' interview*: Similarly, the romantic interview also presumes that there is an authentic self of the interviewee which can be discovered. But in this case the role of the researcher changes decisively and becomes one that is characterised by active and genuine engagement with the respondent. It is through this relationship of trust, which acquires a more conversational and interactional character, that the interviewee's states are accessed.
- *The 'constructionist' interview*: The constructionist interview is concerned with how the topics that are being discussed are organised and socially constructed through language. It focuses particularly on the conversational resources that the interlocutors use and seeks to investigate how the manners through which things are discussed inform the emergence of topics as such. During the interview process, the interviewer attempts to develop an ordinary discussion employing common conversational skills.
- *The 'post-modern' interview*. The post-modern interview treats the generated data as 'situated performances of selves that are co-constructed by both the interviewee and the interviewer' (Roulston, 2010, p. 210). The

assumption of a unified and ‘true’ self is rejected and it is proposed that data rather produce partial and fragmented aspects of a non-unified self that is situationally constructed. In the post-modern interview, the role of the researcher is subjected under critical scrutiny and is equally taken into account in the analysis of results. Specifically, the interviewer’s subjective experiences, positionings, and stakes are examined and reflected upon (i.e. reflexivity) as to how they might have influenced the research.

- *The ‘transformative’ interview:* The transformative interview has basically emancipatory and social justice purposes. It aims to challenge conventional ways of thinking and normative beliefs about a given topic along with generating research data. The interviewer invites the participant to take a much more active role in shaping the research and their relationship takes the form of a constant collaborative dialogue. The researcher is attentive to both participants’ inputs and perspectives, and his/her own sensibilities that might affect the research.
- *The ‘decolonising’ interview:* This type of interview was developed out of the criticism that Western research on indigenous people around the world was part of the European colonisation, often with harmful effects for indigenous communities. The decolonising interview seeks to restore justice for indigenous communities by giving prominence to potentially marginalised voices whilst also respecting their own ways of living and worldviews. The researcher seeks to closely collaborate with participants in order to produce scientific accounts that genuinely reflect the indigenous people’s perspectives and that contribute to their benefit.

Roulston’s (2010) classification reveals the range of variants of qualitative interviews depending on their purpose and epistemological and theoretical framework. It could be said that this diversity expresses a continuum of stances ranging from more neutral approaches to perspectives that explicitly reflect political considerations (Fontana & Frey, 2005).

In the present thesis a middle position was adopted in relation to the conception of the interview as a research method and the management of the material produced. Interviews were primarily treated as a tool through which it was possible to know ‘something’ about

people's worlds and experiences. This material was not, however, considered to be a 'mirror reflection' of the realities that people articulate as a positivist or neo-positivist conception would assume. Rather the performative function of language that social constructionists postulate (Burr, 1995) and the influences of the interactive and situated nature of the interview context itself were acknowledged in their potential to shape and produce certain versions of accounts. Nevertheless, I concur with Miller and Glassner's (2004) view that "narratives which emerge in interview contexts are situated in social worlds" and that "*they come out of worlds that exist outside of the interview itself* [emphasis added]" (p. 131). It was thus considered that qualitative interviews was possible to provide a conduit to these social worlds and enabled to capture elements of people's experiences.

3.3.2 A text analytic study of naturally-occurring online discussions

The vast expansion of the internet usage over the last decades has undoubtedly affected a plethora of human activities and aspects of life. In 2013, 83% of the households in the UK had internet access, and 86% of the adult population, or just above 42 million people, used the Internet (Office for National Statistics, 2013). During the same year over 2.7 billion people worldwide, that corresponds to 39% of the global population, used the Internet and around 750 million households (41%) were connected to it (International Telecommunication Union, 2013). The striking diffusion of this technology has not left untouched the realm of research. Internet-mediated research is rapidly gaining popularity among researchers who recognise the potential of cyberspace to expand and augment their work. Indeed, the *UK Strategy for Data Resources for Social and Economic Research* has acknowledged the research value of data coming from the expansion of electronic communication and the internet usage and has set as one of its priorities, for the period 2013 – 2018, the identification of ways for beneficial exploitation of these data sources (UK Data Forum, 2013).

The potential to research large, diverse and sometimes hard-to-reach through more conventional methods populations along with the resource efficiencies and the novel ways of communication afforded by the Internet make internet-mediated research particularly attractive (Hewson, Yule, Laurent, & Vogel, 2003). Indeed, the range of research that can

be conducted online is noteworthy, encompassing a series of approaches, designs and methods; Lankshear and Leander (2005, p. 326) identify five major groups of studies:

- Ethnographic and participant observation-based studies within online communities
- Text and discourse analytic studies of material and interactions generated within text-based online spaces
- Interview-based studies (e.g. online focus groups, interviews through e-mails)
- Surveys and experiments through the administration of online questionnaires and experimental material, and
- Document-based studies that use the Internet as a tool to access and collect data from online archives and databases.

This categorisation of online research illustrates the obvious advantages that qualitative research can derive from this technology. But beyond the various qualitative approaches that are feasible to conduct through the Internet, an important conceptual distinction concerns the research use of this technology in itself. Markham (2004) suggests that the Internet in qualitative work can be approached either as a *tool* for research, in which case it is primarily seen as a medium for communication, or as a *context* that deserves itself investigation since it affords the possibility of multiple constructions of social reality through language within a setting where the notions of time and space are transformed and acquire plasticity.

In the present thesis, the Internet was principally conceptualised – and by extension used – as a medium for communication through which research material was accessed. Yet, even when the Internet is mainly conceived as a tool for communication, it might be experienced differently by different users. Markham (2004) proposes that the Internet can be experienced (a) simply as a *tool* for exchanging information and communicating, extending existing means for social exchange, (b) as a *place* for communicating where meaningful cultural spaces are built, and (c) as a *way of being* in the world in the sense that people construct and enact identities and shape the ways they connect to others. These different experiences of the Internet as a medium for communication could not but have important ethical and analytic implications even when the researcher uses the Internet instrumentally. Consequently, whilst in the present research the Internet was largely framed as a source of

potentially useful research data, the management, analysis and presentation of data took into account the different experiential tones that this material – and the spaces (i.e. online communities) within which it was produced – might have had for the people who developed the discussions. For example, whilst the online communities were the *space* for data acquisition for the researcher, the fact that these spaces might constitute meaningful cultural *places* or even *ways of being* (Markham, 2004) for some of the people participating in them was not discounted in the analysis of the data.

3.3.3 Ethnographic case study research

The term ethnography, which literally means the writing about cultures, nations or races, originates from cultural anthropologists' study of the writings and memoirs of travellers and missionaries during the last decades of the 19th century in order to gain an understanding of other cultures (Howitt, 2010a; Ybema, Yanow, Wels, & Kamsteeg, 2010). Ethnography was later linked with participant observation and 'fieldwork' conducted by anthropologists themselves, with Bronislaw Malinowski's (1884–1942) work being one of the most influential. Sociologists also engaged with ethnography – or what they would prefer to call 'case study' at the time (Hammersley & Atkinson, 2007) – to examine, not exotic cultures as the anthropologists mainly did, but their own culture and society. The Chicago School of Sociology with an investigative focus on urban environments has been leading in developing this stream of ethnography (Bloor & Wood, 2006; Howitt, 2010a).

The primary preoccupation of ethnography is to closely follow up and to systematically record the details of the everyday practices and meaning-making of the people or the group who is studied from their *own perspective* within their *natural* environment. For this reason, *participant observation* as a method of data collection is at the core of ethnography and usually requires an intensive and prolonged engagement with the 'field' on the part of the researcher (Hammersley & Atkinson 2007; Bloor & Wood, 2006). Though the methodical notation of observations, the so-called 'field notes', is a primary source of data, ethnographers also use other methods or sources to collect data, such as formal or informal conversations with key informants, documents, visual material or even quantitative instruments. In this way, they are able to check and validate their observations and interpretations and to gain a more rounded understanding of the phenomena. It is also

common practice for ethnographers to note down reflective notes and preliminary interpretations and speculations around the data they collect as part of their research diaries (Bloor & Wood, 2006). Due to the detailed, in-depth and focused character of ethnographic work, researchers tend to concentrate their efforts on a few cases, or even a single case (e.g. one setting, one group), and hence ethnography has commonly strong links with case study research (Hammersley & Atkinson, 2007; Goldbart & Hustler, 2005). Indeed, in some disciplines, such as organisational studies, case study research implies work that has been produced using an ethnographic approach (Ybema et al., 2010).

The level of ethnographer's engagement with the group of people who are studied varies from complete participation in the activities occurring in the field to total observation whereby the researcher does not attempt to get involved and simply observes the proceedings. In between those two positions, the ethnographer can adopt a middle-ground stance according to which he/she takes part to some extent in the activities of the field and simultaneously observes (Hobbs, 2006; Howitt, 2010a). Furthermore, the observation can be known (i.e. overt observation) or unknown (i.e. covert observation) to the people studied, though the latter would raise serious ethical concerns within the framework of contemporary research ethos (Hobbs, 2006).

Ethnography as a methodological approach to the study of social world derived from, and became established out of, a reaction towards the positivist paradigm that became dominant in social sciences and which borrows experimental and statistical methods from the 'positive' sciences – mainly physics – to examine social reality. Ethnography was developed on the premises of *naturalism*, a set of philosophical ideas postulating that the social world should be examined in *its natural state*, as it is naturally unfolding without any disruptions or research interventions. In this way, social scientists are able to come closer to the nature and real substance of the phenomenon (Hammersley & Atkinson, 2007). Though several criticisms have been raised with reference to the underlying commitment of naturalism to realism and the value neutrality of research (Hammersley & Atkinson, 2007) – tenets also shared by positivism – ethnography managed successfully to propose an alternative scientific enquiry for social sciences. For this reason, ethnography continues to attract intense interest and has been diffused in many disciplines and research communities beyond anthropology and sociology.

In the present thesis, the ethnographic case study that was designed and conducted retained much of the spirit of naturalism, namely the commitment to observe and record the phenomena of interest as they were *naturally* occurring in the pursuit of a better understanding based on ‘thick descriptions’ (Geertz, 1973) that enable the extension and enrichment of ‘experiential knowledge’ (Stake, 2005). At the same time, the researcher was attentive to the fact that social practices, interpretations and experiences as unfolding in the field are socially constructed and culturally bounded, assumption that bears implications for the degree and sort of ‘realness’ attributed to the things observed. Finally, and within the broader preoccupation with reflexivity, the author of this thesis was also conscientious about her own positioning in the ethnographic field and how this might have influenced the course of the research.

3.4 Quality criteria in qualitative research

Evaluating the quality of a piece of research is an important aspect of academic practice that seeks to warrant the legitimacy and strength of the scientific claims made. This is not only important from a purely epistemic point of view, but it is also essential for the users or commissioners of research, such as policy makers, who seek to base their decisions and actions on evidence. Thus, it is perhaps not accidental that frameworks for appraising the quality of qualitative evaluations which relate to the implementation of social policy programmes have been developed (see for example Spencer, Ritchie, Lewis, & Dillon, 2003).

Whilst certain evaluative criteria have acquired a relatively consensual status as far as the quantitative research is concerned – mainly the indicators of *validity* and *reliability* as these are inferred from, for example, the sampling strategy, the sample size, or the quality of measurement instruments – the scene is much more fragmented and contested when it comes to qualitative research. The difficulty and controversies in establishing quality criteria in qualitative research derives, on the one hand, from its relatively short history as an alternative scientific paradigm in social sciences, and on the other, from the diversity that characterises the field (Yardley, 2000). Nevertheless, and depending on the philosophical premises (i.e. ontological and epistemological tenets) upon which qualitative

research is founded, three main approaches have been advocated with regard to the use of quality criteria in qualitative research (Howitt, 2010b, p. 359)

- The first position, which is associated with an extreme relativist or anti-foundational stance (Seale, 1999), asserts that no quality criteria should be applied to qualitative research since every research endeavour is unique and equally valid.
- The second perspective, commonly linked to an anti-realist philosophical view, posits that since qualitative research constitutes a fundamentally different scientific paradigm, new and different quality criteria should be devised and applied as appropriate.
- Finally, the third approach to the problem of quality control accepts that the traditional criteria of validity and reliability can also be used to evaluate qualitative research, though not in a straightforward manner. This approach is aligned with subtle realism (or critical realism) which affords an ontological substance to some sort of reality, although it disputes the positivist view that this reality can be approached and investigated objectively.

Within the context of the second approach to the problem of appraising the value of qualitative research, several efforts have been made to formulate a set of canons that can guide the evaluation process. For instance, Henwood and Pidgeon (1992) – coming primarily from a grounded theory approach to qualitative research - suggested the following seven criteria:

1. The extent to which the data fit with the theoretical claims or propositions,
2. Whether the theory is well developed and integrated at different levels of abstractions
3. Reflexivity on the part of researcher
4. Sufficient documentation of the research process
5. Theoretical sampling and negative case analysis (i.e. actively seek and account for cases that challenge deriving analytic categories and conceptualisations)
6. Sensitivity to how other stakeholders (e.g. participants) might interpret both the phenomenon studied and the output of the research, and
7. Transferability of results to similar contexts, situations, participants.

Elliott, Fischer, and Rennie (1999) also produced a set of guidelines after several rounds of consultation with experts in the field. The proposed guidelines pertain to the following aspects:

1. The research should own one's perspective which is the equivalent of reflexivity
2. The sample should be well situated in the sense that adequate information for, and contextualisation of, the research participants is provided
3. Claims should be grounded in examples
4. Credibility checks should be performed such as checking results with research participants, using multiple analysts, or analysing the data from different qualitative perspectives
5. The research report should achieve coherence and integrative understanding
6. Accomplishing general vs specific research tasks properly depending on the scope of study, and
7. The results should resonate with readers' understanding and appreciation of the phenomenon.

A further set of rules for discerning the quality of qualitative research was proposed by Yardley (2000). Though these principles are arguably pertinent to quantitative research as well, Yardley customising them suggested that good qualitative research should display:

1. Sensitivity to the context, be it theoretical context, the participants' perspectives, or the socio-cultural environment
2. Commitment and rigour in, for example, engaging with the topic or in collecting and analysing the data
3. Transparency and coherence (e.g. transparent methods and data presentation, reflexivity), and
4. Impact and importance from a theoretical, socio-cultural, and/or practical viewpoint.

Undoubtedly, having available an evaluative framework is useful, especially for the novice researcher who starts engaging with qualitative research. Nevertheless, due to the diversity of qualitative research and the different philosophical stances, evaluative frameworks should be used with caution ensuring that the criteria are rightly applicable to

the particular study. I subscribe to the view expressed by Willig (2013) that the evaluation should, on the one hand, be compatible with the ontological and epistemological underpinnings of the research, and on the other be directed from the extent to which the research objectives were attained and the research questions were answered. Since the principal focus of the present research was to examine and understand the perspectives of two key stakeholders engaging with home medical technology whilst adopting qualitative methodologies, the evaluation could revolve around aspects of *completeness* in capturing these perspectives, the *plausibility* and *strength* of the explanations offered for the phenomena studied, the degree to which this research was *sensitive to the context*, was conducted *rigorously* and is presented *transparently* allowing the arguments and claims to flow *coherently* whilst them being *grounded in evidence*. The degree to which the researcher herself was attentive to, and *reflected upon* her own values and presuppositions could also serve evaluative purposes.

3.5 Exposing the researcher’s ‘footing in the world’: notes on reflexivity

The previous section sought to signal the idea that reflexivity is often considered as a marker of quality in qualitative work. At a very basic level, reflexivity refers to the occasion when researchers ‘turn a critical gaze towards themselves’ (Finlay, 2003, p. 3) to recognise, understand and reflect on their ‘footing in the world’ (Goffman, 1981) and the implications this has on shaping, conducting and reporting research. With the advent and rise of anti-positivist paradigms in social sciences (i.e. interpretive, critical, feminist, post-modern, post-structural approaches), a ‘reflexive turn’ has emerged (Mauthner & Doucet, 2003) which seeks to challenge the modern convictions of objectivity and detachment from the object studied and subjects this awareness of inseparability to scrutiny in quest of ‘better’ research insights.

Notwithstanding the broad consensus around the value of reflexivity, the notion has multiple meanings, is practiced variously and is used for different purposes depending on the ‘school of thought’ into which the qualitative researcher is subsumed. For this reason, talking about ‘reflexivities’ rather than ‘reflexivity’ captures more precisely current qualitative research thought and practice (Gough, 2003).

Using a schematic categorisation – and thus being unavoidably simplistic – reflexivity is employed either as a means to enhance the persuasiveness and credibility of research or as a tool to deconstruct the very process of scientific representation (Gough, 2003). In between those two extremes, there are variants of reflexivity more or less aligned with the respective philosophical starting points of realism and radical constructionism. When reflexivity (also called ‘positional reflexivity’ Macbeth, 2001; ‘reflexivity as introspection and inter-subjective reflection’ Finlay, 2003) is used to afford a greater trustworthiness to the scientific work, the researcher explicates how his/her own values, presuppositions, socio-demographic characteristics, biography, professional commitments and relational aspects of his/her engagement with research participants have influenced aspects of the research process, from the selection of the topic and designing of studies, to the collection, interpretation and reporting of data. The acknowledgement and active processing of these influences is assumed to enable the production of a more integrative and ‘truer’ scientific account. This approach has been criticised on the grounds that it ultimately serves the very same positivist promises of ‘objectivity’ – via incorporating and accounting for subjectivities in this case – and ‘truth discovery’ orientation which supposedly rejects (Macbeth, 2001; Gough, 2003).

The other pole of reflexivity which is compatible with relativist approaches aims to challenge notions of authority – including scientific authority – and to unveil the linguistic devices that produce and preserve authoritative accounts. Since the focus of this sort of reflexivity is commonly on language and its deconstruction, it has been sometimes called ‘textual reflexivity’ (Macbeth, 2001) or ‘ironic deconstruction’ (Finlay, 2003). This radical reflexivity is not without its criticisms; since it is largely rooted on anti-foundational and relativistic premises, it risks succumbing to an endless deconstruction that results in nihilism (Gough, 2003). At the same time, radical reflexivity has been condemned to detract attention from the phenomena studied and to become overly narcissistic (Gough, 2003). Finally, while this sort of reflexivity seeks to destabilise scientific representation, it ultimately relies on the same project to do this (Macbeth, 2001). For this reason, some scholars borrow modes of writing from arts and literature (e.g. poetry) to report their work, in an effort to question conventional forms of scientific representation and to practise reflexivity by challenging the authority of their own authorship.

Occasionally, reflexivity is used as the principal methodological tool in certain research approaches, such as auto-ethnography (Dowling, 2006) while in approaches, such as ethnomethodology, the participants' reflexive capacity becomes the very object of examination as a constituent of the phenomenon studied (Macbeth, 2001; Gough, 2003).

In the present research, and in line with the broader ontological and epistemological commitments (i.e. critical realism), reflexivity is considered to be a tool that can assist with a better appreciation of how the research was formed and developed in conjunction with the researcher's 'footing in the world'. Though my positional confessions do not automatically or necessarily give more credence to this work, I trust that they at least offer a contextualisation of my philosophical, methodological, and theoretical choices.

My educational socialisation has undoubtedly shaped this research in many ways. Having been trained in psychology, which has been dominated – at least, until very recently – from the positivist paradigm, influenced the ontological and epistemological orientation of this research. Feeling quite uneasy to abandon all the modern scientific certainties with which I was trained, I attempted to find a space which would be, on the one hand, compatible with the alternative spirit that the big Q (Willig, 2013) [qualitative] research brings to the social sciences, whilst also retaining some realist foundations. Critical realism (Bhaskar, 1989), as an overarching philosophical context, appeared suitable since it attempts to synthesize and amalgamate the two opposing poles (i.e. realism and relativism). Though the present research was not designed to directly investigate the underlying *real* forces that give rise to the *actual* phenomena, but it focused more on the *empirical* realm, interpretations that implicate aspects of this underlying, latent reality (i.e. discursive and structural) are provided as *plausible* explanations.

The broader research programme I was placed as a PhD student - the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) – also affected the selection of a critical realist standpoint. Since the objective of MATCH was to 'support both companies across the UK healthcare technology sector and user communities...to assess the value of medical devices'¹³ and the research area was predominantly applied, research findings that would indicate some concrete insights into the problem of valuation of medical technology from the perspectives of different stakeholders were considered appropriate.

¹³ <http://www.match.ac.uk/>

Moreover, due to the fact that my PhD topic was an entirely new-for-me territory (along with the paucity of existing research in some areas), I was predisposed to adopt a largely inductive approach that would build descriptions and explanations grounded in empirical evidence. My status as a PhD student, and the element of education in it, also coloured the course of this research. More specifically, as I had been previously engaged exclusively with quantitative methods, I was very interested in ‘experimenting’ with research methods I had no prior experience of, such as qualitative methods. Therefore, pragmatic and education-oriented considerations also played a role in shaping my work.

3.6 Ethical considerations in research with human participants

This chapter would not be complete without some deliberation on the ethical aspects of research. Ethics is a significant consideration in social sciences when conducting research – either quantitative or qualitative – that involves human participants. The necessity to produce written ethical guidelines and standards derived from historical reasons. Specifically, the cruelties that took place in the name of medical science in Nazi Germany during the Second World War led to the development of the ‘Nuremberg Code’ in 1947 and later on the ‘Declaration of Helsinki’ in 1964 (Bloor & Wood, 2006; Howitt, 2010c). The Universal Declaration of Human Rights, published in 1948, was also a product of the atrocities the humanity experienced during the Second World War. All these documents champion and defend the protection of fundamental human rights such as dignity, autonomy, safety, maximisation of benefits and minimisation of harms, and respect for persons and justice (Ess & Association of Internet Researchers, 2002). Several professional organisations have since proceeded to issue ethical guidelines that should regulate research as well as professional practice. The British Psychological Society (2009; 2014), for example, has published a ‘Code of Ethics and Conduct’ that is based on four principles: *respect, competence, responsibility* and *integrity*. Similarly, the American Psychological Association (2002) has developed an ‘Ethics Code’ based on 10 standards.

The development of ethical frameworks in social sciences has primarily been based on principles (i.e. ‘ethics of principle’; Preissle, 2008). Two main doctrines can be discerned: the so-called *utilitarian* or *consequence-based* approach and the *deontological* approach (Ess & Association of Internet Researchers, 2002). The former relies substantially on a

‘cost-benefit analysis’ prescribing that if the benefits expected from the research are significant and the potential risks are minimal, then the research is ethically justifiable. To the contrary, the deontological approach to ethics postulates that no research benefit can be justifiable if it was to be produced by infringing fundamental human rights. More recently with the growth of critical approaches to social research (e.g. action research, feminist research), ethical standpoints that depart from the values of *care* and *justice* have also been advocated as guiding frameworks (Piper & Simons, 2005; Preissle, 2008).

Qualitative research is particularly sensitive to ethical considerations, on the one hand, due to the often different nature of engagement with research participants, as compared to quantitative studies, and on the other, due to the humanistic ideals which have inspired much of the qualitative paradigm. Notwithstanding the attentiveness of qualitative research to ethics, the open-ended character of this sort of enquiry constantly raises questions and challenges. For this reason, a degree of judgment on the part of the researcher is often required to resolve conflicts and to balance competing considerations that might arise in the conduct of work.

The present research largely adopts a *deontological* approach to ethics that prioritises fundamental human rights over and above any research benefit. For the ‘operationalization’ of this approach, the work presented in this thesis relied on the Code of Ethics and Conduct recommended by the British Psychological Society (2009; 2014). As far as the interaction with human participants is concerned, the principles of *informed consent*, *confidentiality*, *anonymity*, *right to withdraw*, *no deception* and *debriefing* were at the core of regulating the present work (Willig, 2013). At the same time, a ‘situated’ approach (Piper & Simons, 2005) to applying ethical principles was espoused by the author of this thesis that created enough space to adjudicate unanticipated ethical dilemmas. In other words, a degree of judgment (or ‘*phronesis*’ in Aristotelian terms) was enacted as appropriate, circumscribed by the broader moral frame of reference.

CHAPTER 4 – EMBEDDING HOME BLOOD PRESSURE MONITORS INTO DAILY LIFE: AN INTERVIEW STUDY

4.1 Overview

Chapter 4 presents the first empirical study that aimed to shed light on the user perspective. Specifically, the research question that this study sought to address asked how lay people come to own and incorporate a home blood pressure monitor (HBPM) into their daily life and what sort of challenges, if any, they encounter in doing this. Qualitative research, based on one-to-one, semi-structured interviews with 18 users of HBPMs was conducted and the data were processed using thematic analysis. Domestication theory (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992) was used to inform both the design of the study and the analysis of the data whilst the researcher was simultaneously attentive to any additional themes emerging from the data. The results showed that the integration of home medical technology into daily life was not always straightforward; the device should first be trusted and for this reason users often invented new device usages that helped them to establish the trustworthiness of the technology. Though the possession and use of the HBPM remained largely a private matter, the practice was commonly communicated to the doctor. The perceived support from doctors varied, whilst tensions were occasionally articulated in participants' efforts to claim a legitimate 'self-tester' status within the doctor-patient relationship.

This chapter proceeds as follows: first, the present study is located within the existing research around HBPMs and domestication theory is then introduced. Second, the details of the methods and the research procedure are described followed by the presentation of the results. Finally, the chapter concludes with a critical discussion of the findings.

4.2 Introduction

Hypertension constitutes an important public health concern due, on the one hand, to the large and constantly increasing numbers of people affected by this condition (Kearney et al., 2005) and, on the other, to its contributing role, as one of the major risk factors, to

cardiovascular and renal disease (Lim et al., 2012). Owing to the asymptomatic character of the disease, the ability to perform accurate blood pressure measurements is critical for the timely detection and diagnosis of hypertension so as then appropriate management plans can be developed for the patient.

Blood pressure measurements are routinely taken in doctors' surgeries but the informational value of out-of-office measurements, such as those taken at home by lay people themselves, has started to be recognised by the medical world. In the UK, this recognition was more formally crystallised in 2011 when the *National Institute for Health and Care Excellence* (NICE), in cooperation with the *British Psychological Society* (BPS) released an updated guidance for the clinical management of hypertension. In this guidance, primary care practitioners were instructed for the first time to offer ambulatory or home blood pressure monitoring as an adjunct to office measurements for purposes of diagnosis and management of hypertension (NICE, 2011).

Home BP monitoring has been shown to be clinically useful as it improves hypertension control compared to conventional office monitoring (Agarwal et al., 2011; Cappuccio et al., 2004; Verberk et al., 2005), has the potential to reduce therapeutic inertia (Agarwal et al., 2011), and presents good predictive value for hypertension-related morbidity and mortality (Verberk et al., 2005; Yarows et al., 2000). Home BP monitoring is also well received by patients; they consider it as the most acceptable and satisfactory method of measurement compared to clinical or ambulatory monitoring, adjudging that it causes little inconvenience and is also easy in use (Aylett et al., 1999; Little et al., 2002). Indeed, research evidence shows that a noteworthy minority of the general public in the UK – around 9% – have self-tested their blood pressure (McManus et al., 2007) whilst the percentage increases considerably when it comes to hypertensive populations (Baral-Grant et al., 2011; Cuspidi et al., 2005; Viera et al., 2008). The growing appetite that lay people demonstrate for self-managing their own health (O'Brien et al., 2003; Parati et al., 2008) and the wide availability of HBPMs on the market for direct purchase (Graves, 2005) contribute to the rising popularity of home BP monitoring.

But how do people who engage with home BP monitoring, view, think about and experience this practice? Though the existing evidence in the field is somewhat sparse, a few qualitative studies have tried to shed some light on the experience of using a HBPM

(Abdullah & Othman, 2011; Jones et al., 2012; Ovaisi et al., 2011; Rickerby & Woodward, 2003). Overall, this research shows that home BP monitoring is generally well accepted by most patients since it is considered a relatively easy activity to perform, that self-evidently enables people to exert more control over the management of their condition and offers greater informational value around blood pressure than simply relying on single readings taken at doctor's surgery (Jones et al., 2012; Ovaisi et al., 2011; Rickerby & Woodward, 2003). In some instances, home BP monitoring was seen to contribute to the strengthening of the relationship between the patient and the doctor (Abdullah & Othman, 2011) whilst it also motivated people to seek information and to learn more about their condition (Abdullah & Othman, 2011; Rickerby & Woodward, 2003). Despite the benefits of home BP monitoring for many users, there were also instances whereby uncertainty around the accuracy of the technology was expressed, as well as confusion around the targeted blood pressure levels (Abdullah & Othman, 2011) or anxiety with received readings (Ovaisi et al., 2011). Though a lot of patients in these studies were quite enthusiastic about using a HBPM, this was not always the case, especially for those patients who encountered difficulties in using the technology due to their physical impairments (Ovaisi et al., 2011).

In summary, the abovementioned research reveals that medical technology has a dual function in that it both solves and creates problems (Lehoux, 2008). Moreover, its value is constructed as a function of the health condition of the patient (e.g. the usefulness of the technology is reduced for patients who cannot effectively use the technology due to physical limitations) as well as the latter's relationship with other implicated actors, the primary example being that of the doctor.

Clearly, this research provides useful insights into the nuances of the experience of using a HBPM. Nevertheless, most of this research tends to focus on specific patient populations (e.g. hypertensive patients; stroke patients) whose use of the technology is closely linked to the healthcare system (e.g. HBPMs offered by doctors; patients participating in a related trial). Thus, little attention has drawn to instances where people themselves initiate the purchase and use of the device (for an exception see Abdullah & Othman, 2011) and therefore the engagement with the health technology is more distanced from any exchanges with the medical profession. Moreover, possibly due to limited evidence in the field, the existing research is largely inductive without seeking to incorporate any theoretical

insights. Occasioned by these two observations, the present study sought to augment the current evidential base around the lay experience of engaging with home BP monitoring by focusing on users who purchased a HBPM for their own use and by seeking to incorporate theoretical insights into the design of the study and analysis of the data. The theoretical framework that was used to inform this study is presented below.

4.2.1 Domestication theory

The theoretical framework which informed this research was domestication theory. Domestication theory (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992) was developed in the early 1990s in the UK, and belongs to the family of theoretical approaches which assume that technological artefacts are socially shaped and co-constructed along with the user (Hynes & Richardson, 2009). These perspectives depart from assumptions of technological determinism or essentialist views of users and propose that both users and technologies are embedded in and co-constructed through social processes and interactions (Oudshoorn & Pinch, 2003).

Influenced by Bourdieu's work, domestication theory focuses principally on users and consumers of technological products and postulates that technology must be culturally assimilated in order to become fully functional. Initially, domestication scholars studied the consumption and appropriation of Information and Communication Technologies (ICTs) within the space of household, but other researchers extended the scope and application of the theory beyond the home environment and studied additional technologies, such as cars (Haddon, 2006).

Domestication theory proposes that the “taming” of technologies and their transformation into familiar objects within the household is characterised by four “non-discrete elements or phases” (Silverstone, Hirsch & Morley, 1992, p. 20): *appropriation*, *objectification*, *incorporation* and *conversion*. Appropriation reflects the process of consumption. During this phase the technological commodity is transformed into an object through possession and ownership. The phase of objectification is represented in the usage and the physical display of the technological object in the spatial arrangements of home and the element of incorporation concerns how and for what purposes the technologies are used. While objectification pertains mainly to the spatial display of the object, incorporation is

related principally to the temporal aspects of usage. Finally, the phase of conversion signifies the importance of owning and using the particular technology as this is communicated outside the home. During conversion, claims of status and identity are attempted to be communicated to other people and relationships to be defined (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992).

This theoretical framework was considered to be appropriate for this research and to provide useful conceptual tools (i.e. appropriation, objectification, incorporation conversion), since the focus of the study was on users who had personally purchased a medical device designed to be used within the home environment.

4.3 Methods

4.3.1 Design, study population and sampling strategy

A qualitative, interview-based study was designed to examine people's perspectives on acquiring and using a HBPM. Through the elicitation of rich and situated data, qualitative interviews enabled a detailed examination of the users' experiences, interpretations and meanings around their engagement with the health technology.

The study population of interest was people who had purchased a HBPM for their own use. Those who had been provided with the technology via their healthcare provider (e.g. National Health Service - NHS) were thus excluded. Since prospective participants were principally conceptualised as users of home medical technology, a purposeful sampling with maximum variation (Patton, 1990) in terms of the health conditions that triggered the device purchase was attempted. Using the sample sizes of previous related research (Abdullah & Othman, 2011 ($N = 24$); Jones et al., 2012 ($N = 23$); Ovaisi et al., 2011 ($N = 26$); Rickerby & Woodward, 2003 ($N = 13$)) as an indication for the determination of the targeted sample size of this study (Marshall, Cardon, Poddar, & Fontenot, 2013), a target of 20 people was set, subject to the criterion of data saturation.

4.3.2 Recruitment strategy and data collection

Participants were recruited through advertisements placed at Brunel University London and at the library and shops of the local community (i.e. Uxbridge). The personal networks

of the researcher were also used to attract participants. Pharmacies in the local community were approached but adverts were not feasible to be placed at these sites. The advert that was created for this study is presented in Appendix A. Table 4.1 presents the sites of recruitment and the number of people who were recruited from these sites.

Prospective participants were initially invited to fill in a short questionnaire which ensured that they were eligible to take part in the study. The questionnaire also included basic demographic information as well as information around the characteristics of the HBPM (e.g. type, brand, cost), its use (e.g. duration of use, frequency of use), and the health condition that triggered the purchase. The screening questionnaire can be found in Appendix B.

Table 4.1

Recruitment sites

Recruitment sites	No of participants
1. Brunel University London	13
<i>Academics</i>	4
<i>Students</i>	4
<i>Staff</i>	2
<i>Contacts of University staff outside the University</i>	3
2. Local Community (i.e. adverts at public library and local stores)	1
3. Researcher's networks	4
<i>Total</i>	18

Eligible participants were then invited to take part in a face-to-face, semi-structured interview at a place and time convenient for them. Interested respondents were initially informed about the purpose and the procedure of the study, were given information about the ethical aspects of the research and were prompted to ask questions or clarifications if they wished to do so (the *Participant Information Sheet* is provided in Appendix C). After they had provided in written form their informed consent (see Appendix D for the *Informed*

Consent Form), the interview was conducted and tape-recorded. At the end, participants were fully briefed (see Appendix E for the *Participant Debriefing Letter*) and were provided with a £15 voucher of their choice as a token for their participation. The study received ethical approval from the research ethics committee of Brunel University, London.

An interview protocol was designed to guide the interviewer through the various aspects of home BP monitoring that were examined. More specifically, the questions aimed to explore the following areas:

- the reasons for purchasing a home BP monitor and the ways through which people had searched for the product as well as the factors that they had taken into account in order to make the purchase,
- the features of the device that were judged as most and least desirable,
- the patterns of usage, and the storage of the device within the home,
- the communication of the practice of home monitoring to the doctor and its perceived influence on the patient-clinician relationship,
- the way people make sense of the readings and the actions they were taking as a result of that, and
- the impact of the practice on images of self and the management of health.

The interview protocol was piloted prior to the main study with a user of HBPM to make sure that the questions were intelligible and clear (the detailed interview protocol is provided in Appendix F). The research interviews were carried out between January and April 2012 and lasted 31 minutes on average.

4.3.3 Data analysis

Tape-recorded interviews were transcribed verbatim by a professional company. Scripts were subjected to thematic analysis, a suitable analytic technique for the identification of ‘repeated patterns of meaning’ (Boyatzis, 1998; Braun & Clarke, 2006). The analytic work proceeded as following: initially there was a familiarisation process through the repeated reading of transcripts that facilitated immersion in the data. Interesting and relevant points were noted and a summary of key information for each participant was produced. Next, extracts of identical meaning were assigned to developing codes, assisted by computer

software (NVivo 9). Semantically related codes were then grouped together and themes and subthemes were progressively developed and refined. The themes and subthemes reported in this chapter were saturated by the 18th interview, a point at which further participant recruitment was not deemed necessary.

4.3.4 Participants

Twenty-one people initially expressed an interest in the study of which 18 were eligible and took part in the interview. Seven were female and 11 were male, aged between 23 and 93 years old. All participants were well educated. The self-reported health conditions that triggered the device purchase were hypertension, hypotension, white-coat effect and blood pressure-related problems as a result of other conditions or medication. Table 4.2 shows the characteristics of participants.

Table 4.2

Characteristics of participants (N = 18)

Characteristic	N
Gender	
<i>Male</i>	11
<i>Female</i>	7
Age	<i>M = 54; Median = 55; Min = 23, Max = 93</i>
Education	
<i>Degree or degree equivalent and above</i>	17
<i>Higher education to less than degree level</i>	1
Nationality	
<i>British</i>	14
<i>British/Egyptian</i>	1
<i>Non-British</i>	3
Employment Status	
<i>Employed</i>	9
<i>Unemployed</i>	1
<i>Retired</i>	4
<i>Other (e.g. student, self-employed)</i>	4
Marital Status	
<i>Married</i>	14
<i>Divorced</i>	2

<i>Single</i>	1
<i>Missing</i>	1
Self-reported health condition prompting the device purchase	
<i>Hypertension or elevated BP readings</i>	8
<i>High BP during pregnancy or fear of high BP during pregnancy</i>	4
<i>BP related problems as a result of other health conditions (e.g. cardiovascular disease, cancer) or medication</i>	3
<i>Hypotension</i>	2
<i>White-coat effect</i>	1

Concerning the device characteristics, all interviewees had an automatic monitor except for one who used a manual device. Two thirds of the monitors cost less than £50 and the remaining ranged between £50 and £100. The features of the participants' devices are shown in table 4.3.

Table 4.3
Device characteristics

Characteristic	N
Clinical validation	
YES	6
NO	2
'Don't know'	10
Type	
Automatic	17
<i>Upper arm</i>	14
<i>Wrist</i>	3
Manual (i.e. mercury)	1
Cost	
< £50	12
> £50 and < £100	6

4.4 Results

The analysis is structured on the basis of the phases/elements the domestication framework proposes to illustrate the process of ‘taming’ new technologies and of embedding them in daily life. Thus, the analysis examines (a) how prospective users consumed and came to own the medical technology (appropriation), (b) how medical technology was displayed within the domestic environment (objectification), (c) how the device was embedded into the temporal structures of daily life and for what purposes it was used (incorporation), and (d) how users communicated to the external world the ownership of the device and the accompanying practice of monitoring (conversion).

The quotes that are used to illustrate the themes are identified by participants’ gender (M for males; F for females), age, and unique identification code.

4.4.1 The phase of appropriation: turning health technology from a commodity to an object of ownership

The phase of appropriation (or commodification) unfolds during the process of consumption; the *commodity* becoming an *object* of desire and in turn an object that is owned and possessed, leaving the scene of public space to enter the domestic space.

In this study, most participants had self-initiated the process of consumption without being directed to do this by their healthcare provider. Only three participants had been advised by their doctor to buy a HBPM. Across all accounts, the underlying motivation for the purchase was a willingness to track closely a medical condition and to develop a deeper, and most importantly an *experiential* and *first-hand* understanding of the problem and its progress. This sometimes generated a sense of control and efficacy that alleviated worries, since users were able to detect potential problems in a timely fashion and to take action accordingly. In answer to my question of how the decision to buy the device was made, one participant explained as follows:

P: Okay. Well, I was lucky enough to find myself pregnant, and em, being, em, an older lady, em, according to clinical definitions for being pregnant, em, my husband particularly, and myself, were worried about pre-eclampsia, which is em...a problem in...in pregnancy, as you probably know, and so...and...I'm a person who tends to worry about things.

I: Okay.

P: So my husband said, well, em, how about we get a monitor, because, that way, you can monitor yourself very closely at home, and if you see your blood pressure start to rise, we can, you know, consult clinical advice very quickly, rather than waiting for the monthly or two-monthly appointments that I had at antenatal clinics. So, that was the main reason for buying it. (F, 46, 1001)

For another participant, who had experienced a heart attack, the acquisition of the device was seen as an opportunity to possess an ‘early warning system’ of potential future episodes.

And then, yeah, having this would be a kind of...if I feel even vaguely like that again, a kind of early warning system. (M, 53, 1011)

Purchasing the device also endorsed respondents’ view that they actively self-managed their condition and did not rely solely on medical professionals.

I was very sure [about the decision to buy the device]. I didn’t want to have to see the doctor, and I didn’t want him to be managing me – I wanted me to manage me. The only way to do that is to know what’s happening. There’s not many things that you can manage yourself...But em, as far as that’s concerned, I knew the only way I could know is having one that worked measuring it myself. (M, 60, 1010)

Some participants saw the device purchase as an opportunity to have available an ‘experimental apparatus’ that would allow them to check out the association of their symptoms to blood pressure variations and to follow up closely the situation.

Initially, I started to get headaches, and as I mentioned before, I work in the area and I know the symptoms. So I had my blood pressure tested at the GP, a couple of times, and it was a little bit higher than average, and he put me on pills, and I decided to have one handy at home to experiment with. If I have a headache, then I can take my blood pressure and see whether it is higher than...than the average. And, in general, I decided to kind of take my pressure every day or every other day and to create a sheet and then to monitor the progress or the degress. (M, 48, 1009)

For others the acquisition of the technology was seen as a useful means to check the effects of medication on their blood pressure. This sometimes occurred against a background of distrust towards the medical profession. The questioning of doctors’ competences and decisions led some users to become more engaged with their health issues

and to adopt a more self-directing stance. The participant below, having described how he came to lose his confidence in doctors, bought the device in order to authenticate whether his blood pressure-related problem was genuine and what the effects of pills were. Here, the device purchase is situated within a context of participant's effort to be aware of and self-regulate his health alongside a more general scepticism towards healthcare professionals.

I had been aware for some many years that I wasn't happy with the medical profession and their various diagnoses. I'd had friends and relatives who had suffered – some had died – due to what I consider to be indifference by the medical profession. I found, in the year 2000, that I started having chest pains. I went to my doctor, who told me I needed more exercise, em, and...this continued over a period of some months, where I felt that, eh, having gone back, that I still wasn't being taken seriously. I went to the local library, looked up some books on chest pains, and found that they predicted I had heart problems. My doctor still refused to accept that, so I paid privately and found that I had a coronary heart disease and a blockage in one of my main arteries. When I produced the evidence from that, she got quite upset [laughing]. And eh, I've subsequently had a stent put in my heart at [name of hospital]Hospital, and em, I started to then take a keen interest in my own welfare, and from that, I decided that – I'd been given a lot of pills to control blood pressure and various other functions, which I wasn't sure that they were doing me any good, and what they were there for, so I decided to buy a blood pressure meter and monitor my own blood pressure, and, along with that, started to take note of the effects these tablets were having on me over the period of time. (M, 65, 1002)

Similarly, another participant saw the device purchase as a way to test out whether her doubts about the medical diagnosis were valid.

I was...I went into hospital. I think it was...January 2011, that's right, and em...The outcome was that they thought my blood pressure was too high and... I didn't really think it was because I felt okay, so we bought an [brand name], the little one, to see what details it could produce for me. (F, 93, 1012)

Arguably, the device purchase does not always come to complement and support doctors' contribution to patient management; rather the self-initiated consumption of home use medical technology may come as a result of the suspicion towards medical acts and the desire to test out their validity. This was expressed clearly in one account, where the

technology was linked to objectivity and science, while doctors' diagnostic acts were considered to be associated with subjectivity.

When I look into that a bit deeper, I find it's always that the doctors have given what I would call subjective opinion, just a guess, an opinion....The great thing about these kind of products and the products that will come in the years ahead is that they will give us actual objective, scientific information about how we are, how our bodies are functioning, and I think a lot of lives will be saved from that. (M, 65, 1002)

Finally, in addition to respondents' desire to understand their health condition experientially and to check themselves closely and proactively, convenience was also provided as a reason for the purchase of the technology. Possessing a blood pressure monitor at home was viewed to facilitate the daily routines as users did not need to visit their doctor that often and they could carry on with their activities. Thus, the ownership of the technology was additionally seen to satisfy pragmatic considerations.

I'm a hypertension person, so I need to keep an eye on my blood pressure....So, by buying the monitor at home, I'll have a clearer image of what is my eh...blood pressure looks like at the moment, and em, it's making my life really easier – that's it. (M, 30, 1004)

In summary, the phase of appropriation – which signifies the process of, and motives for, consumption – highlights people's strong desire to understand better their health status with a view to manage it more effectively. The technology is seen to provide the means through which users can gain a first-hand and experiential knowledge of their invisible bodily functions. This awareness is largely articulated as empowering since it strengthens people's sense of self-efficacy, and has the potential to instigate the right action at the right time (e.g. visit the doctor). Interestingly, the acquisition of health technology does not necessarily come to accompany the doctor's role or advice, but it might be triggered out of scepticism or distrust towards the medical profession more generally or particular medical acts.

4.4.2 The phase of objectification: displaying health technology within the domestic environment

The phase of objectification concerns the display of the technology within the domestic space. The analysis of the data showed that the display of the HBPM within the home environment served mainly instrumental purposes. The participants located and stored their

devices in places that facilitated and supported in various forms the practice of measurement. This was evident from the fact that in many accounts, space was closely interwoven with time. When participants were prompted to describe the place where they kept their devices, they simultaneously invoked the temporal structures within which they had integrated the practice of monitoring.

I: And where do you usually keep or store your machine within the home?

P: It's stored on a shelf in the cupboard in our breakfast room because it's usually in the morning or of a night-time when we take the blood pressure. (M, 77, 1014)

The functional character of the display of the device was further expressed in terms of specific ends participants wished to achieve. In one instance, the position of the monitor within the home operated as a reminder of the practice, similar to the one that was adopted for medication. Keeping the monitor in a visible place helped the user below to remember to take his readings.

Currently, I take my keys, put them on, em, the cupboard in the kitchen when I get in, and I always put the tablets on top to remind me. So, with the blood pressure [monitor], if...if I put it away in the cupboard, I might forget that I wanted to do it, so I'd often leave it on the bed, so that I'd remember I wanted to take my blood pressure over those few days. (M, 60, 1010)

In other instances, the display of the device assisted users to take their readings with comfort and ease.

I keep it in [laughing] – we've got a little kind of cupboard in the living room, so I keep it in the cupboard in the living room, and it's kind of right next to the seat that I sit in, so if I'm bored occasionally, when I'm watching some dreadful television, I think, oh, I'll take my blood pressure [laughing] – it's just there, to hand! (F, 46, 1008)

A few participants linked the position of the monitor within the domestic space to the physical condition of the body that was needed in order to take reliable and accurate readings. Consequently, users stored the device in places where they could be relaxed and calm when taking their readings, trying in this way to attain an optimal environment for measurement.

P: Yeah, it's just there. Because, I mean, there's where the comfortable chairs are and, you know, you can just sit in the comfortable chair and do it. If you had to go into the kitchen or bathroom to do it, it's not...

I: Visible...

P: Well, you've got to...yeah, kind of – well, given what I just said about the ropiness of the reading, I suppose it doesn't really matter [laughing], but if you had to go to the bathroom to get it, you know, then you're probably going to raise your blood pressure. (1011, M, 53)

Finally, one participant associated the space he was storing the device with its maintenance. In this case, the location served to keep the monitor in proper condition in order to be functional.

Interestingly, only two participants mentioned that they stored the devices in a space dedicated to medical supplies (e.g. medication, other medical devices). The position of the technology in this case designated clearly its medical character and its separation from other kinds of goods in the home, in opposition to most of the users who usually kept the device within the boundaries of their personal space within home (e.g. office, bedroom).

I: And where do you usually keep or store your device? Do you keep it out or you put it away?

P: Eh...we've got like a cupboard for medical devices, so...I keep it there (M, 31, 1006)

Overall, the display of the technology within the home, as this was articulated in users' accounts, served primarily functional purposes such as the attainment of an optimal environment and proper physical condition for taking the readings, or the good maintenance of the device. Although, much less can be said from these data about the symbolic functions that the display of the technology might serve, it is interesting that most people did not keep the monitor in a place that would signal its medical nature, but they usually stored it within the boundaries of their personal space.

4.4.3 The phase of incorporation: embedding health technology use into temporal structures

The phase of incorporation characterises the process through which the technology is integrated into the temporal arrangements of domestic life. The analysis illustrated that there was diversity in the way participants incorporated the use of the device into the temporal structures of their daily life. Incorporation, and especially the frequency of using

the device, was largely contingent on the health condition that prompted respondents to buy the monitor, along with its progress. Two broad categories of users were identified based on the longevity of use: the ‘faithful’ users and the ‘transient’ users. The ‘transient’ users measured their blood pressure intensely for certain periods of time till their health condition was stabilized, controlled or completed (e.g. pregnancy) or till they stopped taking medication that affected their blood pressure levels as a side effect. When that period of intense monitoring came to an end, the use of the device diminished significantly; in most cases it was relatively stabilized to a certain but significantly decreased frequency, while in one case it was completely terminated. During the intense period of use, participants took their readings several times a week, some even daily, and usually more than once within the same day.

I: And, okay, let's focus on the present – how often do you use this machine now?

P: Around once a month, possibly less than that even, maybe every six or eight weeks, but not very often at present.

I: And in the past, did you measure your blood pressure every day?

P: Yes. When I knew I had a problem, four or five days, I would take my blood pressure, and I would take it morning, middle of the day, and evening, so I'd have a range of figures to review, and I kept a note of them so I knew whether there was an issue to tell the doctor about. (M, 60, 1010)

Except for the stabilization or the controlling of the medical condition as reasons for the decrease in device use, there was some evidence that users defected from a regular pattern of measurement as a result of their conviction that blood pressure was difficult to be measured accurately. This disbelief sometimes arose from the characteristics of the device itself, such as its brand or the absence of clinical validation.

P: I was never convinced that this would be...accurate measurements.

I: And how do you know that your device tells you the truth?

P: I don't, and I don't trust it 100%. Yeah, as I told you, it's eh...when I bought it, because it was not...I didn't see that it was tested. It was a brand that does not specialise in blood pressure monitors. I knew that I was not buying something that is very accurate, but I also knew that I wanted something for indications. I didn't need exact numbers to the decimal points. Just the trend... (M, 48, 1009)

In other instances, the lack of confidence in the accuracy of the readings originated from the very narrow set of circumstances under which users were instructed to measure their blood pressure, which was after all judged to be unrealistic in the context of daily life.

I mean, I have to say...the instruction booklet that comes with this is quite interesting because it tells you about...all this about posture and the need to avoid, you know, stresses, and don't do this after, you know, immediately after drinking alcohol or when having done exercise or something like this, so it actually kind of rules...makes the sort of window of your life where the readings could be expected to be reasonable and reliable actually rather small [laughing]! So em...I mean, if you...if, as I...in the case of my heart attack, you know, I was out there on my bicycle – even if I'd come in and taken a reading, it wouldn't have been a good reading. So, in fact, it's not that useful. It's only if I feel...feel weak if I was already relaxed and hadn't just drunk alcohol and hadn't just done exercise or something like that, so it's not actually that useful [laughing], em, as a tool. (M, 53, 1011)

After the intense period of use, these participants engaged with the practice of measurement only occasionally and used the readings as a rough indication of their blood pressure status.

The 'faithful' users, on the other hand, described a more longitudinally stable pattern of device use. Most – but not all – owned the monitor for many years and tended to follow the same pattern of usage throughout. The frequency of monitoring the blood pressure varied across these people from several times a week to once a month. Again, there were respondents who reported taking their readings several times a day.

Interestingly, among the 'faithful' users, there was a woman who used the machine periodically following periods of intense use and periods of non-use.

I: How often do you use your blood pressure monitor?

P: Well, I'm a bit odd about this, because I sometimes use it every day, over a period of time, and then I don't do it for maybe a month, and then, once I start doing it, I tend to do it frequently. (F, 70, 1013)

Later on in the interview, the participant explaining this sporadic pattern of using the device argued that the periods of non-use helped her to refrain herself from being psychologically overwhelmed by the practice of monitoring.

Well, that's why...that's why I stopped myself, because I do it every day, for a while, and then I think...this is stupid, you know. I know it's okay because it was okay yesterday – it hasn't changed, so leave it for a bit! And my own doctor said to me just do like, you know, once a month or something....But yes, I could become obsessed very easily. (F, 70, 1013)

Thus far, it has been illustrated how the practice of measuring blood pressure has been routinized and embedded in participants' daily life. Yet, apart from this routinized and roughly scheduled mode of measurement, participants also reported to take their readings when 'not feeling well'. In this case, taking the blood pressure levels served to determine the potential reasons for feeling unwell. People in their effort to explain their somatic sensations were engaged in a process of attribution and the device was used to assist them to differentiate between potential causes of their feelings. Thus, while in the first instance it can be argued that the principal use of the device served monitoring purposes, whereby participants followed up their blood pressure levels routinely and in a relatively structured way, in the second case the main use of the technology aimed at diagnostic purposes. This mode of measurement was unscheduled and unstructured, since it was contingent on participants' physical condition and sensations, and there was a range of somatic symptoms with which blood pressure was associated such as headache, 'feeling weak', 'feeling breathless', or having tinnitus.

Every now and again, I get very loud tinnitus, and I can equate that with when the blood pressure is high. (M, 60, 1010)

I use it more than twice because, once I feel headache, I first measure my BP before doing anything, and then I start to see if it is low or high. (F, 33, 1017)

Most participants in this study reported an embodied awareness of their blood pressure variations. Taking the readings when 'feeling unwell' was triggered by the perception that blood pressure can be felt physically and can be associated with certain symptoms - often different across people. This is particularly interesting, given that blood pressure-related conditions, such as hypertension, are generally asymptomatic. Nevertheless, people appear to link symptoms to their blood pressure (Marshall, Wolfe, & McKeivitt, 2012).

I: When do you know that your readings are normal? How do you know that?

P: You feel it. You feel it in your body. (M, 65, 1002)

I: Okay, so how and when do you know that your blood pressure is normal?

P: Oh, em...I know it's normal like because I can...I don't feel like a weak feeling. (M, 23, 1003)

Somatic sensations were not the only cue participants associated with blood pressure variation. Participants additionally claimed that they could occasionally figure out the level of their blood pressure from their appearance based on cues such as the colour of the skin.

The *monitoring* and *diagnostic* purposes that people were trying to accomplish are arguably *intended* device uses. However, the respondents articulated a parallel use aimed at checking the reliability and accuracy of the machine. This took place in a series of contexts. One such context was when the users were getting an initial problematic reading (i.e. higher or lower than what they expected). In this case, it was reported that a second reading was taken after a while which served to check the reliability of the first one.

I: And how many readings are you taking every time you measure your blood pressure?

P: Just one.

I: Just once, okay.

P: Unless... That's not true. If it was...if it was high, I might take it again, just to check. (F, 57, 1005)

Another way of checking the accuracy of the device was to compare the home readings with those taken at doctor's surgery. The readings taken by a healthcare professional (doctor, nurse, or pharmacist) constituted the referential point against which the home readings were judged. If the office and the home readings were similar, participant had greater trust in the accuracy of their device. From these data, it can be noted that using the device was not a straightforward and unproblematic process; rather the device had to be trusted first and uncertainty around its accuracy had to be resolved. For this reason the technology was repeatedly subjected to uses that aimed to check its trustworthiness.

Em, but also, the other thing I was interested in, em, because I had regular hospital appointments, they'd often put me on a blood pressure device when I was there, and I would make a note of what that one was, so I always had a cross-check against the readings I was doing at home, and they didn't differ that much. (M, 66, 1007)

Summarising the phase of incorporation, it can be noted that there is a great variation in how people embed the practice of monitoring into the temporal structures of their daily life. The frequency and the sustainability of device use is heavily contingent on the health

condition and its progress, but also on people's confidence in the dependability of the device itself as well as the ability to capture valid BP readings within the context of daily life and the constraints this poses for accurate measurements. Apart from using the device for monitoring and diagnostic purposes, people also engaged with measurements that aimed to check the trustworthiness of the technology. Establishing trust in the HBPM was important for the continuation of the practice, and there was some evidence suggesting that when this was not achieved, people's engagement was reduced significantly as the perceived value of the technology diminished.

4.4.4 The phase of conversion: communicating the ownership and use of the health technology to the external world

According to the domestication framework, during the conversion phase the ownership of the technology is communicated outside the boundaries of the household and claims of status and identity are being attempted. To what extent and how the participants of this study discussed the possession and use of their blood pressure monitor?

All participants mentioned that other family members knew that they owned a blood pressure monitor and that they were taking their readings. Communicating the possession of the medical device and the practice of monitoring was mainly confined to relatives and close friends, and participants stated that it was not of great importance or of interest to discuss these issues with other people, outside the close family cycle.

I: Do other people know that you and your wife measure your blood pressure? Is it something that you are discussing with your friends or other family members?

P: Em...well, my son and daughter know...I mean, but we don't...it's not a topic of conversation that we would have with, em, the neighbours or friends. You know, you don't go to a party and say, "Oh, my blood pressure is up tonight," or you know, "You don't look too good – I'll take your blood pressure." (M, 77, 1014)

In some instances, there was evidence that people were concerned about the way they would be perceived by others if they drew attention to the device and the fact that they were using it. For example, a woman employing the psychological discourses of 'hypochondriac' and 'paranoid' was worried that other people might interpret her preoccupation with the device in this way. On the other hand, she wished to let other people know about her practice and the reasons for using the monitor, because in this way she could reinforce the

credibility and authenticity of her concerns if her readings appeared problematic. In the excerpt below, trying to balance the tension between these considerations was a challenge:

P: Yes, I wouldn't say we discuss it at length, but they certainly know I have it and I use it.

I: Was that important for you, that other people know, and why?

P: Oh. Em...I wouldn't say it was very important. Em, I certainly didn't – I felt I didn't want to hide it, but it wasn't something I wanted to make a big issue out of, em, because I'm not a hypochondriac [laughing], so you know, I didn't want them to think, oh God, she's suddenly getting, you know, getting paranoid about her health. But I did want them to know I was doing it, and the reasons that I was doing it, so that they didn't think I was getting paranoid. And also, I suppose, to allow them to take me seriously, if I ever said to them, particularly during my pregnancy, "Look, I think my blood pressure is high," you know, support me, em, emotionally and em...in going to get clinical assistance if I needed it. (F, 46, 1001)

Another participant explicitly mentioned that she avoided talking about health issues, including the medical device, with friends or family members, since she did not wish to be seen by others as 'the one who is always ill'. In this case, talking about the monitor and drawing much attention to health issues was experienced to convey an illness identity which was not desirable within the frame of enjoying the company of other people. Being ascribed with such an identity was experienced by the participant as an obstruction from sustaining 'normal relationships'.

I: Do other people know that you are taking your readings?

P: Yes, my family know.

I: Your family. Your friends – is it something that you discuss?

P: I don't – I try not to talk too much about health problems with friends. (F, 93, 1012)

Later on in the interview she commented:

Yes, you become...yourself becomes enlarged and it's all health and it's not...that's not healthy. It includes this kind of thing, this bit of machinery, and putting all the details and getting involved like that. It includes that. So you should really have...get used to a cut-off stage...that...that means...normal relations...normal relations, which don't involve health, with your family and friends, because, in their turn, if you don't do that, they will think of her as being the one who's always ill. (F, 93, 1012)

Another participant did not communicate her practice to other people as she did not wish to worry them with a health issue that she did not consider as extremely serious and for which she had found ways to manage effectively.

There was also some evidence that using the device was so much ingrained as a practice in daily life that people did not really think of it as a topic for discussion, unless triggered by other people's relevant experiences or concerns during interpersonal exchanges. Using the monitor was 'just something they did' and less of a topic for reflection and elaboration with others. It could be argued that in this case the device had been domesticated and incorporated to such an extent that it was rendered invisible from the sphere of topics people would readily discuss.

But yeah, so...other than that, I don't really talk about it much, no. It's just something I do. (F, 70, 1013)

Although participants mentioned that they did not really discuss with others the usage of the monitor, they often referred to situations whereby they shared their monitor with other people. This was a relatively common experience across participants and it was sometimes seen as a sort of 'amusement', 'game' or even 'competition' with 'winners' and 'losers'.

And em...the only other person that really would be aware is my sister, because she wanted to play with it [laughing] when I bought it! (F, 57, 1005)

So, interestingly, on one occasion when we had the family round, we had quite a game of taking people's blood pressure. (M, 66, 1007)

One participant mentioned that while it was not that important that others knew about his practice, he enjoyed the experience of 'playing the doctor' when other family members and friends were using the device.

No, it wasn't important for me that they knew, but I got quite a lot of fun out of playing doctor [laughing]! (M, 66, 1007)

Finally, sharing the device with other people provided one participant with the opportunity to communicate his experience around his health problems, and to advise in a 'light-hearted way' that a proactive stance towards health should be taken. The metaphor of 'toy' was employed to describe the device, while the interaction was characterised by an element of amusement.

So I really use it as a toy to explain to them that they could also be affected at some later date, because when I became aware of this problem, it was very – it was instantaneous. It wasn't a progressive thing. I suddenly found, literally, walking down the street, it was like a...like a mini-heart attack. You suddenly...you felt you couldn't walk. So, I use it more or less in a very light-hearted way to...warn them that, eh, what the symptoms are and...would they like me to take their blood pressure, for a bit of fun?! (M, 65, 1002)

Overall, it can be noticed that owning the device and engaging with the practice of measurement remained largely a private issue that was shared mainly with the family cycle. In some instances, this resulted from a fear of being ascribed with undesirable identities, while in other cases it seemed that the topic was at the periphery of the discursive consciousness, indicating possibly that it was largely integrated into daily routines. Nevertheless, participants described interactions where they opportunistically shared their monitor with others engaging in group measurements. Sharing and 'playing' with the monitor – and less discussing about it – characterised the conversion phase during which the health technology was re-positioned from the private space to the public sphere.

Apart from friends and family, users also communicated the ownership of the device to their healthcare provider. The analysis showed that most participants in this study ($N = 15$) had notified their doctor that they owned a HBPM and that they were measuring their blood pressure levels. Only three participants reported that they had not informed their GP and this was primarily the result of their conviction that their health condition was not that serious or urgent enough to be worthy of discussion or due to pragmatic reasons such as not having the opportunity to visit the doctor for a while.

Among the users who had discussed the issue with their doctor, there was a great variety of doctor engagement, as this was perceived and articulated in people's accounts. For example, some reported that their doctor did not really engage in extensive discussions or comments when they were notified about the monitor, and that they rather seemed to adopt a neutral stance.

I went back, em, quite soon after the initial diagnosis, em, just to confirm that everything was okay. I think I mentioned that I'd purchased this, but that was it really. We didn't really speak about it any more than that. (F, 57, 1005,)

Other participants mentioned a high level of involvement on the part of their doctor. They described that they were bringing and discussing regularly their home readings in the consultations and that they were in close contact with their doctor when they obtained problematic readings.

I: Do you discuss your readings with your doctor?

P: Yeah. If I've found a very high reading, then I'll discuss it quickly with the doctor...why and...the reasons of how to avoid such high readings.... So it's really a friendship kind of relationship, more than being a doctor and a patient. (M, 30, 1004)

One participant, indeed, expressed surprise from the level of her doctor's engagement with her home readings and the fact that the latter were taken into account, as she was expecting that the healthcare professionals might be suspicious about the trustworthiness of patients' measurements.

I: And did you discuss your readings with your doctor?

P: Yes. Yes, oh God, yes, yes, yeah. So I still had to go in to kind of discuss my blood pressure, but they were happy for me to go in less, and they seemed to accept the readings that I was telling them quite readily, which I was quite surprised at actually.

I: Why? Why were you surprised?

P: I don't know... I kind of thought...you know, do-it-yourself...I mean, I suppose you could just say anything, couldn't you? But then, I suppose there's no motivation for you to kind of make on that your blood pressure is lower than it actually is. But I was surprised that, you know, you could have a do-it-yourself test and they would be quite happy just to... And in fact, they would write down what I'd told them in my notes, which I was really surprised at. (F, 46, 1008)

Several participants felt supported by their doctor in their efforts to monitor and manage their condition. The fact that some users had some sort of medical knowledge as a result of their own professional expertise was believed to be the reason for why the doctor showed faith in their self-monitoring practice.

But she is very happy, but she knows that we both have been involved in medical work and that, you know, so she has a degree of trust in what we say and do. (M, 77, 1014)

Interestingly, the argument of possessing or not medical knowledge was also employed to explain the perceived doctors' distrust that was being experienced by some users. In this case, people felt that their doctor did not have confidence in their home readings due to

their lack of medical background, although doctors might be happy for their patients to monitor their blood pressure if the practice induced secondary positive effects, such as reassurance.

I think his attitude is that I don't have the kind of training he has, and therefore I don't...whatever I do is going to be quite...silly. Em, but if I get some sort of reassurance or amusement out of it, then he's happy for me to do it. (M, 65, 1002)

Indeed, a participant described her efforts to change her obstetrician's negative attitude in order to 'take her seriously' by invoking her professional expertise that allowed her to claim sophistication and intelligence in the interpretation of readings.

P: But, you know, I thought, well, hey, you know, I'm going to tell him because...it's all part of my management, em, and, em, then hopefully he would take me seriously. But I did feel that, because of his attitude, I had to explain to him that...I'd worked with a clinical background, and therefore I'd got the knowledge to be able to, em, interpret the results intelligently. I wasn't going to come to him with one elevated reading, that I would take multiple ones over a couple of days before I then came to see him.

I: Yeah.

P: So, I felt I had to reassure him that, you know, again, I wasn't a hypochondriac, that I was actually doing this for the right reasons, and I knew how to interpret the data. (F, 46, 1001)

It is evident from the quote above that one of the reasons that people think may account for doctors' reservations about self-testing practices is the possibility that lay people become unnecessarily over-concerned, which in turn might increase the visits to the doctor.

A second explanation that was provided for doctors' perceived reservations towards self-monitoring was that they might feel threatened. A few participants, having themselves experienced reservations by their healthcare professionals, expressed the belief that the traditional role of doctor, as one who possesses the knowledge and advises the patient, is questioned and jeopardised when the patients, traditionally seen in a subordinate position, try to acquire more knowledge, to adopt an active role and to assume more responsibility for their health status.

...and if you get a monitor, for whatever reason, whether it's blood pressure or anything else, I think it's important that the clinician doesn't feel threatened by what you're doing. (F, 46, 1001)

Em...but I do feel that the doctors are not keen for people to take control of their own wellbeing. They'd prefer to em...to basically talk to you like the headmaster at school – you know, “You'll do what I tell you, and what I don't know isn't knowledge” sort of thing. (M, 65, 1002)

Ultimately, having the device and engaging with the practice of home measurements allowed participants to claim a status of ‘responsible patient’ who takes health ‘seriously’ and who is able to provide concrete evidence of the condition rather than vague and abstract descriptions. Presenting oneself in this way was expected to positively influence the relationship with the doctor, as the latter would pay more attention in the patient account. However, as was suggested above, negotiating a status of responsible patient within consultations who takes control of health was not necessarily without tension. Participants sometimes felt that they needed to persuade their doctor that their practice was legitimate and that they performed it in the right way. But even then, users still might feel that their doctor’s reservations persisted.

P: I think the doctor will observe that you're being a bit more serious than vaguely talking about this, that and the other. You go to the doctor and you have a pain and you're vague about it, but if in fact you have...you're serious enough to have done this, then I think they'll listen to you, I think.

I: Yeah, is this your expectation?

P: Yeah, that's right, yes, yes...Yes, there is an influence, a slight influence, in the relationship between doctor and patient, if the patient has taken the trouble to do whatever. (F, 93, 1012)

4.5 Discussion

This study, using the theoretical lens of domestication theory (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992) and the phases – as analytical tools – through which technologies are ‘tamed’, sought to examine how lay people come to acquire, use and integrate into their daily life a home use medical technology. The results showed that lay people decided to acquire a HBPM in order to be able to gain an experiential and close understanding of their condition that made them feel more empowered and able to exert greater control. The acquisition of the technology and the accompanying practice of monitoring also endorsed an identity aspect according to which people assumed more

responsibility for their own health through self-management. It is noteworthy that the dominant discourses around patient empowerment, autonomy and control are reproduced in people's accounts regarding their initiative and decision to acquire the health technology. Nevertheless, the alignment of people's accounts with the dominant discourses does not always stem from, or come to, complement smooth relationships with healthcare professionals – as it is officially stated to be an objective or a framework – but might emerge within a background of mistrust, scepticism or disturbed patient-doctor relationships.

The display of the technology within the home environment served overwhelmingly instrumental purposes whilst the integration of the practice of monitoring into the temporal structures of daily life varied across participants and depended heavily on the progress and stability of their health condition as well as on spontaneous somatic sensations people associated with blood pressure; though some users appeared to consistently use the device over a series of years, other displayed a more transient usage pattern that diminished considerably with the passage of the time. Importantly, there was some evidence that the de-investment from the perceived value of the device and the subsequent reduced use – despite perhaps the necessity of using it from a clinical point of view – was due to a failure to build trust in the accuracy of the device *per se* or in the gradual loss of confidence in the practical ability to get reliable measurements within the context of real life. Indeed the doubts often expressed around the trustworthiness of the device generated new uses which departed from the well-intended diagnostic and monitoring purposes. Participants performed measurements in an effort to establish the validity of previous readings or of the technology itself (e.g. by comparing home readings to doctor's readings).

Arguably, the engagement with home monitoring was not particularly discussed outside the family cycle either because it was routinized to such an extent that it slipped the boundaries of discursive consciousness or, in other instances, due to fear of being seen negatively by others, indicating perceived threats to identity (Breakwell, 1983). Yet, and as one would expect, the practice was communicated to the doctor suggesting that lay people wished to link their self-care practices to the formal healthcare system. There was a wide spectrum of perceived responses from doctors, ranging from full support, to neutral stance, to reservations, an observation that is in line with previous literature (Abdullah & Othman,

2011; Jones et al., 2012). The results further clarify the reasons people assume to account for doctors' disinterest or reservations; users' lack of medical knowledge and the possibility of doctors feeling threatened when patients adopt a more active stance in health management were offered as explanations. Though, tensions were created in some instances in the negotiation of a status as 'self-tester' within the patient-doctor relationship, others saw the practice of home monitoring as a means for strengthening the communicative grounds of this relationship.

4.5.1 Limitations of the present study

Despite the useful insights that this study offers with regard to the process of 'taming' HBPMs, it is not without limitations. First, due to the fact that the participant recruitment process took place primarily within an academic institution, all but one respondent (17 out of 18) were well educated, holding a degree or equivalent and above. This sample composition in terms of educational profile diverts significantly from the proportion of people with a degree or equivalent in the UK (24%; Office for National Statistics, July 2012), thus limiting the potential of this sample to reflect HBPM user populations of different educational levels. Second, none of the participants in this study suffered from disabilities or other functional impairments which have been found to influence the user-device interaction adversely (Ovaisi et al., 2011). Therefore, the results of the present study might be skewed to the expression of more favourable stances towards the use of the technology or the notable absence of other people indirectly involved with the technology (e.g. informal carers assisting with the process of measurement) and in this way affecting the user-device relationship.

As a result of aforementioned sample particularities, the transferability of the findings is unavoidably restricted to user populations of similar educational and physical status profiles. Future research could thus attempt to include a more diverse sample in relation to these two characteristics (i.e. education; levels of physical/functional impairment) in order to discern potential commonalities and differences in the themes identified.

CHAPTER 5 – HOW DO PEOPLE BUILD TRUST IN HOME BLOOD PRESSURE MONITORS? A QUALITATIVE ANALYSIS OF ACCOUNTS WITHIN ONLINE COMMUNITIES

5.1 Overview

The research presented in this chapter sought to shed further light on the user perspective and to supplement the interview-based study – reported in Chapter 4 – by drawing attention to the issue of *trust* in medical technology. Specifically, the research question which was progressively and iteratively generated alongside data analysis was how lay people build trust in home blood pressure monitors (HBPMs). To this end, observational data retrieved from naturally occurring discussions around HBPMs within the context of several online communities were thematically analysed. The results suggest that building trust in HBPMs was a multifaceted, dynamic and contingent phenomenon that implicated a series of other trustworthy relationships with other humans, one's self and abilities, other technologies, organisations, and abstract systems of expertise. Indeed, the technology *per se* – through its usage and the perception of its characteristics – only partly, though importantly, accounted for the construction of trust on the part of the user. It was one of a series of elements that were conducive to developing trust in medical technology.

Chapter 5 unfolds as follows: the importance of trust in medical technology and the existing research evidence in the area are initially introduced to contextualise and locate the present study, followed by the details of the methodological approach that was adopted for the conduct of this research. Then, the findings of this investigation are presented and critically discussed.

5.2 Introduction

The importance of trust as a foundational element of social functioning and solidarity has long been highlighted in sociological literature (Luhmann, 1979; 2000). Trust enables the reduction of complexity and operates as 'an alternative to rational prediction' when the latter is not feasible or is significantly limited, as it is often the case in modern, highly

differentiated and complex societies (Lewis & Weigert, 1985, p. 969). Trust is seen to be constituted by cognitive, affective and behavioural (i.e. enactments of trusting behaviours) components that are closely interwoven, recursively reinforcing of each other, and inherently intersubjective (Lewis & Weigert, 1985). Trust is also considered to be intimately linked to situations of risk in the sense that people should have trust that negative outcomes will not occur if they choose to pursue behaviours that entail risks. For this reason, lack of trust is seen to predispose human actors to withdraw from activities (Luhmann, 2000).

Though traditionally the primary focus of scholars is on *interpersonal* (i.e. people's trust in other people) and *system trust* (i.e. people's trust in social institutions and the system), trust in technological artefacts has also been considered as an important element that affects people's interaction with technologies. Parasuraman and Riley (1997) suggest that trust in automation influences the ways people might use, overuse, underuse or inappropriately use technologies and that a critical characteristic for the development of trust is the reliability/dependability of technology and the absence of failures.

More recently, scholars (e.g. Montague, Kleiner, & Winchester, 2009; Montague, Winchester, & Kleiner, 2010; Timmons, Harrison-Paul & Crosbie, 2008; Ziefle, Röcker, & Holzinger, 2011) have started to examine the issue of trust in medical technologies, although it is still poorly explored according to a recent review (Steinke, Fritsch, & Silbermann, 2012). Trust in medical technologies, such as gene technology, has been found to indirectly affect their acceptance through the moderation of the perceived technology risks and benefits (Siegrist, 2000). Similarly, quantitative research with participants across a wide range of ages has shown that their in-principle acceptance of video-based home medical technology is heavily influenced by trust as well as privacy concerns (Ziefle, Röcker, & Holzinger, 2011).

Research evidence indicates that the concept of trust in medical technology is conceptually distinct from trust in technology more generally, though the two constructs share some commonalities (Montague et al., 2009). An analysis of open-ended responses revealed that trust in medical technology incorporated, among other things, ideas of trust in doctors and medical systems as well as reflections on technological advancements and innovation (Montague et al., 2009). The authors speculated that this perceptual

differentiation is due to the unique nature of medical technology whereby a human patient is ‘the object being acted upon by the technology’ (p. 628). Moreover, development and validation of a measurement of trust in medical technology suggested that the construct is multidimensional encompassing aspects of technology characteristics, healthcare provider characteristics and how the healthcare professional uses the technology (Montague, 2010).

A qualitative study explored how obstetricians and women who had recently given birth came to trust foetal monitors (Montague et al., 2010). The results showed that the two user groups developed trust in the technology through different routes; women’s trust was contingent on the extent to which they trusted their doctor’s competence more generally as well as on the latter’s ability to use the technology effectively, and on characteristics of the technology itself such as its perceived reliability, consistency in its functioning and its ability to provide feedback that accorded with women’s experiences and expectations. For obstetricians, developing trust in foetal monitors was a function of their confidence to their own abilities to use the technology correctly and of their faith that the technology has been developed, checked and maintained appropriately. Nevertheless, moments of technology failure were critical in mediating doctors’ trusting stance and often led them to adjust the degree of reliance placed on the technology when making decisions. This indicates that trust was not static or permanently fixed once developed, but it was calibrated and often had to be re-established and re-worked throughout user-technology interactions (Montague et al., 2010).

Another qualitative inquiry into how lay people come to trust automatic external defibrillators, located in public spaces, demonstrated the inherently social and complex nature of the phenomenon (Timmons et al., 2008). Partly, these machines were trusted because they were seen to embody technological systems of expertise. Yet, beyond the direct consideration of the technology itself, a network of other trustworthy relationships with other humans, institutions, and abstract systems of expertise, such as the medical profession, had to be mobilised and act as a springboard of trust towards the technology (Timmons et al., 2008). The link between trusting social institutions, such as science, and accepting novel healthcare technologies has also been documented in survey research (Calnan, Montaner, & Horne, 2005). People who tend to question the value of scientific developments were also more likely to be sceptical towards technological advancements.

Overall, this body of research suggests that developing trust in medical technology is an important parameter for their acceptance and sustainable use. It also indicates that trusting medical technology might influence, and is influenced by, other trustworthy relationships, such as the patient-doctor relationship or the patient-healthcare system relationship (Montague et al., 2010) especially in relation to those technologies that simultaneously involve multiple user groups (e.g. the patient and the doctor; Montague et al., 2010). Moreover, these findings point out that trust in medical artefacts does not only derive from the perception of technological characteristics *per se*, such as reliability and dependability, but is more broadly located within a grid of other relationships of trust (Calnan et al., 2005; Timmons et al., 2008), whose significance might become even more important as the unfamiliarity or the novelty of technology increases.

The present study, building on and extending this corpus of research, sought to enhance our understanding of how people come to trust medical technologies. It did so by examining a different kind of technology, that of HBPMs. This technology is differentiated from other technologies studied in previous research in that it is more disassociated from the healthcare professional as it is used directly by lay people within their home environment. It can also be argued that HBPMs represent a ‘mundane’ medical technology, as it has long been used by medical professionals whilst more recently it has started to migrate to the home environment. Finally, HBPMs are not typically implicated in life-threatening situations, as it is the case with the automatic external defibrillators, but they are used as part of a monitoring routine.

5.3 Methods

5.3.1 Generating context of the study

The objective of this study was to supplement the interview data (described in the previous chapter) with a methodologically different sort of data which could potentially lead to an enrichment of our understanding around the user perspective. Much of the initial thinking around this study derived from the author’s pre-occupation with the question of how much the interventional interview study might have limited the scope of data generated as a result of the research agenda located in a semi-structured interview study

which is unavoidably regulated by implicit norms of social interaction. Despite the fact that the interview questions were designed to be as much as open-ended as possible in order to allow participants to bring into the discussion the material they wished, the semi-structured character of the interviews could not but pose certain boundaries in the content of discussions. Therefore, the present research was initially born out of two questions: (a) Do ever people discuss the technology of HBPMs? And if they do so, (b) what sorts of topics or issues do they spontaneously bring into these discussions? In other words, what are people's preoccupations when they talk about home use medical technologies, such as HBPMs?

These questions already imply the observational, non-interventional nature of the research which would have to be designed. To that end, the Internet was employed as a source of potentially relevant data. The Internet has undoubtedly provided social scientists with a tremendously rich source of qualitative data that can be readily and inexpensively accessed (Hewson et al., 2003). Web pages, usenets, newsgroups, guestbooks, bulletin boards, and chatrooms, and more recently social media platforms are but some of the online sources that can be used to retrieve potentially useful research material, such as information, synchronous and asynchronous communication, first-person narratives, and images (Robinson, 2001). The present research focused on a series of online communities within which threads that were discussing HBPMs were searched and retrieved.

5.3.2 Study design

Online communities have increasingly attracted much research interest as a particular space and context within which human communication is conducted and views and experiences are articulated and shared. Research suggests that online communities, especially those structured around specific health conditions, are used by people mainly to exchange informational and emotional support, and to a lesser extent network and esteem support as well as more tangible forms of help (Coulson, 2005; Coulson, Buchanan, & Aubeeluck, 2007). Comparative research also demonstrates that the content of the experiences that are shared online is largely oriented to 'the here and now' whilst the narratives produced within traditional interviews have a more retrospective orientation (Seale, Charteris-Black, MacFarlane, & McPherson, 2010).

Seale et al. (2010) argue that the Internet now renders observational, naturalistic research – a previously laborious and time-consuming data collection method – readily available to the interested researcher. Moreover, it has been empirically indicated that user generated online data are particularly revealing and frank due to the anonymity that the Internet offers which predisposes people to express themselves more freely and with fewer inhibitions than one would expect in a context of face-to-face communication (Robinson, 2001; Seale, Charteris-Black, MacFarlane, McPherson, 2010). Such an attenuation of self-presentational concerns, commonly present in interview contexts, is particularly important when sensitive issues are discussed (Seale, Charteris-Black, MacFarlane, McPherson, 2010).

Leveraging the advantages that the Internet affords, an observational study was designed to examine the topics around HBPMs that were spontaneously discussed within the context of online communities.

5.3.3 Data collection procedure

Forum search strategy: Using Google search engine, two key phrases were inserted to identify potential forums within which the subject of HBPMs was discussed: ‘*home blood pressure monitor forum*’ and ‘*home blood pressure monitor UK forum*’. For each of those key phrases, the first five result pages – each consisting of 10 individual results – were examined, amounting to a total of 100 individual results. Among these results, *35 threads* within *32 distinct online communities* were identified. The forum search procedure was conducted in November 2013.

Data extraction: A data extraction form was created to store the discussions of the 35 threads along with other useful information that contextualised the narratives. Specifically, the information that was recorded was:

- The name of the forum within which the thread was found
- The title of the thread
- The sequence of topics within which the thread was found
- The Internet link of the thread
- The country in which the forum was created
- The dates during which the thread was developed

- The total number of postings found in the thread
- The total number of participants in the thread
- A description of the character of the online community such as the profile of people that were targeted or the nature of topics and interests that were addressed.

After recording this information, the individual postings were copied in a table. Each posting was numbered according to its presentation order in the discussion; the date of the posting and the authors' username were also recorded (see Appendix G for a template of the data extraction form).

Description of forums: A system of classification based on the topical focus of the forum was developed and applied to the 32 distinct online communities within which discussions around HBPMs were found. The classification provided the opportunity to group communities by common or similar interests, developing in this way a concise picture of the context within which the data corpus was located. Table 5.1 displays this categorisation, along with the number of forums, threads, postings and participants that fell within each category.

Table 5.1
Classification of online communities

Forum categories	N of forums	N of threads	N of postings	N of participants
1. Forums targeting people interested in health conditions (e.g. diabetes, anxiety disorders)	8	10	144	96
2. Forums targeting people interested in sport activities and fitness (e.g. cycling, bodybuilding)	6	6	89	61
3. Forums targeting people interested in health and wellbeing	4	4	31	21
4. Forums targeting women (e.g. pregnant women)	4	5	65	41
5. Forums targeting people interested in technology (e.g. PCs)	4	4	117	47
6. Forums targeting people interested in financial issues (e.g. investments)	2	2	68	42

7. Miscellaneous	4	4	74	53
Total	32	35	588	361

In total, 35 threads with 588 individual postings were identified spanning a period of ten years. The oldest thread was developed during March 2004 and the most recent took place between October 2013 and February 2014, with all the remaining discussions being located in between those dates. Each individual posting could range from a few words to several lines, with the lengthiest posting reaching 1,172 words. The majority of people who took part in the threads appeared to be either UK or US residents (to the extent that this information was discernible). For the interested reader, Appendix H presents in detail the threads that were analysed (e.g. title, *N* of postings, *N* of participants, dates, forum within which it was found). The forums within which the threads were found are grouped together based on their topical focus.

5.3.4 Data analysis

An inductive thematic analysis was applied to the data (Braun & Clarke, 2006) looking for both prevalent and divergent views. The analysis was conducted as follows: initially, the extraction forms were repeatedly read in order to familiarise myself with the data as well as the context, that is, the online community, within which they had been generated. Then, the extraction forms were inserted into the MAXQDA software whereby an initial coding of the data was performed on the basis of the topics that were explicitly discussed. At this stage, higher order, semantically-related categories were created under which individual codes were assigned (e.g. discussions around healthcare professionals; lay notions of blood pressure). Next, all higher-order categories were exported in word documents for further processing and analysis. At this point, I started interrogating the explicit meaning of my data by asking the question of ‘what is really discussed here’ both within and across themes. Progressively, and through an iterative processing of my higher-order themes, it became apparent that much of the discussions were linked to the issue of trust. Participants’ quest to discern those elements that would make them have confidence in HBPMs fuelled a big chunk of the discussions. Once this underlying overarching theme was identified to latently thread the discussions through, the higher-order categories were

re-examined and re-interpreted under this light leading to their revision, refinement, and final consolidation.

5.3.5 Ethical considerations in internet-mediated research

With regard to ethical considerations, internet-mediated research raises a new set of questions and challenges as the definitions of traditional concepts – such as ‘human subject’, ‘data vs person’, and ‘public vs private’ – are reshaped (Eysenbach & Till, 2001; Markham, Buchanan, & Association of Internet Researchers, 2012) under the light of this technological medium and the new ways of human communication that it affords. Though steps to provide ethical guidance to researchers have been taken by several professional societies (British Psychological Association, 2013; Ess & Association of Internet Researchers, 2002; Markham, Buchanan, & Association of Internet Researchers, 2012), ethical tensions and dilemmas deriving from internet-mediated research still remain unresolvable and debatable.

In relation to observational online research that involves the collection and analysis of pre-existing accounts, it has been suggested that to the extent that these narratives appear in a public space, it is then ethically justifiable to use them as research data (Kraut, Olson, Banaji, Bruckman, Cohen, & Couper, 2004; Robinson, 2001). It has also been argued that this research does not require informed consent and can be exempt from ethical review (Seale et al., 2010). In the present study, all postings used in the analysis were located in open access public forums and were not subjected to any password protection (Krotoski 2012). For this reason, these data were considered to be in the public domain. Moreover, to protect the anonymity of individual postings, the pseudonyms of online interlocutors – or any other potentially identifying information – have been removed from the analysis below.

5.4 Results

5.4.1 Overall positioning towards the trustworthiness of HBPMs

Various levels of trust and distrust were expressed with regards to the accuracy and reliability of HBPMs as the online asynchronous discussions around this technology were unfolding. At the extreme, there were forum participants, including a person who self-

identified as belonging to the medical profession, who rejected HBPMs due to being inaccurate. Then again, there were others who rather felt that HBPMs are a trustworthy technology which can provide dependable information.

“Those things are notoriously unreliable.” (T6)

“These home monitors can be quite inaccurate. Mine is. It over-reads my own blood pressure and not my wife's. p.s. I'm a doctor myself.” (T12)

“Usually most major home blood pressure machines are very accurate.” (T26)

“A waste of money? Not really most are pretty accurate even the cheaper ones.” (T27)

Though some participants' views can be located at the extremes of the trust continuum, most accounts were situated in between those two poles of categorical trust and distrust. Indeed, doubts, uncertainty and queries were often expressed as to whether, and to what extent, HBPMs are accurate and how one can discern this quality. It is noteworthy that 5 out of the 35 threads that were analysed were occasioned by concerns and queries linked to the accuracy of these technologies. People wondered, and sought the views of others, about how much trust they can place on the accuracy of these machines, sometimes in comparison to professional monitors, and sometimes between different types of home devices.

“Hi, what's the difference between a wrist model and the pump model blood pressure units? Is there a difference between accuracy?” (T18)

Apart from a more generic positioning towards discerning the trustworthiness of this technology, various levels of trust were expressed with regards to different types of blood pressure monitors. The degree of consensus observed around this allowed for the identification of a hierarchy that ordered the different types of BPMs in terms of their perceived accuracy. Specifically, forum participants considered that:

- manual monitors were more accurate than automatic monitors;
- among manual devices, the mercury sphygmomanometers were considered the gold standard
- among automatic monitors, the upper arm devices were seen as more accurate than the wrist devices, and
- finger monitors were the least trustworthy of all types.

Figure 13 depicts this perceptual hierarchy of BPMs and illustrative quotes are provided which give an indication of the grounds for attributing trustworthiness.

Hierarchy of BPMs in terms of perceived accuracy		
Accuracy	Types of BPMs	Illustrative quotes
	Manual monitors	None of the electronic cuffs are accurate. The manual ones are still best if you want an accurate reading (T34)
	<i>Mercury</i> 	The standard for blood pressure accuracy is the kind that uses a column of mercury. (T12)
	<i>Aneroid</i> 	The manual monitors that involve using a stethoscope are more accurate. (T1)
	Automatic monitors	The new digital monitors are easy to use and accurate. (T26) Manual cuffs/readings are certainly more accurate, but for home use the automated ones are typically recommended. (T34)
	<i>Upper Arm</i> 	Arm cuff monitors are more accurate by far. (T2) Always get the one for the upper arm! (T14)
	<i>Wrist</i> 	Have tested several wrist-cuff devices and found none of them reliably accurate for me. (T32) Also: avoid the wrist ones they aren't very accurate but the home ones that use an upper arm cuff are. (T6)
<i>Finger</i> 	Wrist, thumb, and finger bp cuffs pieces of crap, IMO. (T31) [IMO = In my opinion]	

Figure 13. Perceptual hierarchy of BPMs in terms of their perceived accuracy

But how did people come to trust - or distrust - HBPMs? The analysis showed that building trust in medical technology was a multifaceted, dynamic and contingent phenomenon which did not reside exclusively within the user's direct relationship and interaction with the technology. In fact, the contribution of the technology *per se*, through its usage and perception of its characteristics, to the construction of trust on the part of the user - or prospective user - was only one element of a broader canvas. Importantly, trust towards home use medical technology seemed to emanate from, co-exist, and occasionally influence, other forms of trust. These other forms of trust concerned other people as well as one's self, other technologies, organisations, abstract systems of expertise and popular ideas circulated in society. The elements that appeared to frame and contribute to the construction of trust in HBPMs are examined in detail in the following subsections.

5.4.2 Shifting trust: from the field of professional care to the scene of home use health technologies

Healthcare professionals' views and recommendations about HBPMs provided a strong indication of whether this technology was trustworthy or not. Forum participants recurrently invoked the advice or the views they had received from their doctor or nurse about which types or which brands of HBPMs are accurate and many seemed to have acted according to these recommendations.

“My doc told me he did NOT like the wrist ones and trusted the arm ones more.”
(T7)

“The BP nurse at my GP's surgery recommended [brand name]. I have an [brand name & model]”. (T27)

“I have a wrist monitor, due to my 'bingo wings', as recommended by the consultant at the hospital.” (T30)

Whilst most referred to the opinion of their own healthcare professional, occasionally people pointed to the views of the medical profession more abstractly.

“I also got myself a home blood pressure monitor, but it was the one you put on your wrist, and the docs don't like them!” (T22)

“[Brand name] are a excellent make and are highly recommended by the medical profession.” (T2)

What seems to be trusted here is not directly the technology in itself but the expert knowledge about HBPMs which is attributed to healthcare professionals. It was the forum participants' trust in their doctors' views and expertise that provided a foundation for the development of trust in the technology. Thus, trust in HBPMs appeared to be a derivative of, on the one hand, the interpersonal trust that people had developed with their own doctor and, on the other, of their trust in socially valued institutions such as professional systems of expertise. The reference to medical professional bodies and relevant scientific organisations was not uncommon throughout the online conversations. For instance, forum participants frequently cited the British Hypertension Society (BHS) as a trustworthy source of information around HBPMs, while others used pieces of information provided by the Blood Pressure Association to support their claims or to inform other forum participants.

“The British Hypertension Society website has a list of recommended BP machines (both wrist and upper arm) in a variety of price ranges - ie they have been tested and found to be accurate for home use.” (T20)

“Have a look on the British Hypertension Society site to make sure the model you pick has been validated to the appropriate standards. [web link that directs to the list of monitors approved by BHS]” (T29)

“Would suggest you give this site a good read: [web link that directs to the BHS site]. The message appears to be; if you are going to buy a BP monitor buy a decent one!” (T30)

“A lot of medical advice disagrees with your practice nurse. See, for example, this page from the Blood Pressure Association: Why measure your blood pressure with a home blood pressure monitor?” (T27)

In two instances, the National Institute for Health and Care Excellence (NICE) was invoked or was provided as a source of useful information, whilst in one case an academic organisation was cited for its HBPM recommendations.

“Anyway, good luck, all you need to know is here...[link that directs to a NICE document]” (T32)

“The [name of university]'s hypertension clinic recommends the [brand name & model]. I'm considering buying a one handed cuff, with the bulb, valve and aneroid combined.” (T9)

Occasionally, people employed scientific evidence, found in newspaper articles, internet sources, books or directly in scientific publications, to bolster their arguments or to share it with others. Interestingly, the participant below cited a scientific article to argue for the supremacy of manual BPMs against the automatic ones in terms of accuracy.

“[Web link of the article]. User error is only part of it. Those researchers were well-trained in how to use them and automated blood pressure manometers were still inaccurate. They're just not very good - the mercury ones are still around for a reason.” (T26)

Despite the fact that the faith in scientific knowledge and medical expertise was not always uncontested, mainly when compared and contrasted to experiential knowledge and anecdotal evidence, the explicit or implicit reliance on systems of expert knowledge production and their representatives was widespread.

“Personally, I find my own anecdotal evidence better than any medical study. There are a lot of rarities that medicine can't explain” (T26)

Except for the medical advice and information that was coming either from personal healthcare professionals or from more abstract systems of expertise (e.g. professional bodies, science), the observation that certain types (i.e. automatic vs manual; wrist vs upper arm), models or brands of BPMs were used - or not used - within clinical settings by healthcare workers was a further powerful mark of quality and trustworthiness that led some people to seek and acquire a similar, or even identical, device for home use. The professional monitors operated in this case as a reference technology on the basis of which home devices were compared and judged. Trust in one technology, that is professional BPMs, was channelled into the other (i.e. HBPMs).

“This is the one I use... It is also the one that my transplant unit use and the one the dialysis unit uses. [Brand name & model]. It gives accurate readings...Hope this is helpful?” (T10)

“Yep, all the Docs, Specialist's I see use the automatic ones” (T14)

“I've been told by several different nurses and doctors that they aren't as accurate as the arm cuffs/monitors. I haven't seen them used in hospitals or even local clinics.” (T34)

“[Brand name] are the best of the home monitors, many doctors use them.”
(T29)

Since monitors used by professionals were perceived as the gold standard of accuracy and quality, the consistency of the readings obtained from the doctor’s monitor and the home monitor was a prevalent heuristic which people employed to assess the trustworthiness of their own home device. HBPMs were perceived to be accurate and were trusted as long as their feedback was comparable to the one received at the doctor’s office. Indeed the coherence of professional and home readings was such a strong indication of technology trustworthiness that occasionally outweighed other device characteristics, such as low cost, which were used to appraise the quality of the HBPM.

“I use a cheap as chips [brand name] one, which is in pretty good agreement with the GP.” (T28)

“The [brand name] one is fine. Every time I’ve had my BP checked by a health professional its been just about the same as at home on the [brand name] one.”
(T30)

“I have borderline high blood pressure. My cardiologist recommended an [brand name] upper arm electronic monitor. I have used it for years and its results are very close to those at the doctor’s office.” (T31)

“It was half the price of the manufacturer’s own branded item but gives accurate results which are consistent with those taken by my GP.” (T32)

In a few cases, and provided that this was not explained or documented as ‘white coat syndrome’ (i.e. elevated office readings compared to home readings due to stress), the disagreement between home readings and office readings led participants to wonder about the accuracy of home devices compared to professional devices. The doubts that arose from this inconsistency sometimes spread to both home and professional devices.

“How accurate are home blood pressure monitors vs the GP’s monitor? A mate of mine just found out his home meter was out by 15 points compared to that of his GP. This is about 10% or so. But which is in error? Maybe both are?” (T1)

Many users of HBPMs did not limit themselves to the mere comparison of home readings with those taken at doctor’s surgery, but they actually took their home monitor to the doctor’s office in order the latter to perform a comparative test. Indeed, this process was

sometimes prompted by healthcare professionals who advised their patients to bring their machines in, and many forum participants strongly encouraged their online interlocutors to follow this practice for checking the device trustworthiness.

“I have a wrist one that I take into my doctor's office every year to check it. It is a [brand name] and is always spot on.” (T3)

“I have a blood pressure monitor. I took it to the GPs surgery and it was tested by the nurse to see if it was correct--and it was.” (T6)

“My GP asked me to take our monitor into the practice to have it measured against the one at the practice.” (T25)

“If you use one, bring it to the doctor with you and have them compare. Some are accurate, some are wildly off (like 30 points).” (T26)

“No matter what brand you buy, take to your doctor/medical center and they will make sure it reads ok.” (T33)

5.4.3 Trust in brand

An additional strong indicator of trustworthy technology was the brand of HBPMs. Several forum participants were referring to certain brand names to claim quality and accuracy.

“[Brand name]’s are the best...They are the most accurate and are easy to use. Go to the store and look at the different models and see which one fits you best.” (T17)

“[Brand name] is a good and reliable brand.” (T3)

“Couple of decent deals here: [links that direct to specific HBPMs]. both [brand name], which imo are a very good brand when it comes to this sort of item.” (T15) [IMO: In my opinion]

Lay people’s observation that specific brands were used in clinical settings and were recommended by doctors increased their perceived credibility, and by extension the potential for product trustworthiness. Again, it can be noted how the trust in the medical profession determined the confidence that people felt in manufacturers and specific brands. In the absence of more specific information or technical knowledge around the manufacturing of these technologies, the reliance on shortcuts was fruitful.

“P1: [Brand name] are the best of the home monitors, many doctors use them

P2: Indeed they are, I was recently given one by my doc to take home after suffering from high blood pressure after my recent redundancy.

P3: Agreed - the local blood bank used them as well.” (T29)

“I’ve seen [brand name] monitors used at the doctors. They seem to have a good reputation for producing accurate equipment.” (T25)

5.4.4 Trust in consumer organisations

The reviews and recommendations about HBPMs from consumer organisations was another trusted source of information. Several forum participants claimed that they had consulted the reports published by these organisations before deciding which HBPM to buy and they accordingly advised prospective purchasers in their online community to do so. As was shown in relation to the medical profession and its representative bodies, it was the lay confidence in these consumer advocacy organisations that operated as a springboard for developing trust in particular technologies.

“I bought a [retailer name & brand name] brand. When I first started looking for a new monitor several years ago, a [brand name] was listed by Consumer Reports as one of their top recommendations.” (T5)

“Can anyone recommend a decent blood pressure monitor for home use, please? I have been checking the Which? test and they seem to go for the [brand name & model], but this has been replaced more recently by the [model] which does not yet have a review. The item is for my dad. Thanks for any advice.” (T27)

“I just recently purchased one. First I checked Consumer Reports for their recommendations (April 2013 issue). They gave 2 "best buy" designations...” (T33)

Though the reliance on consumer organisations was quite potent, it was not always unquestioned. Actual user reviews of products were able to disturb the trustworthiness of official recommendations when the former were not in total agreement with the latter. Real experiences reported by people who already used a monitor were thus a powerful source of useful information that was weighted and judged against official recommendations.

“I do have Consumer reports subscription, online....I checked it for cuffs, and they had some highly rated models, all pricier than average, and the actual use

reviews buy real people were all over the place! Some were downright awful for the CR most recommended. weird. I guess the best bet is to read the most current actual use reviews on [online retailer], or wherever I shop, and compare against CR.” (T5)

5.4.5 Trust in self

Building trust in HBPMs was closely interwoven with users’ confidence that they were able to perform the measurements correctly, under the right physical and psychological conditions and within the context of a proper monitoring schedule. Forum participants very often noted the importance of following specific procedures when taking BP readings urging their online interlocutors to be attentive to these parameters if they wished to ensure an accurate feedback.

“I have a bp monitor and it is reliable with the readings. There are factors to consider when taking bp even at home. Rest for at least 10 minutes. Make sure it is properly position whether wrist or arm. It is the right size for you. Don't eat just before. Go to the bathroom first. That creates pressure which is picked up on bp reading. Sit quietly with feet on the floor flat, no crossing at ankles or knees. Breathe. Wait at least 30 minutes between readings, if your first is high and you want to try again.” (T6)

“The main thing you need to make sure and do is position the cuff correctly on your arm and not move, talk, cough, etc while the reading is being made. Those actions will routinely cause a false reading.” (T33)

For some people, feeling confident about their ability to use the technology correctly was linked to repeated performance. Trust in one’s self was not thus immediate and instantaneous or based solely on pure knowledge but it was dynamically developed through the recurrent interaction with the technology.

“I have been using my device 3Xs a day and I love the way it does all the work. It took me a few weeks to get a really good wrap of the cuff (velcro) and now it is a cinch.” (T17)

Feeling assured that one was using the technology properly was important for one more reason; this trust in self and one’s abilities allowed the moderation of the uncertainties that

were provoked from the inherent variability of blood pressure that many forum participants noted. By eliminating as much as possible user-induced ‘errors’ or variation, the output was perceived to be more dependable.

“You will find a lot of variance day to day and time to time. I try to take it at the same time as a part of my morning routine.” (T12)

“BP changes quite a bit during the day so try to measure it at the same time very day.” (T12)

Importantly, as more knowledge, experience and confidence in how to take a blood pressure reading correctly was gained through the ongoing interaction with the technology, some forum participants expressed scepticism towards the extent to which healthcare professionals might follow the right procedure or perform the measurement under the right conditions. Consequently, developing trust in one’s abilities to perform home monitoring appropriately could challenge the credibility of professional measurements.

“I am very keen on having my own monitor. When I read the instructions I realised that my GP doesn’t follow the rules for an accurate reading. One should have been sitting down relaxing for a while, and while the reading is being taken one should not move OR TALK. My GP always asks me questions while the test is going on.” (T11)

“It’s also important to learn how to take a blood pressure reading, which no doctor has ever done correctly for me.” (T31)

“I have often wondered about the exact process used by doctors and nurses to take blood pressure [...] I also thought that the patient needed to be relaxed and calm (at the gym they make you sit for five or ten minutes and won’t do it after you have started exercising) whereas I’ve had mine done at the surgery at all sorts of points, including in the middle of a “difference of opinion” half way through the consultation and after a morning at the gym. (highest ever reading for me).” (T1)

5.4.6 Trust in online community

The commonest reason for which the online conversations were initiated was the forum participants’ desire to learn about other people’s views and experiences of buying and using

a HBPM and to ask their recommendations for a good quality monitor. In 22 out of the 35 threads, people were recurrently seeking views on, and experiential knowledge about, which models or types of monitors (i.e. upper arm vs wrist type) are accurate, which ones are easy to use, and what a reasonable cost might be or what price range should be expected for this technology, with information about accuracy and reliability being the most frequently aspired to. Indeed, several forum participants seemed to largely base their decision making on the advice they received within the context of their online communities. Trusting other people's experiences created an elementary ground for developing trust in the technology. Again, it can be observed that trust in HBPMs was contingent on a pre-existent form of trustworthy relationship with other people, in this case online fellows with whom forum participants usually shared some common interest.

“Well how interesting....After comments on this thread and another I've now bought an arm/cuff monitor to compare and contrast with the wrist one we bought recently.” (T2)

“Sounds good. thanks to all the replies. I'll try and go the arm route first if I could.” (T13)

“Sounds like [brand name] brand is the way to go. Thanks!” (T9)

“Thank you all so very much. This gives me some options to look at and your first hand experiences are extremely helpful.” (T33)

5.4.7 Trust in technology

With regards to the user-device interaction, getting meaningful results constituted the strongest indicator for trust in the technology. Meaningful results usually meant that people could discern a consistent pattern over time, that readings taken consecutively were pretty close or that the device feedback verified the anticipated effect of medication. In other words, perceiving the technology as reliable and consistent and receiving outputs which accorded with participants' mental models and expectations were elements that allowed the gradual building-up of trust.

“Overall I'm very happy with it. It gives good readings. If I test three times in a row, it doesn't give the exact same reading but all three will be very close.” (T14)

“However I’m still very happy with my [brand name] one and its still giving much the same readings as when I got it. My partner though gets lower readings (she does more walking) but her readings, like mine, are much the same as last year so I am sure the model we have is reliable and as accurate as necessary.” (T30)

“Recently prescribed [name of drug] as tendency for BP to be creeping up a bit of late. Can see the difference on the [brand name] already after only a week. Pretty happy with the functionality of the device. Never had reason to query results.” (T32)

On the other hand, getting inconsistent readings that did not allow a meaningful interpretation made people to doubt the accuracy and reliability of the technology and eventually to dispute its usefulness.

“i have one, one minute its 240, the next its 180, the wrist ones are useless.” (T6)

“My step-dad is using a BP monitor at the moment and getting really high readings, so I tested it on myself. It came out as 150/90 - I was horrified (because it's very high compared to my usual). So I did it again, straight away - 140/80. And then I carried on until I'd taken it 5 times one after another. Yep, you got it. 130/70, 120/60, 110/50. At this point I thought it was reasonable to declare the machine useless.” (T6)

“I do wonder though how accurate these machines are as with all the readings had so far got 4 readings that show as E (error)” (T19)

Although the process of building trust in the technology was heavily contingent on a network of other trustworthy relationships (e.g. with doctors, the self, organisations, systems of expertise), a relatively unproblematic interaction of users with their devices and the capability to meaningfully interpret the results were also critical elements. Apart from the concrete experiences of device usage that people described, more abstract notions about technology and technological progress also affected their levels of trust as these were expressed in the discussions. Specifically, the lay assumption that technology in general gradually progresses to more advanced levels in the passage of time led people to declare faith in modern models of HBPMs.

“Some docs insist you should add 5 mmHg to each reading as Home Monitors are unreliable, this was true many years ago, but not with the excellent models we have now.” (T27)

“Definitely take it with you on your next Dr's visit so they can check it against theirs. Most BP machines for home use these days are well made.” (T33)

Though technological innovation was most of the times associated with progress and improvements, faith towards ‘*tried and tested*’ technologies was occasionally expressed, revealing that lay trust in technological progress was not but provisional; sometimes technologies would have first to stand the test of time to prove their value.

“I personally recommend an upper arm pressure band monitor, it's tried and tested (wrist monitors haven't been around that long).” (T13)

5.5 Discussion

The present analysis of naturally-occurring online discussions around HBPMs aimed to explore and understand how people come to trust home medical technology. The results suggest that building trust in medical technology is not a technical matter but an inherently social process (Button, 2006) that implicates a series of human actors, institutions, and values, as well as the technology itself. Trust is simultaneously a symbolic and a practical accomplishment that has to be worked, and sometimes re-worked, in a nuanced and contingent way. It also appears to be constantly conditional, to a greater or a lesser extent, rather than a fixed and stable end-point. Unanticipated real-life instances have the potential to impugn the foundations of trust, for example when a technology fails to operate or its functioning does not accord with user's expectations.

More specifically, these findings indicate the importance of a grid of existing trustworthy relationships acting as platforms for constructing trust in medical devices. Not surprisingly, and in accordance with previous studies (Montague et al., 2010; Timmons et al., 2008) trust in doctors, developed through interpersonal interaction as well as lay people's faith that medical professionals epitomise valued systems of expertise, constitutes an important anchor for building trust in the technology. This is enacted by following, for example, the doctor's recommendation to acquire a specific monitor, by simply observing and imitating his/her technology choices, or more actively by having the home monitor

checked by the doctor. The power of this trustworthy relationship to infuse trust into the technology was also elaborated more abstractly, distanced from a personal patient-doctor relationship, when medical professional organisations and scientific evidence were invoked to ground assertions of technology trustworthiness. And despite the fact that these social institutions were not always unquestionably accepted or valued, people predominantly relied upon them as a trusted source of information around HBPMs.

Beyond the influences of the medical field at different levels (i.e. personal, impersonal) and through diverse routes (i.e. symbolic, practical) in generating trust in medical technologies, other organisational actors, such as the manufacturer and consumer organisations were deployed in the process of building trust in HBPMs. Interestingly, trust towards the manufacturer was sometimes built out of the observation that the medical professionals used monitors of that particular brand. This suggests that the delineation of ‘objects’ that are being trusted (i.e. medical expertise; brand; medical technology) or the actor who ‘does’ trust (i.e. doctors; lay people themselves) are not analytically clear-cut (Timmons et al., 2008) and that there is a degree of suffusion that characterises the process of trusting. Lay people in this case trust the brand on the assumption that doctors, who are themselves trusted, have confidence in the products of the particular manufacturer (Lewis & Weigert, 1985).

Trust in institutions, such as consumer organisations, were not again without tensions especially when their HBPMs recommendations conflicted experiential evidence from ‘similar others’, that is, existing users of the technology. The power of ‘similar others’ and the strength of their experiential evidence in acting as a springboard for building trust in the monitors was also very apparent with regards to the online communities. It has well been documented (Coulson, 2005; Coulson et al., 2007) that online communities, especially those created around a particular health condition, are used for exchanging informational and emotional support. For the ‘uninitiated’ prospective user, the narratives, stories and experiences of existing users or of people who had some knowledge and experience around HBPMs were a resource for forming judgements about the medical technology. The very fact that some decisions to buy particular monitors, as expressed by several online interlocutors, seemed to have been influenced by the advice received within the forum

signifies the importance of this trusted source of information as a base for trust generation towards the technology.

Up to this point the technology itself is not directly implicated in the formation of trust, which rather is constructed through a network of other trustworthy actors – human (e.g. doctors; online interlocutors) institutional (e.g. professional organisations; consumer organisations; science) and technological (i.e. professional BPMs) that facilitate the necessary ‘leap of faith’ (Möllering, 2001) in the absence of technical knowledge. When lay people acquire and start interacting with the technology, two further components, conducive to trust, are progressively added; (a) the trust toward one’s self and (b) the trust towards the perceived characteristics of the technology. It is at this stage that the construction of trust perhaps most profoundly leaves the symbolic field to enter the field of practical and situated accomplishment (Button, 2006). Based on a ‘biographical familiarity’ (Jirotko et al., 2005) that is progressively achieved through repeated interactions with the technology, the users are able, on the one hand, to develop confidence in their abilities to use the technology appropriately and, on the other, to discern whether the technology functions and responds as expected. It should be noted here that the technological feedback, and by extension the technology as a whole, is more likely to be trusted as long as it allows the user to meaningfully interpret the data and according to the mental models held, which might not necessarily corresponds to strictly technical conceptions of dependability. In other words, whilst a reading might be perfectly accurate from a technological point of view, the user might decide to discard it if it does not make sense (e.g. when it deviates significantly from previous readings).

Interestingly, developing trust in one’s ability and skills to perform the measurements correctly, part of which as we have seen means using health professionals as reference points, occasionally went full circle and led to questioning the healthcare professionals’ appropriateness of measurements. Whilst placing trust in one’s skills and acquiring experience was conducive to trusting the technology, it could simultaneously cause doubt in another forms of trust, the one, for example, placed in the doctor’s competency to perform medical acts. In the process of becoming an ‘expert user’, aspects of the healthcare professionals’ expertise were reflected upon and sometimes re-considered.

Overall, this study showed that the characteristics of the technology are but one of a series of elements that contribute to the construction of trust in medical equipment (Montague et al., 2010). Therefore, a narrow focus on technical dependability might not be sufficient for infusing trust in the technology from a lay perspective. But even when technical characteristics are considered, they might be interpreted differently by users, compared to designers and engineers, as they are accommodated within lay mental models that orient the sense-making processes around user-device interactions. Evaluating the trustworthiness of medical technologies is mediated by other forms of trust, both interpersonal and social, whose significance might be intensified as the level of technology unfamiliarity increases (e.g. novel technologies; user inexperience with certain technologies). Medical equipment is not simply conceived as a technological artefact but embodies and reflects relationships, systems, and values. Therefore, a decline of trust in those entities might well affect people's inclination to place trust in, and accept, medical technologies (Calnan et al., 2005).

5.5.1 Limitations of the present study

Despite the great potential that the Internet affords for social scientists, this medium as a tool for research is not without its criticisms and this study is no exception. Much of the debate regarding online research has revolved around the extent to which Internet samples are biased on a number of dimensions, such as demographic (i.e. predominance of white, middle-class, educated males) and psychological characteristics of participants (i.e. socially isolated, depressed) and quality of responses (i.e. non-serious or repeated responses), compared to 'traditional' samples (Gosling, Vazire, Srivastava & John, 2004; Hewson, 2003). However, research (Gosling, Vazire, Srivastava & John, 2004) that compared online survey respondents with 'paper and pencil' participants suggested that online samples were largely comparable, and in some cases more diverse, to traditional samples in psychological research. Despite the fact that online samples have increasingly become more inclusive with the exponential penetration and uptake of the Internet, it should still be acknowledged that it is not feasible in observational online studies to correspond online narratives to participants' demographic or other characteristics, whilst little is also known about the integrity of the data.

Another consideration that should be taken into account is the extent to which the issue of trust that emerged in this study as an important thread across forum discussions might be a derivative – or an ‘artefact’ – of the research context itself, that is, the online communities. Arguably, one cannot readily deny that the online communities render the matter of trust salient since they largely operate as spaces for the provision of support (e.g. informational, emotional) among their members; people commonly participate in these forums in order to seek and share information and to validate their views (Coulson, 2005; Coulson, Buchanan, & Aubeeluck, 2007). Yet, the enhanced salience of the matter of trust within online communities does not eliminate or subtract something from its ontological status; building trust in medical technologies is an important prerequisite for acceptance and sustainable use. In this sense, online communities can provide a fruitful context to investigate the manifestation of elements that are conducive to trust.

Finally, some consideration on the effect of the order of user studies presented in chapter 4 and 5 should be given. Reflecting retrospectively on this matter it should be acknowledged that if the online forums study was conducted first, the design of the interview study would have been affected by the results of the former as the author of this thesis would have acquired a much greater sensitisation around the importance of trust in accepting and using HBPMs. This greater appreciation would have resulted in building the topic of trust in the design of the interview protocol more prominently.

CHAPTER 6 – INSIGHTS FROM THE MEDICAL DEVICE MANUFACTURING INDUSTRY: AN ETHNOGRAPHIC CASE STUDY

6.1 Overview

This chapter presents the empirical work that was conducted to examine the perspective of a key stakeholder, namely the medical device manufacturer. Specifically, chapter 6 aimed to answer the following research question: in what ways do medical device manufacturers try in practice to approach and understand their end-user and what are the potential challenges they face in doing so? To answer this question, a 4-month ethnographic case study was designed and conducted within an organisation that has a leading position in the manufacturing of blood pressure monitoring devices. The manufacturer’s practices and activities to capture the end-user during the development of a new design of home blood pressure monitor (HBPM) were followed up, using participant observation, ethnographic interviews, and analysis of documentary material.

Chapter 6 unfolds as follows: an introduction to the existing literature around the topic of interest is initially presented. Then, the details of the methodological approach that was adopted follow and key features of the organisation are outlined to provide the reader with an understanding of the setting within which the ethnography was conducted. Finally, the results of the research are presented and a critical discussion of them concludes the chapter.

6.2 Medical device manufacturers and user needs: what does existing research tell us?

Medical device manufacturers constitute a particularly heterogeneous industry that produces a vastly diverse product portfolio whilst operating within a highly complex environment. The Association of British Healthcare Industries identifies around 10,000 different medical devices (2009) ranging from simple products, such as wound dressings, to sophisticated equipment, such as MRI scanners. In the UK, the medical device sector employs 50,000 people and consists of around 2000 companies, of which more than 80% are Small and Medium Enterprises (SMEs) (Association of British Healthcare Industries,

2009). The industry is heavily influenced by national and international regulations with which manufacturers must conform in order to be able to position their products into the markets. The sector is also highly competitive with fast-paced innovations and improved iterations being constantly developed (Hourd & Williams, 2008) and with a strong presence of large multinational companies which dominate the field through mergers and acquisition of smaller firms (Topman, 2013). In parallel, the nature of the markets that are being served varies significantly, from whole healthcare systems – such as the NHS in the UK which is the largest customer – to individual consumers, as is the case with over-the-counter medical devices for lay use.

Apart from the intricacy of the broader environment within which medical device manufacturers operate, the medical device innovation process *per se* has its own singularities. Although the medical device development (MDD) cycle is usually shorter compared to pharmaceutical and biological products, it still takes a considerable amount of time to bring new products into the market (on average about 1-2 years for incremental devices and 5-7 years for radical devices; Hourd & Williams, 2008) which increases the risks from competition. Moreover, developing a new medical device requires a significant investment in or across a wide range of expertise (e.g. clinical, engineering, design etc.) whilst successfully articulating the value proposition of the product necessitates committed marketing efforts. The legal protection of the innovation – often in the form of patents – is also very important for safeguarding competitive advantage and signalling business and technological competency (Hourd & Williams, 2008).

Understanding the needs of users of medical devices is an additional prerequisite for successful product development and commercialisation. Indeed, this imperative is often further intensified for medical technologies compared to other consumer products due to their safety-critical nature, the variety of users that are often implicated (i.e. healthcare professionals, patients, maintenance staff) and the complexity of environments within which they are used (e.g. healthcare settings; in conjunction with other medical equipment) (Martin et al., 2008). The accommodation of user needs is also critical when it comes to devices intended to be used by lay people outside the clinical environment due to, on the one hand, the wide range of capabilities/disabilities characterising this population, and on the other due to the unpredictability of the non-clinical setting, such as the home (FDA,

2012). For these reasons, a user-centred design approach that identifies user requirements *throughout* the MDD process has been strongly advocated within the academic literature (Martin et al., 2008; Shah et al., 2009). In fact, the necessity to engage the user is not only acknowledged at a theoretical level but is actually prescribed by International Standards (IEC 62366: 2007; IEC 60601-1-6: 2010) and enforced by regulations (Food and Drug Administration Human Factors Guidance, 2011; Harmonised European Standards EN 62366:2008 & EN 60601-1-6: 2010).

But what does the evidence suggest in terms of the extent to which medical device manufacturers employ a user-centred design approach into their MDD process? Research with SMEs suggests that medical device manufacturers do not always adopt extensive or systematic user-centred design practices, and that to the extent that user research is conducted, it is mainly to meet regulatory requirements (Money et al., 2011). Moreover, the actors that are often approached and consulted are those implicated in purchasing decisions (Money et al., 2011) or have the power to influence the commercialisation process (e.g. investors, licencees) (Miller et al., 2009).

Several barriers to examine user needs during the MDD process have been identified in the literature such as the difficulty to access certain patient populations (Ram et al., 2007) or the challenge to gain ethical approval in order to be able to approach patients (Mihoc & Walters, 2013; Money et al., 2011). Limited resources to invest in expensive user needs research (Martin et al., 2012) as well as poor communication and lack of a shared reference framework between various teams in organisations, which often come from different disciplinary backgrounds (Vincent et al., 2014), have also been reported as obstructing factors. Moreover, the strong focus of markets (e.g. NHS procurement service) on cost considerations predisposes medical device manufacturers to concentrate their efforts on producing low cost products thus marginalising user needs considerations (Mihoc & Walters, 2013). Finally, the prioritisation and the often privileged status of engineering and technological aspects in MDD projects and the limited attention of funding bodies, that financially support the development of health innovations, to user needs considerations attenuates the salience of the value of user needs research (Martin & Barnett, 2012).

Clearly, this research provides important insights with regard to medical device manufacturers’ efforts to account for user needs considerations in the MDD process and

highlights the challenges the sector commonly faces along this process. Nevertheless, the majority of studies focuses on SMEs and academic spin-offs which due to their size are less well-placed resource-wise to support strong and continuous investments on user needs research. As far as larger medical device manufacturers are concerned, there is a paucity of research exploring whether and how these bigger players employ user-centred design approaches. Moreover, most of the research in the field is cross-sectional based on qualitative interviews (for exceptions see Miller et al., 2009 and Ram et al., 2007) thus precluding a detailed examination of the day-to-day activities which the manufacturer performs in order to understand its user population. The present research sought therefore to fill this gap in our knowledge; doing so by adopting an *ethnographic case study* approach, I examined the ways a *medium-to-large* medical device manufacturer tries to understand the needs of its user and to account for these considerations during the MDD process. By allowing the researcher to immerse herself in a real-life situation and to collect naturalistic data, an ethnographic approach is particularly well-placed to illuminate the contingencies, situated character and complexity of human activity and sense-making processes (Greenhalgh & Swinglehurst, 2011). This enables the generation of detailed and rich insights which are difficult to be captured through qualitative interviews alone or quantitative approaches. Finally, this research, using the example of HBPMs, sought to investigate the routine and mundane work of the manufacturer in developing technology that is directed straight to lay users for home use.

6.3 Methods

6.3.1 Gaining insights from ‘inside’: an ethnographic case study design

To pursue the objectives of the present research an ethnographic case study was designed. Ethnography allows the researcher to closely follow up and document the details of the day-to-day practices and meaning-making processes of the people who are studied, through the lens of their own perspective, within their ‘native’ environment. In this sense, ethnographic work enables an understanding ‘from inside’ that is attuned to the *natural* unfolding of the phenomenon (Hammersley & Atkinson, 2007; Bloor & Wood, 2006). The

ethnography was conducted in ComX Europe¹⁴, a medium-to-large medical device manufacturer with a leading position in the manufacturing of blood pressure monitors. The empirical work lasted 4 months – between March and July 2013 – and took place in Amsterdam, the Netherlands, where the headquarters of the company are based. The author of this thesis was situated in the marketing department in the position of the ‘research intern’ during the initial phase of the development of a new HBPM.

6.3.2 Sources of data collection

Data were collected through three main activities: participant observation, ethnographic interviews and analysis of available documentary material. Using multiple sources of data collection helped to triangulate the data in order to increase the confidence in the validity of results.

Participant observation: Participant observation constitutes one of the core methods of data collection in ethnographic work. I had the opportunity to attend and get involved with activities that related to user needs research during the initial stages of a MDD process. Specifically, I was able to participate in meetings (formal meetings related to the MDD process took place on days 19, 27, 33, 48, 67 and 68 of the ethnography), informal discussions and other communicative practices (i.e. e-mails) that were held among marketers, researchers, engineers and designers and to get involved with the workings of the user research that was conducted as part of the MDD process. At the time of observation, I was taking jotted notes highlighting important aspects of events and interactions (Thorpe, 2008) which I then fully developed into detailed field notes at the end of each day (Emerson et al., 2011). Initially the field notes were highly inclusive, recording the majority of my observations even if at the time they did not look highly relevant to my research purposes. This was a purposive decision since there were not any concrete anticipations of what exactly will unfold in the field and which of the unfolding events might be eventually important and relevant for the research purposes. The inclusive character of the field notes during the initial stage of the ethnography also helped to familiarise myself with the people and the organisational environment. The field notes progressively became more targeted as I was able to gradually develop an understanding

¹⁴ A pseudonym is used throughout the report to protect the identity of the organisation.

around the relevance of observations and as the research was acquiring a more focused character. The style of field notes was loose and informal (Goffman, 1989) while reflections and initial speculations around the meaning of observations were also recorded. In total, field notes of 73 working days were recorded which amount to approximately 510 hours of fieldwork.

Ethnographic interviews: One-to-one ethnographic interviews were conducted with seven key informants during the last weeks of the fieldwork (due to practicalities one interview was conducted after the completion of the ethnography). I intentionally left the interviews to be conducted just before the completion of the fieldwork so as to be able to follow up and discuss with the informants important events and activities I had been observing during the previous period. At the same time, this presented the advantage of developing the discussions against the background of the rapport I had established with participants in the course of the ethnography, an element that distinguishes uniquely ethnographic interviewing from other forms (Fielding, 2006).

Participants were located in various departments in the organisation (one from the sales department, one from the Quality Assurance & Regulatory Affairs department and one from the customer service department), though the majority ($n = 4$) were from the marketing department. The details of their roles and responsibilities as well as the date and duration of interviews are presented in table 6.1. I deliberately do not provide the exact job title of the interviewees to ensure their anonymity but all were holding middle and senior managerial positions except for one case.

Table 6.1
Details of key informants participating in ethnographic interviews

Department	Job role and responsibilities	Duration of work experience in the organisation	Date and length of interview
Marketing Department	<ul style="list-style-type: none"> Participant code: P001 Contribution to the development of new HBPMs, management of launch process, marketing and promotion of products in the EMEA region	18 months	13/06/13 1h & 22min
	<ul style="list-style-type: none"> Participant code: P002 Product Life Cycle Management	10 years	26/06/13 1h & 55min

	<ul style="list-style-type: none"> • <i>Participant code: P004</i> Management of new product launches, communication, consumer understanding, product development and strategy development for the product categories of diagnostics and treatment • <i>Participant code: P005</i> Management of organisation’s brand; development and protection of brand guidelines; lead communication initiatives and campaigns in close collaboration with the product management team 	15 months	08/07/13 1h & 15min
		19 months	08/07/13 1h & 20min
Sales Department	<ul style="list-style-type: none"> • <i>Participant code: P003</i> Management of existing customers and further business development in the region of Africa. Responsible for the full range of product categories 	8 years	27/06/13 45min
Customer Service Department	<ul style="list-style-type: none"> • <i>Participant code: P006</i> Management of orders and distribution of products to customers (i.e. business partners); collaboration with the sales department about service provision to the customers 	10 months	09/07/13 1h & 13min
Quality Assurance & Regulatory Affairs (QA/RA) Department	<ul style="list-style-type: none"> • <i>Participant code: P007</i> Quality Assurance: Safeguards that quality management systems in the organisation are in place (e.g. document control) Regulatory Affairs: Supports the compliance of medical device products with Medical Device Directive; management of customer complaints 	15 years	27/09/13 57 min

Approval for interviewing employees was initially sought from the organization, who were fully aware of what the process would involve, what topics would be discussed and of the ethical requirement to keep the interview content strictly confidential between me and the participant. After the organisation had provided me with permission to approach prospective interviewees – and with the assistance of the employee who acted as my manager and gatekeeper in the organisation – several employees were invited via e-mail (see Appendix I for the invitation e-mail) to take part; all of whom agreed to do so. In the invitation e-mail participants were provided in advance with the *Information Sheet* (Appendix J) which described the purpose of the research and the process of interviewing, the *Participant Informed Consent* (Appendix K) which they would need to sign in the actual interview, as well as an outline of the topics that would be raised in the interview.

Though the interview was loosely structured so as to be flexible enough and open to participants’ own contributions, I developed an interview protocol to guide the discussion and to help me cover the areas I intended to raise. The interview protocol consisted of three main sections: section A sought to contextualise the interview by inviting the participants to talk about their position, role, and work experience in the organisation. Section B aimed to explore all those ways that the manufacturer uses to understand its end-user. Though the majority of the main questions of section B were generic (e.g. *In what ways do you try to understand the needs or requirements of users of HBPMs?*) several prompts were developed on the basis of my experience in the organisation and the information I had gained through informal discussions and interactions, documents and formal meetings (e.g. *I have noticed during my internship that one way of accessing your end users is through consumer research. Would you say that this is a standard practice in ComX?*). Moreover, a subset of questions in Section B derived entirely out of my experience in the company. These questions, occasioned by the information that a significant number of HBPMs purchases were made after a doctor’s recommendation, aimed to explore the extent to which the views of the medical worlds are taken into account in the design and manufacture of BPMs for home use and to understand the potential challenges that this might raise for the manufacturer (i.e. in the event, for example, that doctors’ and end-users’ considerations and priorities were different or even competing). Finally, section C sought to elicit conversations and reflections around particular events I had noted during the fieldwork and which were linked to user needs considerations as these were being consolidated during the MDD process I followed up. Therefore, the questions of section C originated exclusively from my participation in the MDD process whilst particular observations were brought in the discussion to elicit participants’ views and comments (e.g. *I noticed during the kick-off meeting that you did not want to limit designers in their thinking about the monitor and that you wanted them to feel free to design something in lines with the results of the consumer research. Would you say that this is a fair comment? If so, why have you adopted this approach?*)

Appendix L provides a typical interview protocol after excluding information that might be sensitive (i.e. confidential). Though the broad rationale for the interviews was identical across participants, a separate interview protocol was created for each participant to

account for the particularities of the person given his/her position in the organisation and his/her level of engagement with user facing activities. All interviews were audio-recorded, lasted on average 76 minutes, and were transcribed verbatim by the author of this thesis.

Documentary material: Finally, various documents that were made available to the researcher (e.g. research reports) or that were publicly accessible (e.g. user instruction manuals) were used as an additional source of potentially useful data. A full list of the documents that were examined is provided in Appendix M.

6.3.3 Data analysis

Informed by the overarching research objective and guided by the research questions as these were evolving and became gradually more focused in the course of the fieldwork, an iterative process to the analysis of the data was adopted (Hammersley & Atkinson, 2007). A certain degree of analytic work started from the point of negotiating access to the organisation and throughout the fieldwork by reflecting on my recorded observations and speculating around their meaning. However, due to the time-consuming and intensive nature of fieldwork, the major part of the analysis was conducted after the completion of the fieldwork.

Against the background of paucity of evidence in the area, the analytic focus of this work was primarily on providing a rich and in-depth *description* of the phenomena of interest reflecting the perspectives of the employees and their organisation (Bloor & Wood, 2006; Hobbs, 2006). For this reason, an inductive approach to the analysis of the data was adopted in my effort to provide a nuanced and rich account grounded in data. Nevertheless, pure induction is never completely feasible since the researcher cannot escape from existing knowledge, ideas and pre-conceptions shaped by previous literature and social experience (Hammersley & Atkinson, 2007). In the present study, for example, this was particularly applicable in relation to the user and market research activities I observed and took part in, whereby the lens of academic research, to which I am accustomed, clearly informed my sense-making process. I deployed this knowledge and experience as a resource to make sense of the ethnographic data around user research, yet I was also attentive to not imposing interpretations based on my own system of reference (Hammersley & Atkinson, 2007) but to interrogate the data from the standpoint of my participants and their context. Further,

while the primary analytic focus of this research was on the production of an in-depth *description*, efforts to explain the results and to articulate their implications were also made.

The analytic work was informed by the principles of thematic analysis (Braun & Clark, 2006; Clark & Brown, 2013) and was developed as follows: initially, I familiarised myself with the material through the repeated reading of the whole corpus of data. Driven by the research questions, I then started coding the data whilst progressively creating broader topic-level groups under which I ascribed relevant codes (e.g. material related to user research; material related to challenges) along with their coded segments of data that were coming from the field notes and the interviews. With regard to the field notes and ethnographic interviews, the process was assisted by computer software (NVivo 10). The management and the analysis of the documents were performed manually. The content of the codes was then analysed and iteratively refined during the process of developing thematic categories. In the course of the analysis, attention was paid to the identification of repeated patterns of meaning as well as cases or instances diverting from dominant ideas. Consideration was also given on how the data from the different sources compare to each other (i.e. field notes, interviews, and documents). The final themes were eventually refined and solidified and are reported in the results section of this chapter.

6.3.4 Ethical aspects: balancing competing considerations

In the process of negotiating my access to the field, the company was made fully aware of my research purposes and intended research activities (i.e. participant observation, interviews, and analysis of documents) to which it consented when I was admitted. Specifically, I provided details of my PhD research project, a summary of research outputs published at the time (i.e. article) as well as my plans for future research. In the process of conducting the ethnographic work I adhered to the principles and code of ethics specified by the British Psychological Society (2009; 2014). I attempted to balance, on the one hand, the requirements of my research to collect useful data from several sources in the most fruitful ways (principle of *competence*) and on the other the company’s requirement to protect confidential information – which also constituted part of my official contractual arrangements (principles of *respect* and *responsibility* towards research participants and

research site). Whenever there was the potential for conflicts between these two considerations, I sought consultation from the organisation in good time. For example, I asked organisational permission before approaching employees for conducting interviews by providing full details of what the interviewing would involve. I also asked permission for taking with me documents for further examination after the completion of the ethnography (beyond those that are publicly available). I was also cautious of respecting the level of access to the various activities and material (e.g. documents) that the organisation provided me and the boundaries that were being established formally or informally. Moreover, with regard to the ethnographic interviews the principles of *informed consent*, *confidentiality*, *anonymity*, and *right to withdraw* were fully applied.

Clearly, in several instances ethical considerations were interwoven with legal arrangements as part of my internship contract, thus augmenting the complexity of the issues. Whenever there was a clear conflict between my contractual arrangements and commitments and the potential for research benefit, the former obviously took precedence (e.g. not reporting or using information signalled clearly by the organisation as confidential despite the relevance to my research purposes). In those occasions that were not covered by contractual arrangements but ethical dilemmas were likely to arise, the protection of research participants’ rights was prioritised against the maximisation of the potential for research benefit. However, within those boundaries, the quality and rigorousness of the research process was attempted to be secured (e.g. for example tape-recording the ethnographic interviews to ensure precision of the data despite the potential sensitivity of the issue for both the organisation and the participants). As the research took place in the context of a research internship, the terms of which were legally agreed, it was not necessary or appropriate for this research to be further considered by the department ethics committee.

6.3.5 Describing the case and setting the scene: key features of the organisation

A. Brief outline of the organisation: ComX Europe is a company of Japanese heritage with a worldwide presence. It is a leading manufacturer in blood pressure monitoring devices with a special emphasis on technologies designed for home use, alongside medical products for professional use. Apart from medical equipment, the manufacturer also

develops and trades wellness & fitness products (i.e. activity monitoring technologies such as step counters) in an effort to provide a wide range of healthcare tools ‘for prevention, diagnosis, and treatment’. Moreover, the organisation has a long-standing tradition of involvement and participation in clinical research programmes around home blood pressure monitoring by offering its equipment into trials. The Ohasama studies in Japan, which contributed to the establishment of blood pressure thresholds outside the clinical environment, exemplify the organisation’s engagement with clinical research (‘The story of the Ohasama study’ - company leaflet).

B. Historical landmarks of the organisation’s blood pressure monitoring innovations: In the beginning of 1960s, and based on the concept of ‘health engineering’, ComX started to invest R&D resources and to develop innovation around blood pressure monitoring. In 1973 the company released its first manual blood pressure monitor – a manometer – and in 1978 developed the first digital blood pressure monitor for home use. During the 80s, the organisation advanced and adapted the oscillometric method of measurement and released a series of innovative products such as its first digital automatic BPM for home use in 1981 and the digital manual BPM in 1984. During the next decade, the ‘fuzzy logic’ technology was developed which allowed a more sensitive blood pressure measurement by accounting for several bio-anthropometric indicators whilst also being more usable (e.g. reduce potential pain to the user by controlling the pressurisation) (field notes days 12 and 13; training material from training sessions). A range of technological innovations were introduced such as the world’s first wrist blood pressure monitor and monitors with the fastest measurement technology. In the decade of 2000s, blood pressure monitoring technologies continued to advance and the company introduced innovations related to cuff technology, positioning of the arm, or morning hypertension.

C. Pinpointing ethnography within the broader organisational structure: ComX is structurally divided into five geographic regions. Four of these divisions serve a series of countries and the fifth, located in Japan, constitutes the headquarters of the entire organisation while simultaneously serving the Japanese market. The ethnographic work was conducted within the headquarters – located in the Netherlands – of the regional division that serves the countries in Europe, Middle East, Africa (EMEA) and Russia.

D. Operational structure of the organisation: The core activities that define the operations of ComX Europe revolve around marketing and sales and, by extension, customer service. In parallel, a Quality Assurance & Regulatory Affairs (QA/RA) department also operates which on the one hand ensures that the organisation adopts and applies suitable quality management systems¹⁵, and on the other supports and facilitates the global headquarters in the implementation of legislative requirements for medical devices across countries. Moreover, a human resources and a finance department support the relevant functions of the organisation.

The commercial transactions of the organisation are with other enterprises (i.e. a business-to-business model) and these ‘business partners’ are selected on the basis of the company’s ‘distribution model’. The primary objective of ComX Europe is to grow existing markets and to expand the business into new ones. The products are typically designed in the global headquarters, which run all the relevant R&D activities, and are then supplied to the regions. For this reason, the company in the EMEA region focuses its resources primarily on marketing and sales.

E. Organisational changes at the time of fieldwork: The ethnographic work took place within a period during which ComX Europe was undergoing some important structural and operational changes which in essence consisted of the strengthening and expansion of the role of the marketing department. This was achieved through two major strategies. One was through the **decentralisation** of part of the activities related to the MDD process from the global headquarters to the regional headquarters. Up to that point, ComX Europe was mainly responsible for trading the products as these were designed and supplied from the global headquarters, with adaptations being limited to labelling (i.e. packaging, user instruction manual). In the new structure, the organisation started to have a more active role in shaping the product development process. This involvement pertained to the examination of user needs – alongside market needs – and the subsequent development of product specifications, which in turn were communicated to the global headquarters in order to inform the development of new products. As one participant explains below:

¹⁵ E.g. particular documents that the organisation produces should have certain formats required by quality standards (field notes day 7).

“So we, our role is changing over time at the moment. So originally ComX was a, or ComX Europe was a sale and distributor. Products were developed in Japan, so our role was really identifying the, identifying the market opportunities and launching products that were available from Japan, mainly with the only changes being the naming, and then instruction manuals, packaging, etc. More recently we have also been involved earlier in the development process, so in providing more detailed specifications, doing consumer research pre-design phase to identify consumer needs and putting those into the specifications. So we are becoming much more involved in that side.” (Marketing department)

Another employee with extensive working experience in both the global and regional headquarters of the company noted:

“In the past ComX Japan was normally doing all the things, and they just changed the translation, they just changed the modification to the local language, and then spread out to the whole region, and that’s how we spread out all the business. But now...we are now in the phase that we should, each region should feedback to ComX Japan, and then they should make some, not general, but some product based on the [regional] marketing. So, we are now, I think, in a different phase.” (Marketing department)

Indeed this shift of activities and delegation of responsibilities closer to the regional headquarters was promoted and stimulated by the overall business strategy.

P: So there is a lot of freedom to do what we believe it’s the right thing to do.

I: To change things, yeah.

P: And that’s also encouraged - although it’s more difficult because of the size of the organisation in Japan and the fact that obviously they need to serve different regions - it’s also encouraged as a business strategy by ComX Japan as well; give the regions more autonomy, more flexibility to define, but then more responsibility to make sure that it works.” (Marketing department)

The second route that led to the reinforcement of the organisation’s marketing operations was through a **centralisation** of communicative practices from the local business partners to ComX Europe. Up to that point, the business partners in several countries had the freedom to design and deliver their communication and to position the products in those ways they thought that their country-level markets would be best served.

In the new structure, the organisation took on the responsibility of designing and shaping the overall communication strategy which in turn informed and oriented the business partners’ relevant activities. This change was reflected in activities such as developing centrally communication material and it was further supported by relevant consumer research which was seen to allow a deeper understanding of end-users and markets and ultimately a better targeting of consumers.

“And then on the downstream side we are also moving from being more of a distributor to business partners and allowing them to do all of the local communication and positioning, to bringing some of that localised staff more centrally and be, creating more centralised communication material, doing more research to enable us to be able to position the products more properly or more accurately within a market with the right consumer group, the right communication.” (Marketing department)

The aforementioned changes led to the increase in the size of the marketing department, the accompanying expansion of jobs and the enrichment of roles. For example, in the course of ethnography, four new marketing positions were created. Existing practices, such as research, also changed to include new techniques, methods or approaches whilst entirely new initiatives were additionally launched.

Summarising the organisational changes that were taking place around the period of the ethnographic work, the company was clearly undergoing a process where resources were heavily invested in personnel, activities and tools that would allow a better apprehension of markets and consumers. ComX Europe’s ability to engage with and influence the product development process, on the one hand, and to develop and actively lead the communication strategies, on the other, with a view to better serve the needs of consumers and markets clearly both necessitated a more intense involvement with the end-user. Within this broader framework of changes and orientation, the opportunity to conduct ethnography around the needs of users of medical devices whilst contributing to the user research activities of the organisation was welcomed.

F. Accessing the field: Negotiating access to the field is an important process that requires delicate handling on the part of the researcher (Goffman, 1989; Hammersley & Atkinson, 2007) especially when it comes to for-profit organisational settings. At the same time, it is a significant source of useful knowledge revealing many of the idiosyncrasies of

the field. Nevertheless, it is noteworthy that the process of accessing the field does not end with a mere permission to enter the field (Hammersley & Atkinson, 2007); it is often an ongoing exercise of recurrent negotiations to access people, situations, and events whilst being already in the field. In the present study, the organisation was initially approached by the researcher (with the assistance of the academic supervisor) with an invitation to conduct ethnographic work around the ways the manufacturer uses to understand end-user considerations during the MDD process. By chance, at the time I approached the company, ComX Europe was embarking on a project of developing a new design of HBPM which included a considerable volume of user and market research. As my PhD research was focusing on HBPMs and I was seen as having a good level of expertise in research methods (having an MSc in research methods), the organisation saw my placement as a useful research resource. After rounds of negotiation whereby the expectations and requirements of both parties were set explicitly and a mutual agreement that balanced commercial sensibilities (i.e. confidentiality considerations) with academic requirements (i.e. academic publication of the ethnography) was reached, I was invited into the organisation.

G. Developing a new home blood pressure monitor: The project concerned the development of a new design of HBPM which ComX Europe had commenced at the time of ethnography and to which my contribution was mainly directed. The initiative aimed to address a different consumer group and identified user needs than those addressed by the existing product portfolio and to explore potentially different distribution models to reach the end-users in the places where they prefer to shop. As a result, that was a project that was expected to be commercially important for the organisation. The design process would take place in Europe through partnership collaboration with external agencies and in consultation with the engineers and designers from the ComX global headquarters. ComX Europe would manage the whole project – which was planned to last around two years from initial pre-concept consumer research all way through to device production and placement on the market – and would provide consumer insights and user specifications in the design process (field notes day 1). The ethnographic work was conducted in the first four months of the MDD project whereby consumer research, pre-ideation user research, and concept development were undertaken. Though my own contribution to the organisation’s activities focused primarily on tasks related to the development of the new

monitor, I also had the opportunity to attend and get involved with other user research projects that the organisation was running at the time (i.e. an experimental study testing a new HBPM function – field notes days 31, 51, and 66 – and a user validation study of a new cuff technology – field notes days 12, 14, 15 and 69).

6.4 Results

The results are structured in two sections. *Section I* presents the ways through which the manufacturer attempted to access and understand its end-user and *section II* describes the challenges the organisation faced in these efforts. Interview extracts are identified by the department in which the interviewee was located.

Section I: Ways to capture and understand the end-user

6.4.1 The role of research

Undoubtedly, user and market pre-concept research possessed a central valued role in the activities of the marketing department in ComX Europe (field notes day 37). The very fact that I was admitted in the position of the ‘research intern’ is illustrative of the value people ascribed to research. For the most part, research was outsourced to relevant agencies, rather than being conducted in-house, but ComX usually attempted to preserve a significant level of involvement in shaping the research requirements (field notes day 20). Indeed for critical studies, such as prototype validation studies (field notes days 14, 15), the company was even more actively involved by designing the research, defining measures and participating in the process of data collection and analysis (field notes from validation research on a new cuff technology). Outsourcing the research was seen to present the advantage of having access to a variety of state-of-the-art methodologies, from which the organisation could select those that best served their needs. But also assigning the research externally served pragmatic reasons as the organisation could not afford to retain research capabilities in-house.

“P: I think em, first of all, I think that research for, should for the biggest part be outsourced.

I: Why are you saying that?

P: Because you, it’s, I think it’s a high investment to have in-house capabilities which are so specific...And the other thing, if you build all those capabilities in-house, you need to make sure that they continuously em...

I: Develop.

P: Develop. Because the market dynamics are changing constantly, so you need to stay on top of that. If you em outsource, and, you can always, can make sure you get the latest insight, the newest, the latest information.” (Marketing department)

Despite the in-house absence of user research expertise in ComX Europe, an adequate level of research understanding was considered necessary to enable the organisation to state suitable research questions in the right way. This ability had been acquired by some employees through their previous and current professional experience who championed an evidence-based approach to the understanding of end-user.

User and market research was either conducted as part of the organisation’s routines to examine and monitor periodically the market or under specific circumstances, such as when a particular user problem arose in the market or when a project or a new initiative was to be launched.

“...so we do that at least once a year, as a matter of course, but then we also do it if we have more specific projects going on. So, generally about a year before we launch a new product, we survey the market place to make sure that what we are going to introduce is fit for purpose.” (Marketing department)

The inclusion of users throughout the product development process was considered by some inevitable as the consumers were seen to increasingly demand products tailored to their needs. Simultaneously, involving the user safeguarded the manufacturer against the risk of creating products that would not be eventually suitable for the targeted market. Below the participant describes vividly how the user is brought in at several stages of the development process, in this case software.

“So, for instance, in the software that we are developing, we are also taking an iterative process, where we, we define a concept that we want to explore and develop, but during that development we take various steps in research. So first we have an idea, a

hypothesis, and we validate if that concept resonates with a certain segment of the market. If it does, OK. Develop, in a sense, em, OK there is resonance. What are the unmet needs that we need to address? What are the behaviour types? What are the things that they like and don't like about the concept? And then if we see that these developments would make sense, we start to develop. Well in this case what I am talking about is a piece of software, and then again you know start to refine it more and more, and then even go into concept testing, user interface testing, acceptance testing, so you, you know, from, from the very early concept stage to the actual launch of the product you constantly measure that what you are doing still makes sense within the target audience and I think that is, it is time and labour intensive but ultimately it will give you the best product.” (Marketing department)

Importantly, user research was sometimes conducted to test the in-principle acceptance of a design concept. The example below is illustrative of the value ComX Europe placed in implementing a user needs-driven approach to device evaluation that begins with questions of *relevance* and *desirability*. The importance of these aspects has been stressed in literature, despite the fact that they usually receive less attention compared to cost-effectiveness considerations (Lehoux, 2008). To answer the question of relevance, ComX designed and run a study that tested design concepts which did not exist in their product portfolio. The users were not thus only brought in to confirm or disprove the appropriateness of an already developed design – “that’s a question for another day” as the participant in the quote below says – but were asked about their in-principle interest in the design concept. Though the evaluation of relevance and desirability is arguably much more critical for *medical device innovation*, it is interesting that similar questions are posed for *design innovations* of established medical devices to inform future iterations.

“[We are] doing some interesting things for [medical device]. We are testing the acceptance of a [new concept design of medical device] with a user group, and we don't have a [new concept design of medical device] of our own. So what we have done is we do run a whole study based on competitor products. So it's a semi-quant kind of 100 users per leg study using a competitor [variation A of the new concept] and a competitor [variation B of the new concept], literally so that we can understand. It sounds a bit strange but that's the best way to get the understanding of whether the technology itself

is accepted or not. And for me that’s the first phase before you go on to ‘does our design look [good]? Does our brand influence it more?’ That’s a question for another day.”
(Marketing department)

As part of the research that was being conducted during the pre-concept development phase, consumer segmentation studies played an important role, determining much of the organisation’s subsequent commercial, communicative, research, and product development decisions; “*so it’s going to be, it will become the fundamental basis of everything that we do*” as a marketer commented. Indeed, the user populations that were to be targeted commercially and to be researched throughout the MDD process were largely defined on the basis of the consumer types that were emerging from the segmentation studies.

Clearly, segmentation studies are not a new research approach but one that is commonly used by businesses to investigate and understand their markets. Nevertheless, the criteria upon which the market is segmented might be revealing of the consumer conceptions the industry holds and develops. My engagement with this sort of studies whilst being in the field showed that ComX Europe was keen to consider and accept a multi-faceted view of the user that departed from a solely consumerist conceptualisation (e.g. based on metrics of willingness to pay and income) or a dichotomous user depiction based on the presence/absence of illness, to incorporate a series of attributes that offered a more sophisticated user representation. Interestingly, psychological constructs, such as user *attitudes* toward health matters and technology or *fundamental motivational states* behind technology use, were employed to classify the surveyed consumers into groups. The profile of consumer groups was then enriched by associating the clusters with other attributes such as socio-economic status, health status, values, technological preferences, brand awareness, and purchase patterns.

As it became apparent during an interview, the company was running at the time an extensive segmentation study that sought to investigate patterns of technology adoption and use as a function of different ‘needs states’ characterising different consumer groups. The insights from this study were expected to enable the organisation to develop suitable product specifications that could better accommodate the underlying fundamental user needs. The participant below vividly describes in qualitative terms the types of users anticipated to emerge based on different motivational states.

“So this person monitors because, due to conformity, the reason is conformity; is because it’s always his wife is telling him ‘you need to measure your blood pressure today, you need to measure this today’ so he does it, he writes it down, so then he can show to his wife that he made the measurements. So that’s one certain group, there is a specific behaviour, and...which would then potentially translate into a different product need versus somebody who is really monitoring for themselves, to monitor their fitness, and to make personal decisions about, each measurement may help contribute to them making different decisions about their lifestyle, or their medication, and this kind of things.” (Marketing department)

Using a more sophisticated approach to characterising the consumers on the basis of psychological constructs (e.g. ‘needs’, ‘attitudes’) was highly appealing to marketers for two main reasons: first, it was seen to present a considerable improvement compared to the past around the ways the organisation conceptualises the user and conducts accompanying research (field notes day 12):

“It might be of a problem in the past that you take a blood pressure monitor and we, the only qualification for testing that in a consumer test is ‘do you have high blood pressure?’” (Marketing department)

Secondly, it was assumed that the psychological states (e.g. needs) upon which consumer groups were constructed have the potential to reveal *essential* or *fundamental* human qualities that “*generalise to really any product, to any good*”. An essentialist user representation thus provided an enduring and ubiquitous image that created a firm ground for decision making across a range of contexts.

On the basis of the results from the segmentations studies, the marketers then created user profiles and personas to textually and visually represent their targeted user groups and to ground the research findings in concrete images. The personas were used to facilitate both the internal communication and the communication with external agencies involved in the MDD process. They promoted a shared understanding among the involved parties and helped to maintain the user vividly present during the technology development.

Overall, it can be noted that the company through the segmentation studies was clearly keen and actively sought to develop a richer and more refined understanding of the users

that encapsulated better their needs. At the same time, this more sophisticated understanding moderated user-device complexities due to the assumption that part of the ‘real essence’ of the users is captured, providing in this way meaningful organisation and solid grounds for action.

Research was not only conducted proactively to test the relevance of concepts or during the product development process, but also when user problems with particular products arose in the market which the organisation usually received through the form of user complaints or less positive feedback. In these cases, the company initiated research to understand the situation and to test their assumptions of the causes of the problem in order to take appropriate actions. For instance, the organisation was encountering some problematic user insights in relation to a nebuliser, which despite the fact that it was quite successful in some markets, in others it had been received less favourably. For this reason, a study was organised to examine the issue of interest that would then allow the organisation to either adapt the product or develop a new one that would fit with the needs of the particular consumers.

“But also if we do have in-market questions then we, so for the same nebuliser launch we are doing a post-market consumer research in Turkey for example. So we had some, we had some let’s say negative consumer insights on part of the product which we think it’s actually part of the product design, it’s just not fitting so well with their needs, but we are running the test to be, to really understand what it is.” (Marketing Department)

Post-market user research did not only respond to a particular problem or complaint reactively, but it was also conducted proactively in an effort to gather user insights that could prove useful for future product iterations. Though this latter sort of research was primarily run within the framework of the legislative requirements for medical device post-market surveillance, the company tried to augment the informational value by asking additional feedback from a consumer standpoint. For example, the employees of the QA/RA department in collaboration with the marketing department had initiated a ‘pilot project’ with one of their nebulisers whereby user questionnaires were included into the products and the consumers were invited to complete and return it to the company.

“I mean, for example, the post-market questionnaires which I discussed before I have also done that in conjunction with marketing. Because first of all we can raise the

typical quality questions, but also marketing at the same time can raise some questions which can be benefit to them.” (QA/RA Department)

Overall, it can be argued that user research constituted an integral element of the organisation’s practices. It was used to test assumptions, to shed light on problems and to enhance understanding that ultimately would inform decisions and ground actions on a sound evidential basis. Essentially, research was perceived as a practice that could protect the organisation from making risky decisions that could impact the utilisation of resources negatively. In this way, the approach to risk management was further systematised in the sense that an evidence-based stance – deriving from user research – against economic risks was adopted. An ongoing and routine user research programme allowed early and proactive risk evaluation.

“Yeah, I mean justifying to the finance department why we spend so much money on research, why we have a research intern, why we are doing you know over, we are doing over [X amount of money] euros with the research, the point is that it’s better to fix it now and understand it now than once we already created a product and launched it which will cost, you know, half a million euros by the time we are done.” (Marketing department)

Interestingly, user research in some instances was seen to ‘de-politicise’ decision making and to neutralise power dynamics. In my question of whether people in different departments may have different views of the user and their needs, a participant narrated a story where there was considerable disagreement across key stakeholders (i.e. business partner, global headquarters, and regional headquarters) as to which functions of a medical device was more important and necessary to include. So, a user study was organised and attended by the main stakeholders in order to actually observe “the fact”, that is, the real users interacting with the device and expressing their views. Evidence coming from user research thus constituted a very convincing and informative tool indicating what decisions should be made whilst also the latter being disentangled from interests or subjective opinions.

“P: ...but we went to the user interview, and see Russian people using the device and em, behind a mirror.

I: Yeah, yeah.

P: And that was actually ComX Japan was also here, and also [name of Marketing Group Manager], and [name of Product Category Manager] was here, and myself, and also the marketing in Russian business partner was there, so we just gathered and see the actual thing. And it was quite working, so all the people were convinced with the [?]. So it’s a complicated process, but I think we need to have this kind of third things, because if we talk about em if we talk without the fact, the end-users, then it’s just a power game, people who speak aloud will be the ‘king’ and it will go, and that is messy so yeah! That was interesting.” (Marketing department)

6.4.2 Online user reviews

Online user reviews about specific products constituted an additional activity with which the employees in the marketing department engaged in order to access user feedback. This was considered a very convenient and useful way that helped them to receive comments directly from users in a timely manner which then informed their actions.

“P: Also we take a lot of feedback from customer comments on forums like for example Amazon. One of the nice things about online sales is that it is a very good way to capture feedback in real time. Cause a lot of people take the time to write comments

I: Reviews?

P: That’s right, yeah, so real user reviews, and they can be either very positive, so we know we will do more of this, or sometimes if they are very negative, we are trying to incorporate that feedback into what we are doing.” (Marketing department)

In my question of how the online user reviews might inform the manufacturer’s actions, the manager who was responsible for HBPMs referred to the following example:

“So for example we produced a product that was at a very low price point that didn’t have batteries included, but we can tell very quickly from the Amazon reviews that it really really upsets people. So where we thought maybe it would mean that they would score the product to 4 instead of a 5, in actual fact we could see that it was making people score products 2 out of 5 instead of what we expected. So, that made us realise that our perception of how much people want batteries included is not the same as what appears to be in the market place. So, we had very quick feedback and we obviously, we

changed that by putting batteries back in the pack as standard, even if that was more expensive, we had a lot fewer customer complaints.”(Marketing department)

The online user reviews provided a direct and concretised picture of the user experience that was more difficult to be captured at a market level whereby the consumer is represented at a more generic or aggregate level and the nuances of experience shrank considerably, if not lost. Indeed, the online user reviews were not only informative about specific products but they were also a valuable material in terms of how the consumers appreciate the brand more generally, often in contradistinction with competitors’ brands. Thus, the informational value of the user reviews was extended to include both the immediate feedback around specific products and the consumer’s judgments about the brand.

“P: What we do see is that a lot of the comments are kind of, when the reviews are positive ‘as expected from ComX this is good, and this is another reliable ComX product, this is another great quality ComX product’ and the inverse when, particularly when we had some problems with wellness & fitness products, what we see is ‘you would not expect this from a quality brand like ComX. So even in the negative reviews they were still referring to the fact that they expect ComX to be a quality brand whereas with some other brands say ‘yeah this is just another piece of junk from x’ [laugh]! (Marketing department)

Though the marketers clearly recognised that the online user reviews should be read with caution since one cannot be sure about who wrote them and due to the fact that the information they provide currently represents a rather small number of consumers (i.e. those who have internet access and purchase online) from the pool of their typical consumer group (i.e. purchasers of HBPMs), it was envisaged that online reviews would become increasingly useful in the future insofar as the now-young or middle-age generations will be using the internet to a greater extent.

“I think as people - the internet usage penetration rather spreads, especially to older age groups - it will become more useful, because at the moment we kind of just scratching the surface because the majority of people - and this is just a generalisation - that buy online are younger and more technology savvy, and our typical consumer for the blood pressure monitor is somebody who is over 65 and at the moment, looking at

usage patterns and penetration, that’s not the core group of people who really use the internet. So we may be picking up 1% of purchases, whereas in the future, as the age, the average age of someone using the internet gets changed, it will be much more useful for us cause it is more representative of the population.” (Marketing department)

Examining the online reviews appeared to be done on a voluntary and individual basis, and there was not any strong evidence that this process was somehow systematised or more formally incorporated into the practices of the marketing department. Perhaps the underlying alignment of the usefulness of the online reviews with notions of quantity – as it is evident from the quote above – did not render this source of information any more attractive.

6.4.3 Peripheral routes to the end user

Apart from the more direct ways employed to access and understand the end user, namely research and online product reviews, the organisation was also able to gather user insights more peripherally from interactions and exchanges with key actors in the field such as the medical professionals and the distributors (the latter being the direct customers – ‘business partners’ – of the company). Finally, imagining the end user through personal experience was a further route that helped to sense their needs and preferences.

A. The interactions with the distributors: Whilst for product development the end user was approached more directly and was formally represented through the user and market research activities (described in section 6.4.1), for communication purposes the manufacturer deployed a different pathway. Here, the focus was on the exchanges with the business partners and in turn of the latter’s exchanges with the retailers and pharmacies (see Figure 14). Alongside the top-down communicative purposes that this pathway served, it also constituted a vehicle for receiving some end user insights. One form of user feedback reaching the manufacturer through this channel was aggregate complaint reports which were compiled by the business partners on a regular basis. Although very occasionally – “maybe once or twice per year” – end users directed their device complaints straight to the manufacturer, the bulk of this information came primarily from the distributors.

The kind of complaints which end on my desk are more the general ones. So in other words they are complaints from our business partners. I mean if you talk about customers, my customers, or our customers, are not end-users but our business partners. (QA/RA department)

User and market insights were also shared in the context of business exchanges, meetings and interactions the manufacturer regularly held with its business partners. Indeed for some departments, the contact with business partners was a significant source of end-user insights.

P: Marketing is different, because that’s their job to markets, so they have to look.

I: To understand yeah.

P: So they are more looking to the market deeply and...and then if you look to finance or if you look to quality, QA, they are also not in contact with the end-users, they are only getting what’s...they are only understand what they are getting from the business partner, the requests they are getting. (Sales department)

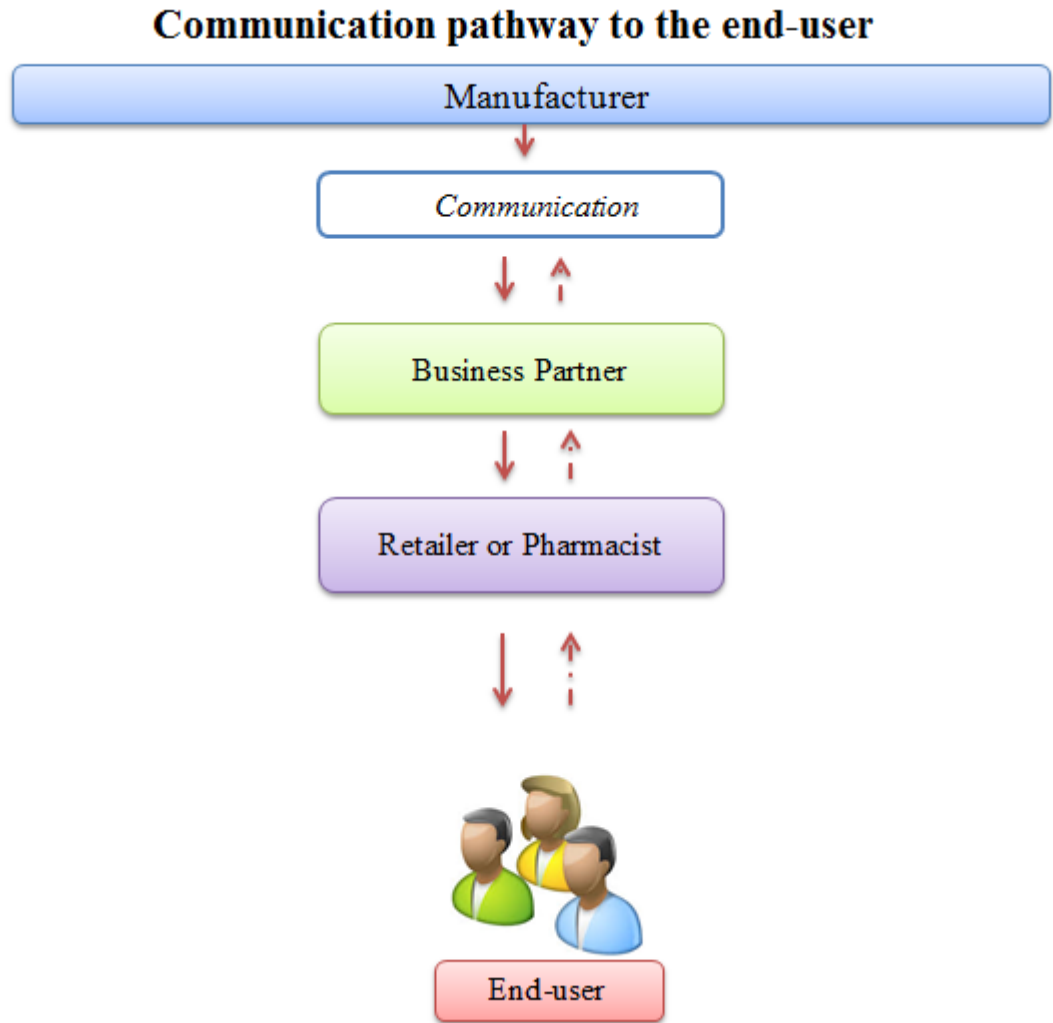


Figure 14. Communication pathway to the end-user

There was a recognition that the distance from the end-user was significant and this created challenges for both top-down and bottom-up communication delivered in a timely manner, alongside the difficulties arising from the linguistic and cultural diversity of the region that was being served.

“But because we have business partners and the chain is too long, and also the language difference, culture difference and that will make the communication flow very difficult. And feedback is also difficult because it’s the other way around.” (Marketing department)

Due to the fact that the business partners were also business-to-business organisations and did not themselves interact with end users, one interviewee expressed the view that these organisations tended to be more sensitive to competition than to information concerning end user needs. As the direct customers of the business partners were pharmacies and retailers, the salience of the final consumer for these parties was seen to attenuate despite the fact that they were closer to the end-user compared to the manufacturer.

“So business partner is doing their business, so the em...end users information em...the competitors information will go faster to them than end-users information, so if some new device happens, then they will have to react, and also have to explain to pharmacies and things like that. And they also - the competitors is one of the three Cs [customer, consumer, competitor] and it’s important to react - but they don’t, they just do too much reaction fast, they forget the consumers. (Marketing department)

In other instances, it was felt that whilst the business partners, by virtue of their position in the chain, gather valuable information from the parties that sell the devices directly to the consumer (i.e. pharmacies, retailers), this was not communicated effectively or at the level of detail that would help the manufacturer sense what is happening on the ground.

“What the business partners do get which we don’t hear so much is the feedback from the first purchasers - the pharmacists and the chains - and I think that information can be very valuable and we are not receiving that from a lot. We get very generic things back like ‘price is too high’ is generally em which generally means that the benefit has not been communicated strongly enough.” (Marketing department)

Overall, the manufacturer’s exchanges with its direct customers – the business partners – partly functioned as a vehicle for receiving some insights from or about end users. Yet, the quantity or the quality of the information coming through this channel was occasionally considered to be partial and even skewed towards certain considerations (e.g. competition) due to the structural constraints within which the distributors operated.

B. The exchanges with the medical profession: The manufacturer historically dedicated a lot of effort to build, establish and maintain collaborative links with influential healthcare

professionals – the so-called ‘key opinion leaders’ – and associated professional organisations, such as the British Hypertension Society or the European Society of Hypertension (field notes days 6, 37, 47, 54). At a practical level, this was primarily fuelled by the need to align the products with the latest standards and guidelines published by professional organisations and the willingness to assign the clinical validation of HBPMs to reputable medical organisations which were seen to be trusted by ‘local’ markets.

“We are going to use them [the professional organisation] to do some studies on the new products that we are launching because we also, we want to leverage more their testing endorsements to help in the local markets too.” (Marketing department)

Moreover, the exchanges with the medical profession helped the organisation to receive regular input, primarily in terms of the clinical needs, but also with regard to user needs as these were understood from the doctors’ interactions with their patients.

“We do work with healthcare professionals, so we speak to them about not just their needs, but the needs of the patients that they see, to try and get some insight in terms of what works and what part of the technology can either been improved upon or could be effectively invented. So for example, if someone says there is a need for a monitor that can be used with people with atrial fibrillation, we take that feedback and then incorporate it into our design process.” (Marketing department)

Occasionally, it was recognised that the doctor’s and the end-user’s primary needs and considerations may not coincide. For instance, the doctor was considered to prioritise accuracy, whilst the end-user was thought to be principally pre-occupied with convenience and ease of use.

“And doctors are only focusing on how they can get the correct measurement from end-user, that’s the only point. So even [if a] device was very expensive or it’s difficult to use, but somehow they could get some correct measurement from end-users, that’s fine.” (Marketing department)

When the foci of considerations were different between doctors and end-users, the manufacturer perceived its role as one that should ‘bridge’ the distance by trying to satisfy both stakeholders. In an interesting example around wrist monitors, which are not typically recommended by the medical profession due to concerns with accuracy but yet are highly

popular among end-users, especially in certain countries (i.e. France), a participant narrated:

“So, we will also talk to doctor, but doctor has their own opinion, then we could suggest to the doctor ‘oh the market and also the end-users would like this kind of device’, and that’s why the wrist type still exists. It’s benefit for end-users, but not benefit for doctors. But why it’s benefit for end-users, because it is convenient to use it on wrist, they don’t have to wrap their shirt and it’s easy. But why it’s not benefit for doctors, because it is inaccurate. Then what we should do, we will make the accurate wrist monitor which has a guide, the advanced positioning sensor¹⁶ or things like that. And then doctors say that the wrist type is now ‘yellow light’.” (Marketing department)

Despite the efforts to balance and account for both stakeholders’ considerations, there were instances that the doctor’s requirements and the end-user needs were seen to be incompatible to such an extent that a product differentiation approach had to be adopted. In this case, the manufacturer designed separately products for professional use and products for home use.

“...you make a device that the doctor thinks will be useful for a lay person - which in fact it’s so complicated that the lay person probably doesn’t ever use it or doesn’t use it correctly. It’s a challenge, em one that at the moment we have not managed to successfully solve. We still very much have products for doctors and products for lay people.” (Marketing department)

Finally, the collaboration and exchanges with healthcare professionals served another important purpose which was the minimisation of risk of potential doctor resistance towards technological innovation. An interesting example that took place in Japan was narrated by one participant; the organisation had created a new HBPM function that allowed the detection of irregular heartbeat which can be an indication of arrhythmias, though the condition requires medical diagnosis. Although the manufacturer had managed to demonstrate to the Department of Health that the new function is legitimate and useful and had significantly invested in educating the end-users, launching eventually the new function to the market, the reaction from the medical world in the country forced the

¹⁶ Question guide: this is a technological function that directs the user to position the monitor correctly in order to get accurate readings.

company to recall the innovation. The innovation was perceived as illegitimate by doctors as they felt that the new function transgressed the boundaries of their professional territory. This example vividly illustrates the potential of technological innovation to redefine domains of expertise and responsibilities in such ways that are unacceptable by the involved parties.

Overall, it can be argued that apart from the value of the clinical input and of some indirect insights about the end-user as a patient, the medical professionals were primarily seen as a *mediator* between the end-user and the manufacturer. The exchanges with the medical profession served to infuse more trust to the products (e.g. through their clinical validation by trustworthy medical organisations and adherence to clinical guidelines) and to increase their salience among consumers in order to influence positively their commercialisation, and to minimise the risk of doctor resistance towards technological innovation which could severely affect the market of HBPMs.

C. Sensing the user through personal experience: In the absence of direct contact with the end-user – at least for the majority of the departments in the organisation – people tried to sense the consumer by relying on their personal experience of being consumers themselves and/or of knowing others in their social circles who might be users of the devices. Whilst using the personal experience as a proxy for visualising the end-user might not provide a detailed picture of the end-user needs and motivations, nevertheless it constituted a heuristic that enabled access to an imagined end-user.

“But in terms of end-users, I think most of the departments here don’t interact with customers directly, so they understand end-users in as much as they are themselves consumers and they probably have family members or friends who use these products, because of course these are products that are quite commonly used. But I think they are not as close to the end-consumers so it’s harder for them to visualise these people, and how they use it, and why.” (Marketing department)

Another participant from the Quality Assurance & Regulatory Affairs department, whilst describing his duty to check the packaging and instruction manual from a regulatory point of view, indicated how he also tried to put himself in the shoes of the end-user who reads the manual and comes across with the packaging and the sort of appreciation they would have.

“But of course if I - I use a special checklist for that [for checking the instruction manual] - if I use the checklist of course I will always have a brief look at the instruction manual and I see ‘come on what is it, nobody can understand this’ or I would read this, I would think about something else, or how can you translate this. So in other words, sometimes I also try to position myself in the role of an end-user, but I think that is mainly the task of marketing.” (QA/RA department)

Section II: Challenges to accessing and understanding the end-users and to serving their needs

The biggest challenge to understand and accommodate end-user needs and requirements, as this was articulated in interviewees’ accounts, stemmed from the hugely diverse nature of the region that was being served by ComX Europe (i.e. countries in Europe, Middle East, Africa, as well as Russia). The variety of cultures and languages but also the differences in broader societal, economic and legislative structures across countries and continents placed considerable demands on the organisation’s strategies to developing and trading medical devices for these markets. At one level this involved practical issues such as the linguistic heterogeneity of European markets which slowed the manufacturer from launching new products quickly since the labelling (i.e. instruction manual and packaging) had to be translated in a series of languages.

“P: I think just the nature of Europe, as a market.

I: Because it’s very diverse?

P: So diverse, yeah. And how do you make a product that makes somebody, the typical consumer in France happy, and the typical consumer in Saudi Arabia happy. When the US get a product, they launch it into effectively one homogenous market. But our market is not homogenous, and it’s a real challenge because we have the language barrier, everything we do has to be done in multiple languages. It takes a lot longer; to create an instruction manual takes 3 months, whereas normally it would take one month because we have to do it in 12 languages. Em, so, yeah the language is a big barrier for us.”

(Marketing department)

At a proactive level of researching consumer considerations, one strategy that ComX Europe adopted in order to reach the end user – for example within Europe – given the

constraints posed by the available resources, was to select a few countries that would ‘represent’ the markets of the remaining European countries (field notes day 1). From a more reactive standpoint, if specific problems arose in certain countries, the company would then examine them in more detail within their context. Though this approach was not considered ideal, it constituted a pragmatic response that balanced competing demands (limited resources; diversity of markets; necessity to understand end-users).

“So we have a lot of ways to approach to end-users, but em, and for this, Healthcare Europe, we have so many countries, so many languages, so it’s difficult, so we have to make a certain choice to which country will be representative to user... that’s what we can do. And if there are some complaints or feedback from certain countries, then we will take it seriously and consider. So to be proactive in this market it’s very difficult. (Marketing department)

To account for the diversity of user needs and preferences, some diversification of medical devices could take place or was already embedded in the existing product portfolio within a product category (e.g. HBPMs).

“And for instance recent research, that recent research shows, you know, consumer ‘yeah it does look too much like a product a doctor would use’, so there is a group who does not like that, there is a group who does like it. There is a group who really wants to have a very simple easy to use wrist monitor, because in their country that is recommended, so we need to have it. While em in other countries wrist type products would be more casual products which are used by people who regularly measure but are not diagnosed. So you have to constantly adapt and take all those considerations into account when you build a product portfolio.”(Marketing department)

Yet, to be able to pursue further diversification of a medical device – based on user requirements – and to produce new design iterations, this had to be accompanied by a strong business case that would defend and justify the new product against appreciable market sizes that would render the product commercially viable and would create significant revenues.

“Because although we have sold over 135,000,000 units of blood pressure monitors, if you compare that to say how many bottles of shampoo are sold by L’Oréal, or how many tins of Heinz baked beans, when you look at those kind of scales you can actually

customise for markets. But for us there is not really that many individual markets, except for Russia, that are big enough to justify their own product.” (Marketing)

Although a more conservative stance was arguably in place regarding the readiness to diversify medical devices and to customise them to specific markets – whereby the differentiation of products was more likely to happen at a regional level (i.e. America vs EMEA vs Asia) – an effort to customise health technologies and to align them more closely to user considerations was in place concerning labelling. Indeed, at the time of the ethnography, the company was setting up a local assembly (field notes day 7) that would enable the manufacturer to adjust and customise labelling to better communicate with consumers in different countries.

“Although we are trying to make it as tailored as possible for a country, that’s why we are setting up the local assembly in [European country]. So to have, for instance, packaging with only four languages on the packaging, so we can communicate better, and post it locally in [European country], so have three skews for groups of countries instead of one box with 16 languages. So those are things that we are doing, but then again in all those countries it will be the same product, only different packing.” (Marketing)

Arguably, a tension was articulated regarding the extent to which medical products *can* and *should* be diversified based on the needs of users of diverse markets. This tension largely derived from structural features and more specifically from organisational configurations around the degree of centralisation/decentralisation of domains of activity, alongside resource constraints (field notes day 8). Thus, whilst the marketing activities (i.e. ComX Europe) had been decentralised on a regional basis to better serve local markets, the R&D activities were held centrally (i.e. in ComX Japan).

“On the other hand, they have an R&D team there [in global headquarters] and America, and Latin America, and South East Asia, and Australia, we are all asking them to do things specifically for our markets, so they get ten requests and they can only do three. So then they need to balance which are the best ones... (Marketing department)

In parallel, although the differentiation of products on the basis of ‘local’ user and market needs was pursued and was considered positively up to a certain extent, excessive

product diversification was seen to compete with the organisations’ effort to standardise its business approach and practices and to hinder the establishment of consistency and coherence in terms of the product portfolio it offered. Moreover, an extensively diversified product portfolio could also have implications on brand recognition and on the organisation’s efforts to communicate a coherent and succinct identity to the external world.

6.5 Discussion

The present ethnographic case study sought to empirically investigate ‘from inside’ how a medium-to-large medical device manufacturer attempted in practice to understand and account for user needs requirements during the development of a new iteration of medical device, namely HBPMs, and what sort of challenges encountered along the way. In contrast to previous research (Martin & Barnett, 2012; Martin et al., 2012; Money et al., 2011) which mainly focused on SMEs using cross-sectional qualitative designs, the results of this study show that there was a clear appreciation of the value to consider and accommodate user needs as this was believed to increase the chances for a successful product through the ‘match’ of user preferences with technological developments. To that end, the manufacturer largely adopted user centred design practices (Martin et al., 2008; Shah et al. 2009) alongside, or within the context of, market research activities privileging in this way an approach informed by user needs and preferences. Though the MDD project was primarily initiated out of business needs (i.e. to supply the device to the market through a new channel), which is reflective of the primary operational focus of ComX Europe (i.e. marketing activities), development of medical device design iterations or of innovative technological functions also emanated from user needs, when for example existing device designs did not accord with the needs of users in certain countries.

Due to the fact that previous academic research with medical device manufacturers has documented limited user needs research activities during the MDD process, the literature on user centred design activities has arguably acquired a normative stance providing guides and principles on how user research *should* be conducted (Martin et al., 2008; Martin et al., 2006; Shah et al., 2009). Though this literature is clearly useful, especially for those industrialists who embark on user needs research and start structuring related practices, it

might be less relevant to the research needs of the manufacturers who routinely engage with user-centred design (UCD) activities. On the basis of the findings of the present research, it appears that user needs research is sometimes conducted in order to elucidate problems arising with existing devices with a view to develop new designs that will solve these issues. On these occasions, the challenge for manufacturers is to select those research approaches, methods and tools that will best examine and uncover the problem at hand. In other words, user needs research is often rooted in very pragmatic problems and highly context-specific circumstances which this analysis suggests are unlikely to be addressed or elucidated by a rather abstract user needs research framework, such as the one developed in the SMEs focused work.

Moreover, for the manufacturers who routinely conduct user needs research, the challenge is perhaps how to move from the accumulation of piecemeal research evidence originating from individual projects to the development of a *knowledge base* which synthesises the available evidence at a higher level. This lack of evidential synthesis – observed in the present case study – could assist the industry to streamline related investments on poorly explored research areas and on higher order research problems illuminated by systematic reviews (e.g. meta-analyses, systematic reviews; narrative reviews) of existing evidence. In this case, a user needs research framework would need to expand to include multiple cycles of user needs activities, that can originate from various organisational needs (e.g. to examine a particular device problem arising in the market; to develop a new device as a response to a business need *vs* technological development *vs* unmet user need; to conduct post-market research), as well as the periodical synthesis of available evidence. Such an expanded framework would also need to account for the interdependencies of research cycles, in the sense that previous research activities – both in term of evidence *per se* and organisational experience – might inform the conduct of future activities, while newly acquired evidence and research experience might reconstruct past knowledge and practices retrospectively inducing in this way alterations and improvements for the future. In sum, whilst the challenge for SMEs seems to be to gather the user evidence in the first place, for larger organisations the challenge is perhaps to leverage the user evidence collected, in ways that would advance the knowledge base more effectively and efficiently.

A closer look at the ethnographic evidence reveals that there was a differentiation of the *directness* and *formalisation* of the routes the organisation used to reach the end-user (Figure 15 depicts the various pathways to the end user based on their degree of directness and formalisation as organisational practices). Perhaps the most direct access to, and reflection of, the end user originated from the monitoring of the online product reviews. Though there was not any strong evidence that this pathway was formalised or leveraged in any systematic way, it was seen to provide valuable information in a timely and inexpensive manner, albeit skewed towards certain populations (e.g. those users who have access to, and use the Internet, and make online purchases). Indeed, the value of online consumer comments around health technologies has started to be recognised in academic literature (Money, Barnett & Kuljis, 2011). Apart from the quick and inexpensive character of the data sourced through this medium, the ability to gather user insights, especially with regards to medical device innovation, and to capture polarised and strong views has been demonstrated acknowledging the research limitations posed by the Internet anonymity and the difficulty to link expressed views to socio-demographic or other participant characteristics (Money et al., 2011). An additional direct access to actual users was attempted through the consumer questionnaires placed within the products. Though this route was still in a pilot phase and there were challenges in terms of the response rate, it provided a straight means of entry to consumers with potential for formal integration in organisational routines.

In terms of more *formalised* activities, albeit less direct than the two mentioned above since the end user was mediated through the *test users*, the user and market research played a key role. Clearly, the organisation from very early on in the development process invested significant resources to examine and understand the market and to test assumptions. Interestingly, questions of *design desirability* were sometimes posed proactively to explore the in-principle interest of users in new designs. Although, this sort of question is arguably much more critical for medical device innovation – and less frequently posed compared to questions of effectiveness and efficiency (Lehoux, 2008) – the fact that it occasionally appeared as one of the manufacturer’s ‘research problems’ demonstrates a heightened sensitivity to user considerations along with efforts to minimise risk. User research activities, either being closely tied to specific product developments (e.g. validation studies;

concept acceptance studies; contextual inquiry) or more loosely connected (e.g. periodical surveying of consumers), informed the MDD process, influenced decision making and shaped the employees’ images and conceptions of the user.

With regards to even less direct routes to accessing the end user, insights were also gathered via the manufacturer’s interactions and exchanges with a network of key actors, namely the medical professionals and the distributors who were the company’s customers. The user-related information coming from these actors could either be shared in a formalised way, as the case was with the aggregate complaint reports, or in a more loosely manner within the context, for example, of interactions with different foci; for instance discussions with medical organisations around the process of clinical validation. The user insights fed back to the manufacturer by these actors were arguably interpreted and evaluated against the filters of the latter stakes, interests, and position to the end-user. At the same time, one cannot ignore the stakes implicated in the manufacturer’s working relationship with these actors as a broader context within which the user insights were interpreted and enacted.

Finally, the last representation of the end user was realised either through projecting the self into the position of the user and imagining their needs, preferences and desires – the well-known I-methodology (Akrich, 1992) – or through invoking personal experiences of users from the family and friends’ environment. These strategies were spontaneously mentioned by some employees who, due to their position, were particularly distant from the end-user. Indeed, the implicit imagined user has been well documented in scholarship around the production of new products (Akrich, 1995) whilst its role has also been examined in the work of experts (Maranta, Guggenheim, Gisler & Pohl, 2003). The expectations created on the basis of user or public imaginaries influence the course of activities and actual encounters (Walker, Cass, Burningham, & Barnett, 2010).

Despite the considerable distance of the organisation from the end users due to structural characteristics (i.e. B2B model), the abstract notion of the end-user is still brought into being and variously concretised, sometimes quite forcefully (e.g. research evidence), through various channels, processes and shapes: a *reflected end user* is embodied via online product reviews and returned questionnaires from actual consumers; a *represented end user* appears through the research evidence that test users provide; a *mediated end user* comes

into being via the accounts and experiences of key actors in the fields (e.g. medical professionals; distributors); and an *imagined end user* is constituted through projections as well as invocation of personal experiences with real users. The plethora of end user ‘embodiments’ is arguably noteworthy and the questions that arise are: to what extent,

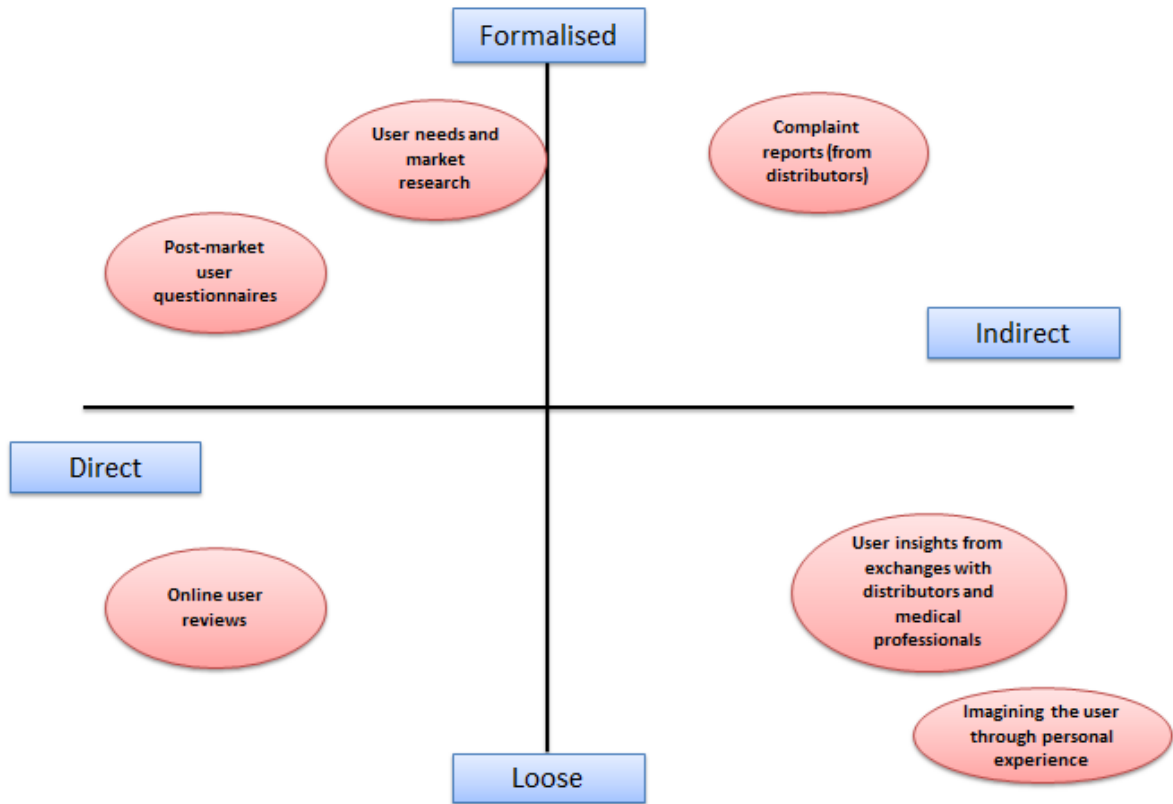


Figure 15. Directness and formalisation of the routes to the end user

when, and how these different end user representations might intersect to provide guidance, direct action and inform decision making; which ones might be particularly dominant or marginalised and under what circumstances; and finally which user representations, to what extent, and how are eventually projected onto technological objects.

6.5.1. Strengths and limitations of the present study and recommendations for future research

An important strength of the present study is that it sheds light on an area that is relatively underexplored, namely the practices and activities adopted by the medical device industry to understand its end user. Indeed, when it comes to middle and large organisational contexts, there is a paucity of relevant evidence which the present study sought to gather. It did so by employing an ethnographic research approach which allowed an in-depth examination of the day-to-day activities as well as of the challenges encountered along the way. A detailed, rich and contextualised description of the phenomenon of interest, observed ‘from inside’, is thus provided contributing an initial development in our understanding of the field.

The ethnographic work revealed the various modes and shapes that the end user takes in the process of embodiment and concretisation from an abstract and generic notion to the man on the street who is to purchase and be using the health technology. Within an organisational context which by virtue of structural features is located at considerable distance from the end user, the results demonstrated that a series of end user embodiments and representations were constructed, circulated and were at play: the *reflected*, *represented*, *mediated*, and *imagined* end user. At the same time, some of the challenges the industry faces were highlighted resulting largely from broader structural and functional organisational configurations under which the company operated. These challenges might be also applicable in other medical device manufacturers who work under similar structures (e.g. decentralised marketing but centralised R&D).

In terms of limitations, this study was able to follow up a limited period of the product development process that focused on the pre-concept research and related activities of the project and it was not possible¹⁷ to observe the projection of user specifications onto the medical device design in the light of other design considerations (e.g. technical capabilities, production limitations). Moreover, the particularity and the multiplicity of ‘cases’ that were followed up in this ethnographic work constrain both the completeness and the transferability of the results. Specifically, the ethnographic insights from the device development project, *as a case study of a MDD process*, cannot be readily transferred to

¹⁷ Pragmatic reasons precluded such an opportunity

other MDD processes *intra-organisationally* due to the novelty of the project and its importance to economic targets. Indeed, it is unclear whether the user research activities tied to this project would continue and be routinized for future MDD projects. Moreover, the economic and business significance of the project as a whole might have predisposed the organisation to invest unusually heavily in user research activities rendering the project an *extreme* or *unique* case (Yin, 2011). Nevertheless, the case does not lose its intrinsic value (Stake, 2005) to elucidate the intricacies involved in the understanding of the end user from an industry perspective, even if it constitutes a unique snapshot of the organisation’s life.

A second level of case-ness comes from the organisational context itself. Again, the idiosyncrasies of the organisation – e.g. historical, structural, operational – call for attention as to what findings might be transferable to other contexts. Finally, a last level of case-ness relates to the nature of the medical device involved in this research. Specifically, the health technology that was studied was a design iteration of a well-established medical device – as opposed to medical device innovation that has often been the focus of academic research – that was commercially central for the organisation and closely tied to its history, and finally a health technology for home use targeting directly end-users. These features imply that the company probably had in place established structures and routines that configured the MDD process in certain ways due to the considerable experience with, and knowledge of, the technology. Moreover, the fact that HBPMs fall within the category of over-the-counter technologies makes the lay user more readily salient.

Future research would benefit from an examination of how user specifications are projected onto health technologies and how and to what extent this might accord or compete with other considerations. Moreover, comparative research within different organisational contexts and with different types of medical devices (lay use *vs* professional use; innovation *vs* iteration; diagnostic *vs* treatment devices) would enrich our understanding and would help to detect patterns and variations as a function of different parameters implicated in a MDD process.

This chapter would not be complete without reflections regarding the influence of contractual agreements around confidentiality in shaping the reporting of research findings. As part of the legal agreement I signed with the organisation, any scientific report (i.e. PhD

chapter; journal articles) would have to be checked and approved first by the organisation to ensure that confidential information is not released unintentionally. As a result of this process, the present chapter has slightly been altered from the initial draft I sent to the company for approval. Specifically, pictorial illustrations of the structure of the organisation and of the research activities taking place during a MDD process, as well as specific examples of personas created during the user-centred design activities were removed. Moreover, due to the fact that the product development process which I followed was still in progress at the time of chapter approval and commercially sensitive, some details were removed and the project was described in more generic terms. This was arguably challenging from a research perspective since the pictorial illustrations I had created aimed to communicate succinctly to the reader important information and to elucidate the text by providing examples and synoptic representations. Nevertheless, the changes made in this chapter reveal the sensitivities of the industrial sector which are located mainly around the competition and the capability of competitors to identify the company and retrieve sensitive information around activities and practices.

CHAPTER 7 – DISCUSSION AND CONCLUSIONS

7.1 Synopsis of empirical contributions

The ubiquity of technological artefacts in contemporary healthcare systems is undeniable. Indeed, the plethora of health technologies, and the constant production of new ones have called attention to the necessity of valuation (Lehoux et al., 2008; Office of Technology Assessment, 1976). Articulating and adjudging the value of health technologies is an important task as it assists societies with deciding which technologies to adopt and which not, especially within a context of limited resources and changing healthcare needs (Johri & Lehoux, 2003; Young & McClean, 2008). The importance of appraising health technologies from a User standpoint has been gradually recognised, constituting one of the dimensions of valuation (Facey et al., 2010; Facey & Hansen, 2011; Grocott et al., 2007; Shah et al., 2009). Accounting adequately for user needs is not simply desirable but it is considered essential for producing technologies that will be safe, satisfying, and will aid sustainable use. As a result, usability research has flourished in the field of medical technologies (Martin et al., 2006; Martin et al., 2008) and has been simultaneously reinforced by relevant regulatory requirements (Food and Drug Administration Human Factors Guidance, 2011; Harmonised European Standards EN 62366:2008 & EN 60601-1-6: 2010).

Despite the clear benefits of usability research for designing technologies that are more closely tailored to the needs of users, the focus is often narrowly placed on analysing and preventing use errors and on supporting, by design, intended and proper use. Minimising use-related risks is therefore a primary objective of usability research. As a consequence, usability research tends to concentrate on and investigate the user-technology interaction. Research methods such as *contextual inquiry* try to account for immediate contextual factors (e.g. the location in which the technology is used; what other technologies might be used in conjunction with) that might influence device use (Martin & Crowe, 2010). The broader life circumstances and routines within which medical technologies are come to be embedded (or not) in day-to-day routines, and the meanings with which they are imbued have been less satisfactorily attended to. Building on previous research endeavours (e.g.

Lehoux et al., 2004; Money et al., 2013; Peel et al., 2007; Thomson et al., 2013; Timmons et al., 2008) that attempt to broaden the scope of ‘user needs’ research to incorporate psychosocial dimensions, the present thesis first aimed to explore symbolic as well as practice-related elements in the user-technology relationship that extend beyond the device use in itself. To that end, two exploratory, qualitative studies with users of home medical technology were conducted. Using the example of home BP monitoring, the first study attempted to examine how home blood pressure monitors (HBPMs) are integrated into people’s daily life and how the acquisition and use of technology shapes images of self and communication with the external world. The second investigation sought to examine the elements that are conducive to building trust in HBPMs.

Employing the analytical lens of domestication theory (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992), the results of the interview study (presented in Chapter 4) suggest that the acquisition of a home use medical technology satisfied people’s strong appetite to understand better their health condition with a view to self-manage it more effectively and proactively at their own convenience. Technology thus was a means through which knowledge of and meaning around the state of illness could be constructed. The benefits of self-management, such as greater control, empowerment, convenience, and autonomy, were invoked in participants’ accounts, largely reproducing the dominant discourse around the value of self-care. Importantly, whilst the self-care practice of home BP monitoring was mostly viewed to complement and aid the role of healthcare professionals, in a few instances self-care came to replace or to ‘audit’ professional care within a context of lost trust and scepticism towards the medical profession. Self-care can thus operate either harmoniously or competitively alongside professional care. Though the perceived credibility and meaning of home readings were not straightforward or unproblematic and required quite a lot of ‘health work’ on the part of users (Vasileiou et al., 2013), the technology was often imbued with ‘objectivity’ as it afforded the capacity to produce impartial evidence.

The display of the technology within the home environment primarily served instrumental purposes, such as the good maintenance of the device, or the facilitation of reliable measurement, and it was also closely linked to the temporal integration of monitoring into daily routines. Unsurprisingly, the frequency and longevity of device use

depended on the health condition and its progress, but there was also some evidence that the practice of monitoring failed to be sustained, despite the existence of clinical need, due to distrust towards the dependability of technology or doubts around the practical ability to represent accurately the physiological phenomenon of BP within the routines of real life. Apart from using the technology in a relatively structured way to monitor BP, people also engaged with the practice of home monitoring for a particular diagnostic purpose, that of examining whether certain somatic sensations were associated with BP variations. The lay association of BP with somatic sensations is interesting given that high blood pressure is not typically linked to symptoms (Marshall, Wolfe, & McKevitt, 2012). This diagnostic use of the technology provoked an unstructured pattern of use alongside the routine monitoring schedule. Interestingly, a further device use was articulated when people took measurements to check the dependability of the technology and the accuracy of readings, especially during the early phases of owning and interacting with the technology. This suggests that HBPMs were not necessarily accepted at face value; rather the ability to develop trust in the technology emerged as an important prerequisite for sustainable use.

Although the user-device interaction generated its own challenges around the interpretation of readings and the actions this required (Vasileiou et al. 2013), a further set of ‘identity management’ negotiations were required around communicating the ownership of the device and the practice of home monitoring outside the domestic environment. The positive qualities of claiming an identity of a person who takes control and responsibility over his/her health through self-management could be threatened if this was seen by others as an excessive preoccupation with health, which in itself was considered ‘unhealthy’. Users sometimes expressed concerns that they could be ascribed with undesirable identities, such as ‘hypochondriac’ or ‘paranoid’, if they drew much attention to the practice of self-monitoring. The risk of making the identity of an ‘ill person’ overly salient was also a consideration, especially within the framework of enjoying social exchanges. Although self-monitoring and the evidence it could produce for users was seen as a means for strengthening the patient-doctor relationship, occasionally people felt that they had to negotiate the legitimacy of this practice with their doctor. Again the threat to be seen as ‘over-preoccupied’, ‘obsessed’, ‘unskilful user’ or ‘incapable to interpret the readings intelligently’ had to be worked out in the communication with healthcare professionals.

Though it was not the main focus of the interview study (Chapter 4), people's narratives occasionally connoted the importance of trust in medical technology for the continuation of the practice of home monitoring. The qualitative analysis of the online, naturally-occurring accounts (Chapter 5) directly shed light on this aspect by documenting the elements that appear conducive to building trust in HBPMs. The results suggest that building trust in medical technology is not merely a technical matter but an inherently socio-technical process that implicates a series of actors. Building trust in HBPMs is contingent on other forms of trustworthy relationships with other humans, one's self, socially valued institutions, and other technologies. Trusting is also both a symbolic (i.e. have faith in doctor's recommendation to buy a particular monitor) and a practical accomplishment (i.e. actual engagement with and use of the device) (Button, 2006) that requires the gradual establishment of a 'biographical familiarity' with the technology (Jirotko et al., 2005). Trust also appears to be more or less conditional rather than a permanent accomplishment since unexpected real-life events (e.g. technology failure) have the potential to rupture the foundations of trust.

Whilst the investigation of user needs during the process of *technology consumption* is clearly important, it is equally crucial to understand how the issue of 'user needs' is conceived and addressed during the process of *technology production*, since these understandings will eventually be projected onto the technology (Akrich, 1992). This was precisely the domain that the ethnographic case study of this thesis (presented in Chapter 6) sought to explore by documenting the user-related activities that a leading manufacturer in the field of home BP monitoring performed during the development of a new HBPM.

Unlike previous research which focuses on SMEs and has indicated industry's limited engagement with user needs research (Martin & Barnett, 2012; Martin et al., 2012; Money et al., 2011), the findings from this study, conducted within a medium-to-large manufacturer, showed not only the appreciation for a user needs-informed approach to medical device development (MDD) but also the extensive investment on user needs research throughout the MDD process. But beyond the conduct of user needs research, the manufacturer used additional routes, more or less formalised, to reach and understand its user, such as product reviews on the Internet, aggregate reports of user complaints, or information about the user coming from other actors in the field (e.g. product distributors;

doctors). The deployment of various pathways to the user, especially for an organisation which by virtue of its structural features (i.e. business-to-business model) is distant from the ‘man on the street’, aimed to concretise the abstract notion of user. Depending on how direct and formalised the pathways to the user were an analytical categorisation of ‘user embodiments’ was developed revealing a *reflected*, *represented*, *mediated*, and an *imagined* user. The user thus comes into being in various forms and shapes and in one form or another was a constant presence in the MDD process. This led to a consideration of how these different user representations are projected onto the technology and how they intersect with other product development specifications (e.g. production, economic and technological constraints).

7.2 Theoretical contributions

The research presented in this thesis makes three main theoretical contributions. First, it shows the value of applying domestication theory (Silverstone & Haddon, 1996; Silverstone & Hirsch, 1992) in the field of home medical technologies. This theoretical framework was useful for understanding how technological artefacts find (or not) their place within the domestic space and everyday routines making the theory particularly relevant to medical technologies designed to be used at home. Moreover, the four “non-discrete elements or phases” of domestication (Silverstone, Hirsch & Morley, 1992, p. 20) – appropriation, objectification, incorporation and conversion – provide a useful conceptual map to follow up the process of ‘taming’ and expands the scope of user-device relationship to include not only the device use *per se* – a focus that often characterises user needs studies from an ergonomic perspective – but also the construction of meanings around the ownership and use of the technology and the communication of relevant identities outside the home. In other words, this theory pays particular attention to the symbolic processing and content along with practice-related aspects (e.g. temporal integration of device use; display within the home environment), making it suitable for exploring psycho-social dimensions in technology use. Domestication theory has not been used in the field of medical devices thus far (for a recent exception that uses the technology of electric toothbrushes see Carter, Green, & Thorogood, 2013) and the study presented in Chapter 4

is the first to use this framework to explore psycho-social user needs considerations in this domain.

The second theoretical contribution of this research is that it uncovers the elements that appear to be conducive to the development of trust in home medical equipment. Though the issue of trust has been previously studied in relation to professional medical devices (e.g. Montague et al., 2010) and devices located in public spaces (Timmons et al., 2008), the research presented in chapter 5 is the first consideration of trust with regard to home medical devices. Interestingly, despite the distancing of this group of technologies from the formal healthcare system – in the sense that people can buy them over-the-counter out of their own initiative – and the blurring of boundaries between ‘health goods’ and ‘consumer goods’ that characterises domestic health technologies, the strong reliance on the medical profession as a springboard for developing trust in HBPMs reveals the perceived medical character that this technology still retains from a lay user perspective.

Finally, the ethnographic case study (presented in Chapter 6) developed an analytical contribution with regard to the various ‘embodiments’ or ‘concretisations’ of the user; a *reflected, represented, mediated, and imagined* user came into being. These embodiments are based on the directness of routes used to access the users and the degree of formalisation of the activities through which the medical device industry tries to capture them. This research also uncovered an important challenge encountered by medical device manufacturers who routinely engage with user needs research. This relates to the need to synthesise the piecemeal evidential base from various user needs research projects in order to develop a knowledge base around the user. On the basis of this finding, an expansion of existing user needs research frameworks was proposed to include multiple cycles of user needs activities as well as periodical syntheses of accumulated evidence (National Patient Safety Agency, 2010).

7.3 Implications of the present findings

The results of this thesis offer some important insights that can inform the design and conduct of user needs research around the development of HBPMs. First, the findings suggest that it is not sufficient to study the user alone as an individual, abstracted from the network of relationships with other people, most importantly the relationship with

healthcare professionals. As it was demonstrated, the doctor plays an important role in helping the user to build trust in HBPMs, to use the technology and interpret the readings appropriately and to sustain the motivation behind use. Therefore, although the practice of home BP monitoring is most of the times a self-care activity which is physically distant from the healthcare professional, it appears that it is so much ingrained within this relationship both at an imaginative (e.g. people's thoughts of how the doctor will receive this practice) and a real level (e.g. when people seek their doctor's advice on which monitor to buy or how to use it) that this element should be integrated into user needs research. In order to corroborate the importance of this aspect, user needs research could explore for example the effect of patient-doctor relationship in conjunction with different design solutions on acceptance as well as sustainable and proper technology use, assuming that other things were remaining constant (e.g. user illness status). Similarly, user needs research should also take into account how the user's relationships with 'significant others' might influence device use and vice versa, especially when these other people share the domestic space with the user or indeed assist the user with monitoring (e.g. informal carers).

This research also suggests that the device use and the meanings constructed around it cannot fully understood without accounting for illness representations. Indeed as the evidence showed people are motivated to acquire the device with a view to understand better their illness. Therefore, user needs research would benefit if it explored in greater depth how people conceive and experience their illness or illnesses in cases of co-morbidities. For example, to the extent that the device might symbolize the presence of illness for some people and the latter have difficulty in coming to terms with it, the potential technology rejection in this case would not relate to insufficiencies of the artefact itself but to what it signifies at an identity level.

The results from the ethnographic case study showed that as part of the product development process, the manufacturer used contextual inquiry in an effort understand how the device use is located within its immediate context. Despite the value of this approach in capturing important contextual information and the obvious advantage of efficiency it offers compared to longer term ethnographic approaches, it limits the ability to investigate the user's broader life context of routines and practices within which the device finds its

place (or not) over a longer period of time. Indeed, the findings from the user studies suggest that the relationship with technology evolves and changes not only as a result of the persons' illness status but also as a result of changes in other parameters (e.g. psychological states; other routines). For example, there were participants who refrained from using the HBPM for certain periods of time to protect themselves from feeling overwhelmed, in this way constructing a periodical use pattern. Although it is recognized that a traditional ethnographic approach to the study of users would not be appropriate for product development within an industrial context, a comparative case study following a few carefully sampled cases over time could produce important insights about the user's broader life context and its impact on device use.

To what extent are the results of the user studies in this thesis transferable to other home medical devices? The evidence suggests that the broader level themes that were identified – such as the importance of the exchanges with the healthcare professional, the implication of identity considerations with device use, the interpretative work the user does in relation to the output of the device (Vasileiou et al., 2013), or the elements that help to build trust into the technology – are pertinent to other home monitoring technologies. Examples here might include blood glucose meters used by people with diabetes or coagulometers used by patients who are under oral anticoagulation therapy. Previous research has documented the challenges people have in interpreting the results of coagulometers and in making sense of the fluctuations in their International Normalized Ratio (INR) levels (Shah & Robinson, 2011) whilst longitudinal research (Peel et al., 2007) with people suffering from diabetes has indicated the significance of the quality of the patient-doctor exchanges for a continuing engagement with self-monitoring. This alignment of such insights with the results of this research increases the confidence to claim the transferability and relevance of the present evidence to other home medical devices.

7.4 Limitations of the present research

One limitation of the present research is that the examination of the user perspective is based exclusively on people's narratives and is not accompanied by observational data of behaviours and practices which could act a useful cue for further, and potentially alternative, elaboration on the issues of interest. Despite the lack of observational data,

there was an attempt to gather different sorts of narratives that would act in a complementary fashion with a view to enrich their overall informational value. Therefore, accounts both produced within the framework of research interviews and occurring naturally within the context of online communities were gathered and analysed. Fuelled by a consideration that the interview data are unavoidably bound by the agenda that the researcher poses (Potter & Hepburn, 2005), the analysis of the online narratives aimed to compensate for this potentially restrictive effect. Moreover, online forums are a setting that predisposes people to share experiences that are more oriented to the ‘here and now’ whilst interviews typically have a more retrospective orientation, and thus the ‘pressure’ for constructing a ‘coherent’ narrative self is perhaps stronger (Seale et al., 2010).

The ability to generalise from qualitative research has provoked long-standing discussions within the community of qualitative researchers (Lewis & Ritchie, 2003), whilst misunderstandings are not uncommon among quantitative researchers who evaluate qualitative work. Due to the different nature of qualitative research, scholars have proposed the term of *transferability* as an alternative to *generalisation* (Lincoln & Guba, 1985; Henwood & Pidgeon, 1992). Perhaps the problem of transferability becomes even more salient when it comes to case study research. With regards to the ethnographic work presented in this thesis, there is a particular challenge with any attempt to transfer the insights produced to different contexts due to the multiple levels of *case-ness* that characterise this study. The idiosyncrasy of the organisation itself, the distinctiveness of the product development process that was followed up, and the particularities of the medical technology that was developed (HBPMs) render uncertain as and to what extent the analytical contributions might be relevant to other organisations, MDD processes, and medical technologies. Though the intrinsic value of the case cannot be ignored in advancing our understanding (Stake, 2005) the validation of these findings in different contexts would be required if the needs of the medical device industry were to be addressed reliably.

7.5 Directions for future research

The increasing recognition of Users as an important actor in shaping the use and meanings of health technologies and the expansion of the content of ‘user needs’ to include psycho-social dimensions are arguably indisputable if artefacts more closely tailored to user

needs and preferences are to be designed and produced. Nevertheless, an exclusive focus on *use* and *users* might not necessarily reveal the whole picture. The importance of *non-use* in making salient all those potentialities for creating better or even alternative health technologies has been highlighted in literature (Wyatt, 2003).

Wyatt (2003) in her study of the Internet non-use identified four categories of non-users: the *resisters* who never used the technology out of choice; the *rejecters* who stopped using the technology; the *excluded* who were not able to use the technology; and the *expelled* who stopped using the technology involuntarily. If this analytical categorisation of non-users was transferred to the field of medical technologies, it could potentially provide a fruitful conceptual map to identify and explore less ‘visible’ actors, whose perspectives could nevertheless challenge dominant assumptions around the value of technology and perhaps raise interesting policy questions.

The *resisters* and *rejecters* are two interesting categories of non-users since they signify *voluntary* non-use. When it comes to medical technology, and assuming that the resisters and rejecters have a clinical imperative for using the technology (e.g. people who suffer from hypertension in the case of HBPMs) future research could usefully explore their perspective on non-adoption or rejection after a period of use. Understanding the reasoning around resistance to or rejection of the adoption of health technologies could potentially lead to design alterations or the creation of completely new technological solutions. But resistance to technology could also signal people’s preference for remaining within traditional structures of care delivery (e.g. people who do not want to self-monitor and prefer to visit their doctor for checking their BP). In an era when healthcare provision is shifting closer to home and technologically-mediated self-care activities increasingly diffuse and seem to acquire a normative status, such research findings would raise important policy questions about what services should be designed and delivered within formal healthcare systems and in what forms in order to cover a range of different population needs.

The *excluded* and *expelled* are two groups of non-users who represent *involuntary* non-use. Given the increasing commodification of several means through which self-care activities can be performed, such as medical equipment that targets directly the consumer and can be bought over-the-counter, the question which could be posed is to what extent

divides might be created between people whose socio-economic status allows the engagement with self-care and those who lack the necessary resources. Indeed, there is some evidence which points to this direction; research in the US, for example, has shown that the use of HBPMs is associated with higher educational and economic status (Poon, Etti, & Lal, 2010) whilst research in the UK has indicated that the engagement with various forms of self-care (i.e. over-the-counter medicine, private sector complementary and alternative medicine, home blood pressure monitoring) is more likely among affluent people (Ryan et al., 2009). To the extent that self-care is actively promoted at a policy level and healthcare services are adjusted to meet this orientation, there is a need to consider how the lack of social and economic capital required to perform self-care might operate in an exclusionary manner both in realistic (i.e. access to services, products) and in symbolic terms (i.e. if self-care becomes a socially valued norm, one might wonder whether people who do not enact it would be deprived of any positive connotations, if not blamed for their ‘failure’ to perform it).

This thesis shed light on the perspectives of two key stakeholders, namely the users and the medical device industry. Yet, the strong influence of another key actor – that of the health care professional – was evident both in the use and production of home medical technology. Healthcare professionals, more or less directly, were invoked and implicated in the development and use of HBPMs thus shaping these trajectories. For instance, the analysis of the online forums (Chapter 5) suggest that the medical professionals play a key role in the process of developing trust in HBPMs on the part of the lay user. But also during the technology development, the involvement of the medical profession, through for example the clinical validation of HBPMs by reputable medical organisations, served to infuse trust and credibility to the technology. Future research could thus examine the views and perspectives of doctors regarding self-care more broadly and home BP monitoring more specifically.

In relation to home BP monitoring, the existing literature suggests that primary care practitioners appear supportive of this practice, whilst simultaneously raising important concerns. For instance, a survey conducted in the US among community and university-based primary care physicians revealed the conviction that home BP monitoring can be proved useful and economical but also problematic due to increased calls or visits from

patients who become anxious with their home readings (Cheng, Studdiford, Diamond, & Chambers, 2003). In Hungary, home monitoring seems to receive strong support from doctors as the majority tended to encourage its adoption, used it for diagnostic and therapeutic purposes and attributed considerable significance to home readings. Yet, Hungarian doctors expressed concerns about the use of non-validated monitors, the lack of patient training, the possibility of excessive preoccupation and the haphazard recording and display of readings by patients (Tislér et al., 2006).

Similarly, in Canada doctors reported that they often encouraged their hypertensive patients to self-monitor their BP, but the majority preferred ambulatory and/or office readings to home measurements for diagnostic and treatment decisions. Again, purchasing inaccurate devices, patient preoccupation, and display and averaging of home readings were pointed out as potentially problematic aspects (Logan, Dunai, McIsaac, Irvine & Tisler, 2008). Finally, a regionally representative survey in the UK (McManus et al., 2014) showed that the majority of general practitioners (GPs) were using home BP monitoring to exclude or confirm a diagnosis of white coat hypertension and to support the long-term management of hypertension, but only 37% used it to confirm a diagnosis of hypertension. In this study, patient anxiety with home readings was invoked as a reason for not recommending home monitoring.

Overall, these studies present a relatively favourable stance of doctors towards home BP monitoring (see also Jones et al., 2013). Concerns mainly revolve around the accuracy of home monitors, the patient preoccupation and lack of training, and the handling of home readings when these are being passed to the healthcare professional. Indeed, the processing and management of home readings emerged as an even more profound challenge in a trial that tested home BP tele-monitoring against usual care (Hanley, Ure, Pagliari, Sheikh, & McKinstry, 2013) since the existing working practices and roles needed to change in order to accommodate the inflowing information of home readings.

Clearly, this literature provides important insights into the ways doctors view and utilise home BP monitoring. However, one common underlying assumption in all these studies is that home monitoring is initiated by the healthcare professional (through recommendation for purchase or lending of a clinic monitor) to achieve specific clinical ends such diagnostic, therapeutic and medication adherence purposes. Yet, many self-care activities

are instigated and initiated by patients themselves without any prior doctor recommendation, including home BP monitoring. Consequently, future research might usefully investigate how front-line healthcare professionals (e.g. GPs) view and respond to instances when home BP monitoring has been initiated by patients themselves. For example, how do the healthcare practitioners' concerns around home monitoring – as these have been identified in previous literature – unfold against a background of patient initiation of HBPM? And how do doctors respond to these patients, given that perceived reservations, lack of support, or indifference are sometimes reported by patients (see results of Chapter 4)?

Beyond home BP monitoring, it would be useful, but also timely given the policy impetus to self-care, if future research aimed to understand GPs perspectives on self-care activities more broadly. Explorations around the impact that self-care may have on GPs' working patterns, the potential benefits and risks for patients, and the potential ways that self-care could best work would be valuable additions to the current state of knowledge.

7.6 Epilogue: a few reflections on working across disciplinary boundaries

Designing and conducting research in the field of the needs of users of medical technologies is a challenging endeavour for a doctoral student. It is challenging because an intense engagement with literature from a range of disciplines, such as information systems, ergonomics, epidemiology, clinical/medical research, and sociology – to name but a few – as well as multidisciplinary scientific work, such as the field of Health Technology Assessment (HTA), is required in order to gain a firm understanding of the area. Apart from the initial struggles to become familiar and assimilate concepts, knowledge, assumptions, and methodological and epistemological preferences, even linguistic tones, from each discipline, the encounter with several disciplines creates a constant anxiety around the extent to which you are able to grasp existing knowledge. Especially for students who have been previously educationally socialised within a very well delineated disciplinary specialisation, the ongoing sense that you can only superficially touch upon knowledge from different disciplinary fields can feel frustrating. But once you learn to manage these anxieties and the knowledge and input from different disciplines starts to be organised, processed and structured intellectually, in the long run you come to realise that it

is precisely this space – the interdisciplinary space – that can be the most creative. Having been released from the strong scientific norms often being typical of disciplinary specialties and within a polymorphic and polyphonic context characterising interdisciplinary fields, scientific thinking and research can become more imaginative.

REFERENCES

- Abdullah, A. & Othman, S. (2011). The influence of self-owned home blood pressure monitoring (HBPM) on primary care patients with hypertension: A qualitative study. *BMC Family Practice*, *12*, 143.
- Abelson, J., Giacomini, M., Lehoux, P., & Gauvin, F-P. (2007). Bringing ‘the public’ into health technology assessment and coverage policy decisions: From principles to practice. *Health Policy*, *82*, 37 – 50.
- Agarwal, R., Bills, J.E., Hecht, T.J.W., & Light, R.P. (2011). Role of home blood pressure monitoring in overcoming therapeutic inertia and improving hypertension control. *Hypertension*, *57*(1), 29 – 38.
- Ajzen, I. (1985). From intentions to actions: A theory of planned behavior. In J. Kuhl, & J. Beckmann (Eds.), *Action control: From cognition to behaviour* (pp. 11 – 39). New York: Springer.
- Ajzen, I., & Fishbein, M. (1980). *Understanding attitudes and predicting social behavior*. Englewood Cliffs, NJ: Prentice-Hall.
- Akrich, M. (1992). The de-scription of technical objects. In W.E., Bijker & J. Law (Eds.), *Shaping technology / building society: Studies in socio-technical change* (205 – 224). Cambridge: The MIT Press.
- American Psychological Association (2002). *Ethical principles of psychologists and code of conduct*. Washington, DC: American Psychological Association. Retrieved from: <http://www.apa.org/ethics/code/index.aspx>
- Anderson, G., & Horvath, J. (2004). The growing burden of chronic disease in America. *Public Health Reports (1974-)*, *119*(3), 263-270. doi: 10.2307/20056677.
- Association of British Healthcare Industries (2009). *Enhancing patient care in the NHS: The role of medical devices industry – recommendations*. London: Medibrand Limited

- Atkinson, P. & Silverman, D. (1997). Kundera's immortality: The interview society and the invention of the self. *Qualitative Inquiry*, 3(3), 304-325. doi: 10.1177/107780049700300304
- Aylett, M., Marples, G., & Jones, K. (1999). Home blood pressure monitoring: its effect on the management of hypertension in general practice. *British Journal of General Practice*, 49(446), 725 – 728.
- Ayman, D., & Goldshine, A.D. (1940). Blood pressure determinations by patients with essential hypertension: The difference between clinic and home readings before treatment. *American Journal of the Medical Sciences*, 200(4), 465 – 474.
- Bagozzi, R.P. (2007). The legacy of the Technology Acceptance Model and a proposal for a paradigm shift. *Journal of the Association of Information Systems*, 8(4), 244 – 254.
- Bagozzi, R.P., Davis, F.D., & Warshaw, P.R. (1992). Development and test of a theory of technological learning and usage. *Human Relations*, 45, 659 – 686.
- Bakker, J.I. (2010) Interpretivism. In In A.J. Mills, J. Eurepos, & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 486 – 492). London, UK: Sage Publications.
- Baral-Grant, S., Haque, M.S., Nouwen, A., Greenfield, S.M., McManus, R.J. (2011). Self-monitoring of blood pressure in hypertension: a UK primary care survey. *International Journal of Hypertension*, 2012. doi:10.1155/2012/582068
- Bella, L. (2010). In sickness and in health: Public and private responsibility for health care from Bismarck to Obama. In R. Harris, N. Wathen, & S. Wyatt (Eds.), *Configuring health consumers: Health work and the imperative of personal responsibility* (pp. 13 – 29). Hampshire, UK: Palgrave Macmillan.
- Bhaskar, R. (1989). *Reclaiming reality: A critical introduction in contemporary philosophy*. London, UK: Verso.
- Bhaskar, R. (2008). *A realist theory of science*. Oxon, UK: Routledge.
- Bhattacharya, H. (2008). Interpretive research. In L.M. Given (Ed.), *The Sage encyclopedia of qualitative research methods* (pp. 464 – 467). London, UK: Sage Publications.

- Bitterman, N. (2011). Design of medical devices – a home perspective. *European Journal of Internal Medicine*, 22, 39 – 42. doi: 10.1016/j.ejim.2010.09.017
- Blaikie, N. (2000). *Designing social research: The logic of anticipation*. Cambridge, UK: Polity Press.
- Bloom, D.E., Börsch-Supan, A., McGee, P., & Seike, A., (2011) *Population aging: facts, challenges, and responses*. Program on the Global Demography of Aging Working Paper No. 71. Retrieved from: http://www.hsph.harvard.edu/program-on-the-global-demography-of-aging/WorkingPapers/2011/PGDA_WP_71.pdf
- Bloor, M., & Wood, F. (2006). *Keywords in qualitative methods: A vocabulary of research concepts*. London, UK: Sage Publications.
- Bodenheimer, T., Lorig, K., Holman, H., & Grumbach, K. (2002). Patient self-management of chronic disease in primary care. *The Journal of the American Medical Association*, 288(19), 2469-2475. doi: 10.1001/jama.288.19.2469.
- Booth, J. (1977). A short history of blood pressure measurement. *Proceedings of the Royal Society of Medicine*, 70(11), 793 – 799.
- Boyatzis, R.E. (1998). *Transforming qualitative information: Thematic analysis and code development*. Thousand Oaks, CA: Sage.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77-101.
- Breakwell, G.M. (Ed.) (1983). *Threatened identities*. Chichester, UK: Wiley.
- Brinkmann, S. (2008). Interviewing. In L.M. Given (Ed.), *The Sage encyclopedia of qualitative research methods* (pp. 470 – 472). London, UK: Sage Publications.
- British Psychological Society (2013). *Ethics Guidelines for Internet-mediated Research*. INF206/1.2013. Leicester, UK: British Psychological Society. Retrieved from: www.bps.org.uk/publications/policy-andguidelines/research-guidelines-policydocuments/research-guidelines-poli
- British Psychological Society (2009). *Code of ethics and conduct guidance published by the Ethics Committee of the British Psychological Society*. Leicester, UK: British

Psychological Society. Retrieved from:

http://www.bps.org.uk/system/files/documents/code_of_ethics_and_conduct.pdf

British Psychological Society (2014). *Code of human research ethics*. Leicester, UK:

British Psychological Society. Retrieved from:

http://www.bps.org.uk/system/files/Public%20files/code_of_human_research_ethics_dec_2014_inf180_web.pdf

Britten, N. (1995). Qualitative interviews in medical research. *British Medical Journal*, *311*, 251 – 253.

Burr, V. (1995). *An introduction to social constructionism*. London: Routledge.

Busse, R., Blümel, M., Scheller-Kreinsen, D., & Zentner, A. (2010). *Tackling chronic disease in Europe: Strategies, interventions and challenges*. Observatory Studies Series No 20. Copenhagen: WHO Regional Office for Europe. Retrieved from:

http://www.euro.who.int/_data/assets/pdf_file/0008/96632/E93736.pdf

Button, G. (2006). Introduction: A new perspective on the dependability of software systems. In K. Clarke, G. Hardstone, M. Rouncefield, & I. Sommerville (Eds.), *Trust in technology: A socio-technical perspective* (pp. ix – xxv). Dordrecht, The Netherlands: Springer.

Caffrey, C., Sengupta, M., Moss, A., Harris-Kojetin, L., & Valverde, R. (2011). *Home health care and discharged hospice care patients: United States, 2000 and 2007*. National health statistics reports, no 38. Hyattsville, MD: National Center for Health Statistics.

Callum, W. & Mahiben, M. (2013). “Healthconomic crises”: Public health and neoliberal economic crises – editorial. *American Journal of Public Health*, *103*(1), p. 7 – 9.

Calnan, M., Montaner, D., Horne, R. (2005). How acceptable are innovative healthcare technologies? A survey of public beliefs and attitudes in England and Wales. *Social Science & Medicine*, *60*, 1937 – 1948.

Canadian Healthcare Association (2009). *Home Care in Canada: From the Margins to the Mainstream*. Ottawa: Canadian Healthcare Association.

- Cappuccio, F.P., Kerry, S.M., Forbes, L., & Donald, A. (2004). Blood pressure control by home monitoring: meta-analysis of randomised trials. *British Medical Journal*, *329*(7458), 145 – 148.
- Carrera, P.M. & Dalton, A.R.H. (2014). Do-it-yourself healthcare: The current landscape, prospects and consequences. *Maturitas*, *77*(1), 37 – 40. doi: 10.1016/j.
- Carter, S., Green, J., & Thorogood, N. (2013). The domestication of an everyday health technology: A case study of electric toothbrushes. *Social Theory & Health*, *11*(4), 344–367.
- Cartier, C. (2003). From home to hospital and back again: economic restructuring, end of life, and the gendered problems of place-switching health services. *Social Science & Medicine*, *56*(11), 2289-2301. doi: 10.1016/s0277-9536(02)00228-9
- Celis, H., Hond, E.D., & Staessen, J.A. (2005). Self-measurement of blood pressure at home in the management of hypertension. *Clinical Medicine & Research*, *3*(1), 19-26. doi: 10.3121/cmr.3.1.19.
- Cheng, C., Studdiford, J. S., Diamond, J. J., & Chambers, C. V. (2003). Primary care physician beliefs regarding usefulness of self-monitoring of blood pressure. *Blood Pressure Monitoring*, *8*(6), 249-254.
- Christensen, K., Doblhammer, G., Rau, R., & Vaupel, J. W. (2009). Ageing populations: the challenges ahead. *Lancet*, *374*, 1196–1208. DOI: [http://dx.doi.org/10.1016/S0140-6736\(09\)61460-4](http://dx.doi.org/10.1016/S0140-6736(09)61460-4).
- Clar, C., Barnard, K., Cummins, E., Royle, P., & Waugh, N. (2010). Self-monitoring of blood glucose in type 2 diabetes: systematic review. *Health Technology Assessment*, *14*(12), 1 – 140.
- Clark, A.M. (2008). Critical realism. In L.M. Given (Ed.), *The Sage encyclopedia of qualitative research methods* (pp. 167 – 170). London, UK: Sage Publications.
- Clarke, V. & Braun, V. (2013) Teaching thematic analysis: Overcoming challenges and developing strategies for effective learning. *The Psychologist*, *26*(2), 120 – 123.
- Coulson, N.S. (2005). Receiving social support online: An analysis of a computer-mediated support group for individuals living with irritable bowel syndrome. *CyberPsychology & Behavior*, *8*(6), 580 – 584.

- Coulson, N.S., Buchanan, H., & Aubeeluck, A. (2007). Social support in cyberspace: A content analysis of communication within a Huntington's disease online support group. *Patient Education and Counseling*, *68*, 173–178.
- Council of the European Communities (1993). Council Directive 93/42/EEC concerning medical devices. *Official Journal of the European Communities*, *No L*, 169/1 – 169/43.
- Coyle, A. (2007). Introduction to qualitative psychological research. In E. Lyons & A. Coyle (Eds.), *Analysing qualitative data in psychology* (pp. 9 – 29). London, UK. Sage Publications.
- Coyte, P.C., & McKeever, P. (2001) Home care in Canada: Passing the buck. *Canadian Journal of Nursing Research*, *33*, 11 – 25.
- Creswell, J.W. (2009). *Research design: Qualitative, quantitative, and mixed methods approaches* (3rd ed.). London, UK: Sage Publications.
- Cuspidi, C., Meani, S., Lonati, L., Fusi, V., Magnaghi, G., Garavelli, G., Palumbo, G., et al. (2005). Prevalence of home blood pressure measurement among selected hypertensive patients: results of a multicenter survey from six hospital outpatient hypertension clinics in Italy. *Blood Pressure*, *14*, 251 – 256.
- Daar, A.S., Singer, P.A., Persad, D.L., Pramming, S.K., Matthews, D.R., Beaglehole, R., . . . Bell, J. (2007). Grand challenges in chronic non-communicable diseases. *Nature*, *450*(7169), 494-496. doi:10.1038/450494a.
- Dans, A., Ng, N., Varghese, C., Tai, E.S., Firestone, R., Bonita, R. (2011). The rise of chronic non-communicable diseases in south-east Asia: time for action. *The Lancet*, *337*, 680 – 689.
- Davis, F. (1989). Perceived usefulness, perceived ease of use, and user acceptance, of information technology. *MIS Quarterly*, *13*(3), 319 – 340.
- de la Maisonneuve, C. & Martins, J.O. (2013). *A projection method for public health and long-term care expenditures*. OECD Economics Department Working Papers, No. 1048. OECD Publishing. Retrieved from: <http://dx.doi.org/10.1787/5k44v53w5w47-en>

Denzin, N.K., & Lincoln, Y.S. (2005). Introduction: The discipline and practice of qualitative research. In N.K. Denzin & Y.S. Lincoln (Eds.), *The Sage handbook of qualitative research - 3rd edition* (pp. 1 – 32). London, UK: Sage Publications.

Department of Health (2000). *The NHS plan: A plan for investment, a plan for reform*. London, UK: DH Publications. Retrieved from:
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_118522.pdf

Department of Health (2002). *Delivering the NHS plan: next steps on investment, next steps on reform*. Norwich, UK: The Stationary Office. Retrieved from:
<http://www.nhshistory.net/deliveringthenhsplan.pdf>

Department of Health (2004a). *The NHS improvement plan - Putting people at the heart of public services*. Norwich, UK: The Stationary Office. Retrieved from:
<http://pns.dgs.pt/files/2010/03/pnsuk3.pdf>

Department of Health (2004b). *Choosing health: Making healthy choices easier*. Norwich, UK: The Stationary Office. Retrieved from:
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_133489.pdf

Department of Health (2005a). *Self-care – A real choice / Self-care support – A practical option*. London, UK: DH Publications. Retrieved from:
http://webarchive.nationalarchives.gov.uk/20090120141703/http://dh.gov.uk/en/PublicationSandStatistics/Publications/PublicationsPolicyAndGuidance/DH_4100717

Department of Health (2005b). *Public attitudes to self-care: Baseline survey*. Retrieved from:
http://webarchive.nationalarchives.gov.uk/20090120141703/http://dh.gov.uk/en/PublicationSandStatistics/Publications/PublicationsPolicyAndGuidance/DH_4111260

Department of Health (2006a). *Supporting people with long term conditions to self-care: A guide to developing local strategies and good practice*. London, UK: DH Publications. Retrieved from:
http://webarchive.nationalarchives.gov.uk/+/dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4130725

- Department of Health (2006b). *Our health, our care, our say: A new direction for community services*. Norwich, UK: The Stationary Office. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/272238/6737.pdf
- Department of Health (2008). *Delivering care closer to home: Meeting the challenge*. London, UK: DH Publications. Retrieved from: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_086051.pdf
- Department of Health (2010). *Equity and excellence: Liberating the NHS*. Norwich, UK: The Stationary Office. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213823/dh_117794.pdf
- DiCicco-Bloom, B., & Crabtree, B.F. (2006). The qualitative research interview. *Medical Education*, 40, 314 – 321.
- Direct-to-consumer genetic testing. [Editorial]. (2012, July 14). *The Lancet*, 480, 76.
- Dowling, M. (2006). Approaches to reflexivity in qualitative research. *Nurse Researcher*, 13(3), 7 – 21.
- Elger, T. (2010). Critical realism. In A.J. Mills, J. Eurepos, & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 253 – 257). London, UK: Sage Publications.
- Elliott, R., Fischer, C.T., & Rennie, D.L. (1999). Evolving guidelines for publication of qualitative research studies in psychology and related fields. *British Journal of Clinical Psychology*, 38, 215 – 229.
- Emerson, R.M., Fretz, R.I., & Shaw, L.L. (Eds.) (2011). *Writing ethnographic fieldnotes – 2nd edition*. Chicago: University of Chicago Press.
- Ess, C. & Association of Internet Researchers ethics working committee (2002). *Ethical decision-making and Internet research: Recommendations from the aoir ethics working committee*. Retrieved from: www.aoir.org/reports/ethics.pdf
- Eucomed (2013). *Medical technology: Contributing to Europe's health, innovation and economy*. Retrieved from:

http://www.medtecheurope.org/uploads/Modules/Publications/medtech-medicaltechnology_broch_v05_pbp.pdf

Eurostat (2013). *Key figures on Europe - 2013 digest of the online Eurostat yearbook*. Luxembourg: Publications Office of the European Union. Retrieved from: <http://ec.europa.eu/eurostat/documents/3930297/5969538/KS-EI-13-001-EN.PDF/98fe7e02-d76a-45b9-9c72-7af791c672c2?version=1.0>

Eysenbach, G., & Till, J.E. (2001). Ethical issues in qualitative research on internet communities. *British Medical Journal*, 323, 1103 – 5.

Facey, K.M., Boivin, A., Gracia, J., Hansen, H.P., Lo Scalzo, A., Mossman, J., & Single, A. (2010). Patients' perspectives in health technology assessment: A route to robust evidence and fair deliberation. *International Journal of Technology Assessment in Health Care*, 26(3), 334 – 340. DOI: <http://dx.doi.org/10.1017/S0266462310000395>.

Facey, K.M. & Hansen, H.P. (2011). Editorial: patient-focused HTAs. *International Journal of Technology Assessment in Health Care*, 27(4), 273 – 274. DOI: <http://dx.doi.org/10.1017/S0266462311000572>.

Falaszchetti, E., Chaudhury, M., Mindell, J., & Poulter, N. (2009). Continued improvement in Hypertension management in England. *Hypertension*, 53(3), 480 - 486. doi: 10.1161/hypertensionaha.108.125617

Fattal, J., & Lehoux, P. (2008). Health technology assessment use and dissemination by patient and consumer groups: Why and how? *International Journal of Technology Assessment in Health Care*, 24(4), 473 – 480.

Fielding, N.G. (2006). Ethnographic interviewing. In V. Jupp, (Ed.), *The Sage Dictionary of Social Research Methods* (pp. 99 – 101). London, UK: Sage Publications.

Finlay, L. (2003). The reflexive journey: mapping multiple routes. In L. Finlay & B. Gough (Eds.), *Reflexivity: A practical guide for researchers in health and social sciences* (pp. 3 – 20). Oxford, UK: Blackwell.

Finney-Rutten, L.J., Gollust, S.E., Naveed, S., & Moser, R.P. (2012). Increasing public awareness of direct-to-consumer genetic tests: Health care access, internet use, and population density correlates. *Journal of Cancer Epidemiology*, 2012, 309109.

Flick, U., von Kardorff, E., & Steinke, I. (2004). What is qualitative research? An introduction to the field. In U. Flick, E. von Kardorff, & I. Steinke (Eds.), *A companion to qualitative research* (pp. 3 – 11). London, UK: Sage Publications.

Fontana, A. & Frey, J.H. (2005). The interview: From neutral stance to political involvement. In N.K. Denzin & Y.S. Lincoln (Eds.), *The Sage handbook of qualitative research - 3rd edition* (pp. 695 – 727). London, UK: Sage Publications.

Food and Drug Administration. (2010). *Medical Device Home Use Initiative*. Center for Devices and Radiological Health. Retrieved from:
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/UCM209056.pdf>

Food and Drug Administration (2011). *Applying human factors and usability engineering to optimize medical device design*. Draft Guidance for Industry and Food and Drug Administration Staff. Retrieved from:
<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm259748.htm>

Food and Drug Administration (2012). *Design Considerations for Devices Intended for Home Use*. Draft Guidance for Industry and Food and Drug Administration Staff. Retrieved from:
<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm331675.htm>

Food and Drug Administration (2013). *Mobile medical applications guidance for industry and food and drug administration staff*. Retrieved from:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm255978.htm>

Fox, N.J. (2008). Induction. In L.M. Given (Ed.), *The Sage encyclopedia of qualitative research methods* (pp. 429 – 430). London, UK: Sage Publications.

Freedman, D., Furness, P., Green, A., Hallworth, M., McCartney, M., Prasad, A., Wright, C. (2008). *Making sense of testing: a guide to why scans and health tests for well people aren't always a good idea*. Report by Sense about Science.

Gantz, S. B. (1990). Self-care: Perspectives from six disciplines. *Holistic Nursing Practice*, 4(2), 1-12.

Geertz, C. (1973). *The interpretation of cultures: Selected essays*. New York, NY: Basic Books.

Genet, N., Boerma, W.G.W., Kringos, D.S., Bouman, A., Francke, A.L., Fagerström, C., Melchiorre, M.G., et al. (2011). Home care in Europe: a systematic literature review. *BMC Health Services Research*, 11, 207.

Gibbons, R. & Ward, H. (2011, August). *The availability and quality of online tests for sexually transmitted infections*. Poster. Retrieved from:

<http://www.reubengibbons.info/iustiposter.pdf>

Godfrey, C. M., Harrison, M. B., Lysaght, R., Lamb, M., Graham, I. D., & Oakley, P. (2011). Care of self – care by other – care of other: the meaning of self-care from research, practice, policy and industry perspectives. *International Journal of Evidence-Based Healthcare*, 9(1), 3-24. doi: 10.1111/j.1744-1609.2010.00196.x

Goffman, E. (1981). *Forms of talk*. Philadelphia: University of Pennsylvania Press.

Goffman, E. (1989). On fieldwork. *Journal of Contemporary Ethnography*, 18, 123 – 132. Doi: 10.1177/089124189018002001.

Goldbart, J. & Hustler, D. (2005). Chapter 1: Ethnography. In B. Somekh & C. Lewin (Eds.), *Research methods in the social sciences* (pp. 16 – 23). London, UK: Sage Publications.

Goodwin, N. (2010). The state of telehealth and telecare in the UK: Prospects for integrated care. *Journal of Integrated Care*, 18(6), 3 – 10.

Gosling, S.D., Vazire, S., Srivastava, S., & John, O.P. (2004). Should we trust Web-based studies? A comparative analysis of six preconceptions. *American Psychologist*, 59(2), 93–104 DOI: 10.1037/0003-066X.59.2.93

Gough, B. (2003). Deconstructing reflexivity. In L. Finlay & B. Gough (Eds.), *Reflexivity: A practical guide for researchers in health and social sciences* (pp. 21 – 35). Oxford, UK: Blackwell.

Graves, J.W. (2005). A survey of validated automated home blood pressure monitors available for the Internet shopper. *Blood Pressure Monitoring, 10*(2), 103 – 107.

Greenfield, S., Pattison, H., & Jolly, K. (2008). Use of complementary and alternative medicine and self-tests by coronary heart disease patients. *BMC Complementary and Alternative Medicine, 8*, 47. doi:10.1186/1472-6882-8-47.

Greenhalgh, T. & Swinglehurst, D. (2011). Studying technology use as social practice: the untapped potential of ethnography. *BMC Medicine, 9*, 45. Doi:10.1186/1741-7015-9-45.

Grispen, J.E.J., Ronda, G., Dinant, G.J., de Vries, N.K., & van der Weijden, T. (2011). To test or not to test: A cross-sectional survey of the psychosocial determinants of self-testing for cholesterol, glucose, and HIV. *BMC Public Health, 11*, 112.

Grocott, P., Weir, H., & Ram, M.B. (2007). A model of user engagement in medical device development. *International Journal of Health Care Quality Assurance, 20*(6), 484 – 493. DOI: 10.1108/09526860710819422.

Gu, D., Reynolds, K., Wu, X., Chen, J., Duan, X., Muntner, P., . . . Group, f. t. I. C. (2002). Prevalence, awareness, treatment, and control of hypertension in China. *Hypertension, 40*(6), 920-927. doi: 10.1161/01.hyp.0000040263.94619.d5.

Haddon, L. (2006). The contribution of domestication research to in-home computing and media consumption. *The Information Society, 22*, 195-203.

Hammersley, M. (2006). Induction. In V. Jupp, (Ed.), *The Sage Dictionary of Social Research Methods* (pp. 146 – 147). London, UK: Sage Publications.

Hammersley, M. & Atkinson, P. (2007). *Ethnography: Principles in practice - 3rd edition*. London, UK: Routledge.

Hanley, J., Ure, J., Pagliari, C., Sheikh, A., & McKinstry, B. (2013). Experiences of patients and professionals participating in the HITS home blood pressure tele-monitoring trial: A qualitative study. *British Medical Journal Open, 3*(5). doi: 10.1136/bmjopen-2013-002671

Hauskeller, C. (2011). Direct to consumer genetic testing: Regulations cannot guarantee responsible use; an international industry certificate is needed. *British Medical Journal*, 342, d2317 doi: 10.1136/bmj.d2317.

Health and Social Care Act 2012, (c 7). Norwich, UK: The Stationary Office.

Health and Social Care Information Centre (2013a). *Community care statistics, social services activity - England, 2011-12, final release*. Retrieved from: <http://www.hscic.gov.uk/catalogue/PUB10291/comm-care-stat-eng-2011-12-soci-serv-act-rep.pdf>

Health and Social Care Information Centre (2013b). *Community care statistics, social services activity - England, 2012-13, final release*. Retrieved from: <http://www.hscic.gov.uk/catalogue/PUB13148/comm-care-stat-act-eng-2012-13-fin-rep.pdf>

Henwood, K.L., & Pidgeon, N.F. (1992). Qualitative research and psychological theorizing. *British Journal of Psychology*, 83, 97 – 111.

Herman, W.A. (2001). Health technology is coming home (and how!). *FDA Consumer*, 35(3), 36.

Herman, W.A. & Devey, G.B. (2011). *Medical device technology forecast 2008: Future trends in medical device technologies*. FDA: Center for Devices and Radiological Health. Retrieved from: <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm234726.htm>

Hewson, C. (2003). Conducting research on the internet. *The Psychologist*, 16(6), 290 – 293.

Hewson, C., Yule, P., Laurent, D., & Vogel, C. (2003). *Internet research methods: A practical guide for the social and behavioural sciences*. London, UK: Sage Publications.

Hivon, M., Lehoux, P., Denis, J-L., Tailliez, S. (2005). Use of health technology assessment in decision making: Coresponsibility of users and producers? *International Journal of Technology Assessment in Health Care*, 21(2), 268 – 275.

Hobbs, D. (2006). Ethnography. In V. Jupp (Ed.), *The SAGE dictionary of social research methods* (pp. 101 – 103). London, UK: Sage Publications.

Hogarth, S., Javitt, G., & Melzer, D. (2008). The current landscape for direct-to-consumer genetic testing: Legal, ethical, and policy issues. *Annual Review of Genomics and Human Genetics*, 9, 161 – 182.

Holden, R.J., & Karsh, B-T. (2010). The Technology Acceptance Model: Its past and its future in health care. *Journal of Biomedical Informatics*, 43, 159 – 172.
doi:10.1016/j.jbi.2009.07.002

Hoover, M., & Rotermann, M. (2012). Seniors' use of and unmet needs for home care, 2009. *Health Reports*, 23(4). Statistics Canada, Catalogue no. 82-003-XPE.

Hourd, P.C., & Williams, D.J. (2008). Results from an exploratory study to identify the factors that contribute to success for UK medical device small and medium-sized enterprises. Proceedings of the Institution of Mechanical Engineers, Part H, *Journal of Engineering in Medicine*, 222 (5), 717 – 735. Doi: 10.1243/09544119JEIM125.

Howitt, D. (2010a). Chapter 5: Ethnography/participant observation. In D. Howitt, *Introduction to qualitative methods in psychology* (pp. 111 – 133). Harlow, UK: Pearson.

Howitt, D. (2010b). Chapter 14: Ensuring quality in qualitative research. In D. Howitt, *Introduction to qualitative methods in psychology* (pp. 357 – 382). Harlow, UK: Pearson.

Howitt, D. (2010c). Chapter 15: Ethics and data management in qualitative research. In D. Howitt, *Introduction to qualitative methods in psychology* (pp. 383 – 411). Harlow, UK: Pearson.

Humphries, R. (2013). *Paying for social care: Beyond Dilnot*. London, UK: The King's Fund.

Hunter, D.J. (2008). Key challenges facing health systems. In D.J. Hunter, *The health debate* (pp. 1-22). Bristol, UK: The Policy Press.

Hynes, D., & Richardson, H. (2009). What Use is Domestication Theory to Information Systems Research? In Y. Dwivedi, B. Lal, M. Williams, S. Schneberger & M. Wade (Eds.), *Handbook of research on contemporary theoretical models in information systems* (pp. 482 – 494). IGI Global.

Ickenroth, M.H.P., Grispen, J.E.J., Ronda, G., Tacken, M., Dinant, G.J., de Vries, N.K., & van der Weijden, T. (2011). Motivation and experiences of self-testers regarding tests for

cardiovascular risk factors. *Health Expectations*, 17, 60 – 72. doi: 10.1111/j.1369-7625.2011.00733.x

Ickenroth, M.H.P., Ronda, G., Grispen, J.E.J., Dinant, G.J., de Vries, N.K., & van der Weijden, T. (2010). How do people respond to self-test results? A cross-sectional survey. *BMC Family Practice*, 11, 77. doi: 10.1186/1471-2296-11-77.

IEC 62366: 2007. *Medical devices - Application of usability engineering to medical devices*

IEC 60601-1-6: 2010. *Medical electrical equipment: General requirements for basic safety and essential performance. Collateral standard: Usability*

IEC 60601-1-11: 2010. *General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment.*

International Telecommunication Union (2013). *ICT facts and figures*. Geneva, Switzerland: ICT Data and Statistics Division.

Jirotko, M., Procter, R., Hartswood, M., Slack, R., Simpson, A., Coopmans, C.,Voss, A. (2005). Collaboration and trust in healthcare innovation: The eDiaMoND case study. *Computer Supported Cooperative Work*, 14, 369–398. DOI 10.1007/s10606-005-9001-0.

Johri, M. & Lehoux, P. (2003). The great escape? Prospects for regulating access to technology through health technology assessment. *International Journal of Technology Assessment in Health Care*, 19(1), 179 – 193.

Jones, M.I., Greenfield, S.M., Bray, E.P., Baral-Grant, S., Hobbs, F.D.R., Holder, R.,.... & McManus, R.J. (2012). Patients' experiences of self-monitoring blood pressure and self-titration of medication: the TASMINH2 trial qualitative study. *British Journal of General Practice*, 62(595), e135-e142.

Jones, M. I., Greenfield, S. M., Bray, E. P., Hobbs, F. D. R., Holder, R., Little, P., . . . McManus, R. J. (2013). Patient self-monitoring of blood pressure and self-titration of medication in primary care: the TASMINH2 trial qualitative study of health professionals'

experiences. *British Journal of General Practice*, 63(611), e378-e385. doi: 10.3399/bjgp13X668168.

Kane, R.A. (1995). Expanding the home care concept: Blurring distinctions among home care, institutional care, and other long-term-care services. *The Milbank Quarterly*, 73(2), 161-186. doi: 10.2307/3350255.

Kaplan, A.V., Baim, D.S., Smith, J.J., Feigal, D.A., Simons, M., Jefferys, D., Fogarty, T.J., et al. (2004). Medical device development: From prototype to regulatory approval. *Circulation*, 109, 3068 – 3072. doi: 10.1161/01.CIR.0000134695.65733.64.

Kearney, P.M., Whelton, M., Reynolds, K., Muntner, P., Whelton, P.K., & He, J. (2005). Global burden of hypertension: analysis of worldwide data. *The Lancet*, 365(9455), 217-223. doi: 10.1016/s0140-6736(05)17741-1.

Klein, E. (1966). *A comprehensive etymological dictionary of the English language*. Amsterdam, the Netherlands: Elsevier Publishing Company.

Kraut, R., Olson, J., Banaji, M., Bruckman, A., Cohen, J., & Couper, M. (2004). Psychological research online: Report of Board of Scientific Affairs' Advisory group on the conduct of research on the Internet. *American Psychologist*, 59(2), 105–117 DOI: 10.1037/0003-066X.59.2.105

Krotoski, A.K. (2012). Data-driven research: open data opportunities for growing knowledge, and ethical issues that arise. *Insights*, 24(1), 28 – 32.

Last, J. M. (2007). *A dictionary of public health*. Oxford University Press.

Lankshear, C. & Leander, K.M. (2005). Social science research in virtual realities. In B. Somekh, & C. Lewin (Eds.), *Research methods in the social sciences* (pp. 326 – 334). London, UK: Sage Publications.

Lehoux, P. (2004). Patients' perspectives on high-tech home care: a qualitative inquiry-into the user-friendliness of four technologies. *BMC Health Services Research*, 4, 28. doi:10.1186/1472-6963-4-28

Lehoux, P. (2008). The duality of health technology in chronic illness: how designers envision our future. *Chronic Illness*, 4(2), 85-97. doi: 10.1177/1742395308092475

- Lehoux, P. (2008). Why examining the desirability of health technology matters. *Healthcare Policy*, 3(3), 29 – 39.
- Lehoux, P., & Blume, S. (2000). Technology assessment and the socio-politics of health technologies. *Journal of Health Politics, Policy and Law*, 25(6), 1083 – 1120. doi: 10.1215/03616878-25-6-1083.
- Lehoux, P., Daudelin, G., Williams-Jones, B., Denis, J.L., & Longo, C. (2014). How do business model and health technology design influence each other? Insights from a longitudinal case study of three academic spin-offs. *Research Policy*, 43, 1025 – 1038. doi:10.1016/j.respol.2014.02.001.
- Lehoux, P., Denis, J-L., Tailliez, S., Hivon, M. (2005). Dissemination of health technology assessments: Identifying the visions guiding an evolving policy innovation in Canada. *Journal of Health Politics, Policy and Law*, 30(4), 603 – 641.
- Lehoux, P., Saint-Arnaud, J., & Richard, L. (2004). The use of technology at home: what patient manuals say and sell vs. what patients face and fear. *Sociology of Health & Illness*, 26(5), 617–644.
- Lehoux, P., Tailliez, S., Denis, J-L., & Hivon, M. (2004). Redefining health technology assessment in Canada: Diversification of products and contextualization of findings. *International Journal of Technology Assessment in Health Care*, 20(3), 325 – 336. DOI: <http://dx.doi.org/10.1017/S026646230400114X>.
- Lehoux, P. & Williams-Jones, B. (2007). Mapping the integration of social and ethical issues in health technology assessment. *International Journal of Technology Assessment in Health Care*, 23(1), 9 – 16. DOI: <http://dx.doi.org/10.1017/S0266462307051513>.
- Lehoux, P., Williams-Jones, B., Miller, F., Urbach, D., & Tailliez, S. (2008). What leads to better health care innovation? Arguments for an integrated policy-oriented research agenda. *Journal of Health Services Research & Policy*, 13(4), 251–254. DOI: 10.1258/jhsrp.2008.007173
- Levin, L. S. (1976). The layperson as the primary health care practitioner. *Public Health Reports* 91(3), 206-210.

Lewis, C. (2001). Emerging trends in medical device technology: Home is where the heart monitor is. *FDA Consumer Magazine*, 35, 10-15.

Lewis, J., & Ritchie, J. (2003). Generalising from qualitative research. In J., Ritchie, & J., Lewis (Eds.), *Qualitative research practice: A Guide for social science students and researchers* (pp. 263 – 286). London: Sage Publications.

Lewis, J.D., & Weigert, A. (1985). Trust as a social reality. *Social Forces*, 63(4), 967 – 985.

Lim, S.S., Vos, T., Flaxman, A.D., Danaei, G., Shibuya, K., Adair-Rohani, H., Amann, M., et al. (2012). A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*, 380, 2224 – 2260.

Lincoln, Y.S. & Guba, E.G. (1985). *Naturalistic inquiry*. Beverly Hills, CA: Sage.

Little, P., Barnett, J., Barnsley, L., Marjoram, J., Fitzgerald-Barron, A., & Mant, D. (2002). Comparison of acceptability of and preferences for different methods of measuring blood pressure in primary care. *British Medical Journal*, 325(7358), 258 – 259.

Locke, K. (2010). Abduction. In A.J. Mills, J. Eurepos, & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 1 – 3). London, UK: Sage Publications.

Logan, A. G., Dunai, A., McIsaac, W. J., Irvine, M. J., & Tisler, A. (2008). Attitudes of primary care physicians and their patients about home blood pressure monitoring in Ontario. *Journal of Hypertension*, 26(3), 446 – 452. DOI: 410.1097/HJH.1090b1013e3282f1092fdd1094.

Luhmann, N. (1979). *Trust and Power*. Chichester: Willey.

Luhmann, N. (2000). Familiarity, confidence, trust: Problems and alternatives. In G. Diego (Ed.), *Trust: Making and breaking cooperative relations* (pp. 94 – 107). Retrieved from: <http://www.sociology.ox.ac.uk/papers/luhmann94-107.pdf>

Macbeth, D. (2001). On "reflexivity" in qualitative research: Two readings, and a third. *Qualitative Inquiry*, 7(1), 35 – 68.

Marshall, B., Cardon, P., Poddar, A., & Fontenot, R. (2013). Does sample size matter in qualitative research?: A review of qualitative interviews in IS research. *Journal of Computer Information Systems*, 54(1), 11 – 22.

McManus, R. J., Wood, S., Bray, E. P., Glasziou, P., Hayen, A., Heneghan, C., . . . Hobbs, F. D.R. (2014). Self-monitoring in hypertension: a web-based survey of primary care physicians. *Journal of Human Hypertension*, 28, 123 – 127. doi: 10.1038/jhh.2013.54.

Manley, L. (2000). A look back: The sphygmomanometer. *Journal of Emergency Nursing*. 26(2), 168.

Markham, A.N. (2004). Internet communication as a tool for qualitative research. In D. Silverman (Ed.), *Qualitative research: theory, method and practice - 2nd edition* (pp. 95 – 124). London, UK: Sage Publications.

Markham, A., Buchanan, E., & Association of Internet Researchers (2012). Ethical decision-making and Internet research: Recommendations from the AoIR Ethics Working Committee (Version 2.0). Retrieved from: <http://www.aoir.org/reports/ethics2.pdf>

Maranta, A., Guggenheim, M., Gisler, P., & Pohl, C. (2003). The reality of experts and the imagined lay person. *Acta Sociologica*, 46, 150 – 165.

Marshall, I.J., Wolfe, C.D.A., & McKevitt, C. (2012). Lay perspectives on hypertension and drug adherence: Systematic review of qualitative research. *British Medical Journal*, 344(e3953). doi: 10.1136/bmj.e3953.

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*, 12, 74.

Martin, J.L., Clark, D.J., Morgan, S.P., Crowe, J.A., & Murphy, E. (2012). A user-centred approach to requirements elicitation in medical device development: A case study from an industry perspective. *Applied Ergonomics* 43, 184 – 190.

Martin, J.L., Craven, M.P., & Norris B.J. (2005). MATCH: a new industry-focused approach to medical device development. In *Healthcare systems ergonomics and patient safety: human factor, a bridge between care and cure*. Proceedings of the International

Conference HEPS 2005, Florence, Italy, 30th March - 2nd April 2005. Taylor & Francis, Leiden, London, pp. 294-297.

Martin, J.L., & Crowe, J.A. (2010). Contextual inquiry for medical device development: A case study. In V.G. Duffy (Ed.), *Advances in Human Factors and Ergonomics in Healthcare* (pp. 549–557). CRC Press.

Martin, J.L., Murphy, E., Crowe, J.A., & Norris, B.J. (2006). Capturing user requirements in medical device development: The role of ergonomics. *Physiological Measurement*, 27(8), R49 – 62.

Martin, J.L., Norris B.J., Murphy E., & Crowe, J.A. (2008) Medical device development: The challenge for ergonomics. *Applied Ergonomics*, 39(3), 271-283.

Mason, J. (2002). *Qualitative researching – 2nd edition*. London, UK: Sage Publications.

Mauthner, N.S. & Doucet, A. (2003). Reflexive accounts and accounts of reflexivity in qualitative data analysis. *Sociology*, 37(3), 413 – 431.

McGregor, S. (2001). Neoliberalism and health care. *International Journal of Consumer Studies*, 25(2), p. 82–89.

McManus, R.J., Ryan, A., Greenfield, S., Pattison, H.M., Clifford, S., Marriott, J., Wilson, S. (2007). Self measurement of blood pressure: a community survey. *Journal of Human Hypertension*, 21, 741 – 743.

MEDDEV 2. 4/1 Rev. 9. (2010). *Medical devices: Guidance document - Classification of medical devices*. European Commission, Directorate B, Unit B2: Cosmetics and medical devices.

Medicines and Healthcare Products Regulatory Agency (2014). *Devices in Practice: Checklists for using medical devices*. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403401/Devices_in_practice.pdf

Medicines and Healthcare Products Regulatory Agency (2013). *Blood pressure measurement devices*. DB 2006(03) v2.0; MHRA. Retrieved from: <http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2024245>

- Mihoc, A. & Walters, A. (2013). External barriers to user-centred development of bespoke medical devices in the UK. In A. Chakrabarti, & R.V. Prakash (Eds.) *ICoRD'13 Global Product Development* (pp.1039-1049). Lecture Notes in Mechanical Engineering: Springer.
- Miller, J. & Glassner, B. (2004). The 'inside' and the 'outside': Finding realities in interviews. In D. Silverman (Ed.), *Qualitative research: theory, method and practice – 2nd edition* (pp. 125 – 139). London, UK: Sage Publications.
- Miller, F.A., Sanders, C.B., & Lehoux, P. (2009). Imagining value, imagining users: Academic technology transfer for health innovation. *Social Science & Medicine*, 68, 1481–1488. Doi:10.1016/j.socscimed.2009.01.043.
- Mollering, G., 2001. The nature of trust: From Georg Simmel to a theory of expectation, interpretation and suspension. *Sociology*, 35, 403–420.
- Money, A., Barnett, J., Kuljis, J., Craven, M., Martin, J., & 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), 15.
- Money, A., Barnett, J., & Kuljis, J. (2011). Public claims about Automatic External Defibrillators: An online consumer opinions study. *BMC Public Health*, 11, 332.
- Money, A., Barnett, J., Kuljis, J., & Lucas, J. (2013). Patient perceptions of epinephrine auto-injectors: exploring barriers to use. *Scandinavian Journal of Caring Sciences*, 27, 335 – 344. doi: 10.1111/j.1471-6712.2012.01045.x.
- Montague, E.N.H. (2010). Validation of a trust in medical technology instrument. *Applied Ergonomics*, 41, 812–821.
- Montague, E.N.H., Kleiner, B.M., Winchester, W.W. (2009). Empirically understanding trust in medical technology. *International Journal of Industrial Ergonomics*, 39, 628 – 634.
- Montague, E.N.H., Winchester, W.W., & Kleiner, B.M. (2010). Trust in medical technology by patients and healthcare providers in obstetric work systems. *Behaviour & Information Technology*, 29(5), 541 – 554.

Moran, R. & Davidson, P. (2011). An uneven spread: A review of public involvement in the National Institute of Health Research's Health Technology Assessment program. *International Journal of Technology Assessment in Health Care*, 27(4), 343–347.

National Association for Home Care & Hospice (2010). *Basic statistics about home care*. Washington DC. Retrieved from http://www.nahc.org/assets/1/7/10HC_Stats.pdf

National Institute for Health and Clinical Excellence (2011). *Hypertension -The clinical management of primary hypertension in adults: Clinical Guideline 127*. London: National Institute for Health and Clinical Excellence. Retrieved from: <http://guidance.nice.org.uk/CG127>

National Patient Safety Agency (2010). *Design for patient safety: user testing in the development of medical devices*. Reference Number: 1184. Retrieved from: <http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=74946>

NVivo (2008). *Qualitative Data Analysis Software (Computer Programme)*. QSR International Pty Ltd: Version 9.

O'Brien, E., Asmar, R., Beilin, L., Imai, Y., Mallion, J.-M., Mancia, G., et al. (2003). European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. *Journal of Hypertension*, 21(5), 821-848.

Office for National Statistics (2013). *Internet Access - Households and Individuals, 2013*. Retrieved from: <http://www.ons.gov.uk/ons/rel/rdit2/internet-access---households-and-individuals/2013/stb-ia-2013.html>

Office for National Statistics (2012). *Measuring National Well-being, Education and Skills*. Retrieved from: <http://www.ons.gov.uk/ons/rel/wellbeing/measuring-national-well-being/education-and-skills/index.html>

Ong, K.L., Cheung, B.M.Y., Man, Y.B., Lau, C.P., & Lam, K.S.L. (2007). Prevalence, awareness, treatment, and control of hypertension among United States adults 1999– 2004. *Hypertension*, 49(1), 69 - 75. doi: 10.1161/01.hyp.0000252676.46043.18.

- Oudshoorn, N. & Pinch, T. (2003). Introduction: How users and non-users matter. In N. Oudshoorn & T. Pinch (Eds.), *How users matter: The co-construction of users and technology* (pp. 1 – 25). Cambridge: The MIT Press.
- Ovaisi, S., Ibison, J., Leontowitsch, M., Cloud, G., Oakeshott, P., & Kerry, S. (2011). Stroke patients' perceptions of home blood pressure monitoring: a qualitative study. *British Journal of General Practice*, e604-e610. doi: 10.3399/bjgp11X593893.
- Parasuraman, R., & Riley, V. (1997). Humans and automation: use, misuse, disuse, abuse. *Human Factors*, 39(2), 230–253.
- Parati, G., Stergiou, G. S., Asmar, R., Bilo, G., de Leeuw, P., Imai, Y., et al. (2008). European Society of Hypertension guidelines for blood pressure monitoring at home: a summary report of the Second International Consensus Conference on Home Blood Pressure Monitoring. *Journal of Hypertension*, 26(8), 1505 - 1526. Doi: 1510.1097/HJH.1500b1013e328308da328366.
- Patton, M.Q. (1990). *Qualitative evaluation and research methods – 2nd edition*. Newbury Park, CA: Sage.
- Peel, E., Douglas, M., & Lawton, J. (2007). Self monitoring of blood glucose in Type 2 diabetes: Longitudinal qualitative study of patients' perspectives. *British Medical Journal*, 335(7618), 493-496.
- Pickering, T.G., Miller, N.H., Ogedegbe, G., Krakoff, L.R., Artinian, N.T., Goff, D. (2008). Call to action on use and reimbursement for home blood pressure monitoring. *Hypertension*, 52, 1 – 9.
- Pinch, T.J. & Bijker, W.E. (1984). The social construction of facts and artefacts: Or how the sociology of science and the sociology of technology might benefit each other. *Social Studies of Science* 14, 399 – 441.
- Piper, H. & Simons, H. (2005). Ethical responsibility in social research. In B. Somekh & C. Lewin (Eds.), *Research methods in the social sciences* (pp. 56 – 63). London, UK: Sage Publications.
- Pollock, A., & Price, D. (2013). *Policy Paper - Duty to care: In defence of universal health care*. The Centre for Labour and Social Studies. Retrieved from:

[http://classonline.org.uk/docs/2013_05_Policy_Paper_-_A_duty_to_care_\(Allyson_Pollock_David_Price\).pdf](http://classonline.org.uk/docs/2013_05_Policy_Paper_-_A_duty_to_care_(Allyson_Pollock_David_Price).pdf)

Pollock, A., Price, D., & Roderick, P. (2012). Health and Social Care Bill 2011: A legal basis for charging and providing fewer health services to people in England. *British Medical Journal*, *344*, e1729. doi: 10.1136/bmj.e1729

Pollock, A., Price, D., & Roderick, P. & Treuherz, T. (2012). A flawed Bill with a hidden purpose. *The Lancet*, *379*, p. 999. DOI:10.1016/S0140-6736(12)60246-3.

Poon, I.O., Etti, N., & Lal, L.S. (2010). Does the use of home blood pressure monitoring vary by race, education, and income? *Ethnicity & disease*, *20*(1), 2 – 6.

Potter, J. & Hepburn, A. (2005). Qualitative interviews in psychology: Problems and possibilities. *Qualitative Research in Psychology*, *2*, 281 – 307.

Prainsack, B., Reardon, J., Hindmarsh, R., Gottweis, H., Naue, U., & Lunshof, J.E. (2008). Misdirected precaution. *Nature*, *456*(6), 34 – 35.

Preissle, J. (2008). Ethics. In L.M. Given (Ed.), *The Sage encyclopedia of qualitative research methods* (pp. 273 – 277). London, UK: Sage Publications.

Privitera, M.B. & Murray, D.L. (2009). *Applied ergonomics: Determining user needs in medical device design*. 31st Annual International Conference of the IEEE EMBS Minneapolis, Minnesota, USA, September 2-6.

Rafi, I., Qureshi, N., Lucassen, A., Modell, M., Elmslie, F., Kai, J.,...Hodgson, S. (2009). 'Over-the-counter' genetic testing: What does it really mean for primary care? *British Journal of General Practice*, *59*(561), 283 – 287.

Raftery, J., & Powell, J. (2013). Health Technology Assessment in the UK. *The Lancet*, *382*, 1278 – 1285.

Rajanen, M. (2003). *Usability Cost-Benefit Models – Different Approaches to Usability Benefit Analysis*. In proceedings of 26th Information Systems Research Seminar In Scandinavia (IRIS26), Haikko, Finland.

Ram, M.B., Grocott, P.R., & Weir, H.C.M. (2007). Issues and challenges of involving users in medical device development, *Health Expectations*, *11*, 63 – 71. Doi: 10.1111/j.1369-7625.2007.00464.x.

Research2guidance (2014, May). *mHealth app developer economics 2014 - The State of the art of mHealth app publishing: 4th annual study*. Retrieved from: <http://mhealthconomics.com/mhealth-developer-economics-report/>

Research and Markets (2010) [cited in UL, 2012]. *Home healthcare equipment: an overview*. Retrieved from: www.frost.com/prod/servlet/cpo/251073197

Rickerby, J. & Woodward, J. (2003). Patients' experiences and opinions of home blood pressure measurement. *Journal of Human Hypertension*, 17, 495-503.

Robinson, K., M. (2001). Unsolicited narratives from the Internet: A rich source of qualitative data. *Qualitative Health Research*, 11(5), 706 – 714.

Rogers, E.M. (1983). *Diffusion of Innovation – 3rd edition*. New York: The Free Press.

Roguin, A. (2006). Scipione Riva-Rocci and the men behind the mercury sphygmomanometer. *International Journal of Clinical Practice*, 60(1), 73 – 79.

Ronda, G., Portegijs, P., Dinant, G.-J., Buntinx, F., Norg, R., & van der Weijden, T. (2009). Use of diagnostic self-tests on body materials among Internet users in the Netherlands: prevalence and correlates of use. *BMC Public Health*, 9(1), 100. doi:10.1186/1471-2458-9-100.

Roulston, K. (2010). Considering quality in qualitative interviewing. *Qualitative Research*, 10, 199 – 228. DOI: 10.1177/1468794109356739.

Rubin, J. & Chisnell, D. (2008). *Handbook of usability testing: How to plan, design, and conduct effective tests - 2nd edition*. Wiley Publishing.

Ryan, A., Greenfield, S., McManus, R., & Wilson, S. (2006). Self-care - has DIY gone too far? *British Journal of General Practice*, 33, 907 – 908.

Ryan, A., Ives, J., Wilson, S., & Greenfield, S. (2010). Why members of the public self-test: an interview study. *Family Practice*, 27, 570 – 581. doi:10.1093/fampra/cm043.

Ryan, A., Wilson, S., & Greenfield, S. (2010). Prevalence of the use of self-tests by adults in the United Kingdom: a questionnaire survey. *Journal of Public Health*, 32(4), 519-525. doi: 10.1093/pubmed/fdq018

Ryan, A., Wilson, S., Greenfield, S., Clifford, S., McManus, R. J., & Pattison, H. M. (2006). Range of self-tests available to buy in the United Kingdom: an Internet survey. *Journal of Public Health, 28*(4), 370-374.

Ryan, A., Wilson, S., Taylor, A., & Greenfield, S. (2009). Factors associated with self-care activities among adults in the United Kingdom: a systematic review. *BMC Public Health, 9*, 96. doi:10.1186/1471-2458-9-96.

Sanders, C., Rogers, A., Bowen, R., Bower, P., Hirani, S., Cartwright, M., Fitzpatrick, R., et al. (2012). Exploring barriers to participation and adoption of telehealth and telecare within the Whole System Demonstrator trial: a qualitative study. *BMC Health Services Research, 12*, 220.

Saukko, P. (2013). State of play in direct-to-consumer genetic testing for lifestyle-related diseases: Market, marketing content, user experiences and regulation. *Proceedings of the Nutrition Society, 72*, 53 – 60.

Seale, C. (1999). Quality in qualitative research. *Qualitative Inquiry, 5*(4), 465-478.

Seale, C., Charteris-Black, J., MacFarlane, A., & McPherson, A. (2010). Interviews and Internet forums: A comparison of two sources of qualitative data. *Qualitative Health Research, 20*(5) 595 – 606. DOI: 10.1177/1049732309354094.

Shah, S.G.S., Barnett, J., Kuljis, J., Hone, K., & Kaczmarek, R. (2013). Factors determining patients' intentions to use point-of-care testing medical devices for self-monitoring: the case of international normalized ratio self-testing. *Patient Preference and Adherence, 7*, 1 – 14.

Shah, S.G.S., Robinson, I. (2006). User involvement in healthcare technology development and assessment: Structured literature review. *International Journal of Health Care Quality Assurance, 19*(6), 498 – 513.

Shah, S.G.S., Robinson, I. (2007). Benefits of and barriers to involving users in medical device technology development and evaluation. *International Journal of Technology Assessment in Health Care, 23*(1), 131–137. DOI: <http://dx.doi.org/10.1017/S0266462307051677>.

- Shah, S. G. S., & Robinson, I. (2011). Patients' perspectives on self-testing of oral anticoagulation therapy: Content analysis of patients' internet blogs. *BMC Health Services Research, 11*, 25. doi:10.1186/1472-6963-11-25.
- 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), 514–521. doi: 10.1017/S0266462309990328.
- Shank, G. (2008a). Deduction. In L.M. Given (Ed.), *The Sage encyclopedia of qualitative research methods* (pp. 207 – 208). London, UK: Sage Publications.
- Shank, G. (2008b). Abduction. In L.M. Given (Ed.), *The Sage encyclopedia of qualitative research methods* (pp. 1 – 2). London, UK: Sage Publications.
- Sharples, S., Martin, M., Lang, A., Craven, M., O'Neill, S., & Barnett, J. (2012). Medical device design in context: A model of user–device interaction and consequences. *Displays, 33*, 221 – 232.
- Shove, E., Pantzar, M., & Watson, M. (2012). *The dynamics of social practice: Everyday life and how it changes*. London: Sage.
- Siegrist, M. (2000). The influence of trust and perceptions of risks and benefits on the acceptance of gene technology. *Risk Analysis, 20*(2), 195 – 203.
- Silverstone, R., & Haddon, L. (1996). Design and the domestication of technologies: Technical change and everyday life. In R. Mansell & R. Silverstone (Eds.), *Communication by design: The politics of information and communication technologies* (pp. 44-74). Oxford: Oxford University Press.
- Silverstone, R., & Hirsch, E. (Eds.). (1992). *Consuming technologies: Media and information in domestic spaces*. London: Routledge.
- Silverstone, R., Hirsch, E., & Morley, D. (1992). Information and communication technologies and the moral economy of the household. In R. Silverstone & E. Hirsch (Eds.), *Consuming technologies: Media and information in domestic spaces* (pp. 15–31). London: Routledge.

- Smith, M.J. (2006). Realism. In V. Jupp, (Ed.), *The Sage Dictionary of Social Research Methods* (pp. 254 – 257). London, UK: Sage Publications.
- Soghikian, K., Casper, S. M., Fireman, B. H., Hunkeler, E. M., Hurley, L. B., Tekawa, I. S., & Vogt, T. M. (1992). Home blood pressure monitoring: Effect on use of medical services and medical care costs. *Medical Care*, 30(9), 855 – 865.
- Spencer, L., Ritchie, J., Lewis, J., & Dillon, L. (2003). *Quality in qualitative evaluation: A framework for assessing research evidence*. Government Chief Social Researcher's Office. Retrieved from: http://www.civilservice.gov.uk/wp-content/uploads/2011/09/a_quality_framework_tcm6-38740.pdf
- Stake, R.E. (2005). Qualitative case studies. In N.K. Denzin & Y.S. Lincoln (Eds.), *The Sage handbook of qualitative research - 3rd edition* (pp. 443 – 466). London, UK: Sage Publications.
- Steinke, F., Fritsch, T., & Silbermann, L. (2012). Trust in Ambient Assisted Living (AAL) - A systematic review of trust in automation and assistance systems. *International Journal on Advances in Life Sciences*, 4(3 & 4), 77 – 88.
- Steventon, A., Bardsley, M., Billings, J., Dixon, J., Doll, H., Hirani, S., Cartwright, M., et al. (2012). Effect of telehealth on use of secondary care and mortality: findings from the Whole System Demonstrator cluster randomised trial. *British Medical Journal*, 344, e3874. doi: 10.1136/bmj.e3874.
- Stone, L. (2008). Epistemology. In L.M. Given (Ed.), *The Sage encyclopedia of qualitative research methods* (pp. 264 – 268). London, UK: Sage Publications.
- Suanet, B., Van Groenou, M.B., Van Tilburg, T. (2012). Informal and formal home-care use among older adults in Europe: can cross-national differences be explained by societal context and composition? *Ageing & Society*, 32, 491 – 515. DOI:10.1017/S0144686X11000390.
- Tarricone, R., & Tsouros, A. (2008). *The solid facts: Home care in Europe*. Milan, Italy: World Health Organization.

Thomé, B., Dykes, A.K., Hallberg, I.R. (2003). Home care with regard to definition, care recipients, content and outcome: Systematic literature review. *Journal of Clinical Nursing*, 12, 860 – 872.

Thomson, R., Martin, J.L., & Sharples, S. (2013). The psychosocial impact of home use medical devices on the lives of older people: a qualitative study. *BMC Health Services Research*, 13, 467. doi:10.1186/1472-6963-13-467.

Thorpe, R. (2008). Field notes. In R. Thorpe & R. Holt (Eds.), *The Sage dictionary of qualitative management research* (pp. 97 – 99). London, UK: Sage Publications.

Timmermans, S., & Berg, M. (2003). The practice of medical technology. *Sociology of Health & Illness*, 25, 97 – 114.

Timmons, S., Harrison-Paul, R., & Crosbie, B. (2008). How do lay people come to trust the Automatic External Defibrillator? *Health, Risk & Society*, 10(3), 207-220. DOI: 10.1080/13698570802160939

Tislér, A., Dunai, A., Keszei, A., Fekete, B., Othmane, T. E. H., Torzsa, P., & Logan, A. G. (2006). Primary-care physicians' views about the use of home/self blood pressure monitoring: nationwide survey in Hungary. *Journal of Hypertension*, 24(9), 1729-1735. DOI: 1710.1097/1701.hjh.0000242396.0000215097.f0000242393.

Topman, D. (2003). *Medical devices: The UK Industry and its technology development*. Loughborough, UK: PRIME Faraday Partnership. Retrieved from: http://www.lboro.ac.uk/microsites/mechman/research/ipm-ktn/pdf/Sector_profile/medical-devices-the-uk-industry-and-its-technology-development.pdf

UK Data Forum (2013). *UK Strategy for Data Resources for Social and Economic Research 2013-2018: A five-year plan to inform and guide the development and utilisation of data and related resources for social and economic research*. Retrieved from: <http://www.esrc.ac.uk/research/data/ukdf/> Last accessed: 7 July 2014

UK Home Care Association (2013). *An overview of the UK domiciliary care sector*. Retrieved from: <http://www.ukhca.co.uk/pdfs/domiciliarycaresectoroverview.pdf>

U.S. Congress Office of Technology Assessment (1976). *Development of medical technology: Opportunities for assessment*. Washington, DC: U.S. Government Printing Office. Retrieved from: http://govinfo.library.unt.edu/ota/Ota_5/DATA/1976/7617.PDF

Vasileiou, K., Barnett, J., & Young, T. (2013). Interpreting and acting upon home blood pressure readings: A qualitative study. *BMC Family Practice, 14*, 97. doi:10.1186/1471-2296-14-97

Veinot, T. (2010). Power to the patient? A critical examination of patient empowerment discourses. In R. Harris, N. Wathen, & S. Wyatt (Eds.), *Configuring health consumers: Health work and the imperative of personal responsibility* (pp. 30 – 41). Hampshire, UK: Palgrave Macmillan.

Verberk, W.J., Kroon, A.A., Kessels, A.G.H., & de Leeuw, P.W. (2005). Home blood pressure measurement: a systematic review. *Journal of the American College of Cardiology, 46*(5), 743 - 751.

Viera, A.J., Cohen, L.W., Mitchell, C.M., Sloane, P.D. (2008). Use of home blood pressure monitoring by hypertensive patients in primary care: survey of a practice-based research network cohort. *The Journal of Clinical Hypertension, 10*(4), 280 – 286.

Vincent, C. J., Li, Y., & Blandford, A. (2014). Integration of human factors and ergonomics during medical device design and development: It's all about communication. *Applied Ergonomics, 45*, 413–419.

Walker, G., Cass, N., Burningham, K., & Barnett, J. (2010). Renewable energy and sociotechnical change: imagined subjectivities of 'the public' and their implications. *Environment and Planning A, 42*, 931 – 947.

Wanless, D. (2002). *Securing our future health: Taking a long-term view – final report*. London, England: HM Treasury. Retrieved from: <http://www.yearofcare.co.uk/sites/default/files/images/Wanless.pdf>

Wilkinson, A., & Whitehead, L. (2009). Evolution of the concept of self-care and implications for nurses: A literature review. *International Journal of Nursing Studies 46*, 1143–1147. doi: 10.1016/j.ijnurstu.2008.12.011.

Williams, A. (2002). Changing geographies of care: Employing the concept of therapeutic landscapes as a framework in examining home space. *Social Science & Medicine*, 55(1), 141-154. doi: [http://dx.doi.org/10.1016/S0277-9536\(01\)00209-X](http://dx.doi.org/10.1016/S0277-9536(01)00209-X)

Willig, C. (2013). *Introducing qualitative research in psychology* - 3rd edition. Berkshire, UK: Open University Press.

Wilson, S., Ryan, A., Greenfield, S., Clifford, S., Holder, R., Pattison, H., . . . McManus, R. (2008). Self-testing for cancer: a community survey. *BMC Cancer*, 8(1), 102. doi:10.1186/1471-2407-8-102.

Wolf-Maier, K., Cooper, R. S., Banegas, J. R., Giampaoli, S., Hense, H.-W., Joffres, M., et al. (2003). Hypertension prevalence and blood pressure levels in 6 European countries, Canada, and the United States. *JAMA: The Journal of the American Medical Association*, 289(18), 2363 - 2369. doi:10.1001/jama.289.18.2363.

Woolgar, S. (1990). Configuring the user: The case of usability trials. *Sociological Review*, 38, 58 - 99. DOI: 10.1111/j.1467-954X.1990.tb03349.x

World Health Organisation (2009). *Self-care in the context of primary health care: Report of the Regional Consultation Bangkok, Thailand*. New Delhi: World Health Organization, Regional Office for South East Asia. Retrieved from: http://www.searo.who.int/entity/primary_health_care/documents/sea_hsd_320.pdf

World Health Organisation (2011). *Global status report on non-communicable diseases 2010*. Geneva: WHO Press. Retrieved from: http://www.who.int/nmh/publications/ncd_report_full_en.pdf

Wyatt, S. (2003). Non-users also matter: The construction of users and non-users of the Internet. In N. Oudshoorn & T. Pinch (Eds.), *How users matter: The co-construction of users and technology* (pp. 67 – 79). Cambridge: The MIT Press.

Yach, D., Hawkes, C., Gould, C., & Hofman, K.J. (2004). The global burden of chronic diseases: Overcoming impediments to prevention and control. *The Journal of the American Medical Association*, 291(21), 2616-2622. doi: 10.1001/jama.291.21.2616

Yardley, L. (2000). Dilemmas in qualitative health research. *Psychology & Health*, 15(2), 215-228, DOI: 10.1080/08870440008400302.

Yarows, S.A., Julius, S., & Pickering, T.G. (2000). Home blood pressure monitoring. *Archives of Internal Medicine*, 160, 1251-1257.

Ybema, S., Yanow, D., Wels, H., & Kamsteeg, F. (2010). Ethnography. In A.J. Mills, G. Eurepos, & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 347 – 351). London, UK: Sage Publications.

Yin, R.K. (2011). *Qualitative research from start to finish*. New York, NY: The Guildford Press.


Young, T.P. & McClean, S.I. (2008). A critical look at Lean Thinking in healthcare. *Quality and Safety in Health Care*, 17(5), 382 – 286. doi:10.1136/qshc.2006.020131.

Ziefle, M., Röcker, C., & Holzinger, A. (2011). *Medical technology in smart homes: Exploring the user's perspective on privacy, intimacy and trust*. Paper presented at the 35th IEEE Annual Computer Software and Applications Conference Workshops. DOI 10.1109/COMPSACW.2011.75.

Ziguras, C. (2004). *Self-care: Embodiment, personal autonomy and the shaping of health consciousness*. London, UK: Routledge


APPENDIX A

Study advert for recruiting users of home blood pressure monitors



Brunel
UNIVERSITY


Research Study Advertisement



MATCH[®]

Have you ever bought a blood pressure monitor?

Do you monitor your blood pressure at home?



Would you be willing to talk to us about this?

What is this study about? Increasingly, there are medical devices that can be bought and used without necessarily needing to be advised by a doctor. Studies show that **Home Blood Pressure Monitors** are used by 10% of the population in the UK. This study is designed to explore people's experiences of using **home blood pressure monitors**.

Who is conducting this study? Julie Barnett (Reader in Healthcare Research) and Konstantina Vasileiou, (PhD research student) in the School of Information Systems & Computing at Brunel University.

Who can participate in this study? People over 18 who have purchased a home blood pressure monitor and are using it for measuring their blood pressure levels.

What does it involve? At the first stage, people will be asked to fill in a short questionnaire. This will gather some basic information which will help to ensure that people are eligible and willing to take part in the study. In a second stage, people will be invited to take part in a one-to-one interview discussion which will take 45-60 minutes. At this stage people will need to bring their home blood pressure monitor with them. On completion of the study, all participants will receive a **£15 voucher** in recognition of their contribution to this research.

What do I do if I would like to take part?
Please contact: Konstantina Vasileiou
E-mail: Konstantina.Vasileiou2@brunel.ac.uk
Mobile phone: 07516 09 90 34

APPENDIX B

Screening questionnaire



Home Blood Pressure Monitors Questionnaire

The aim of this questionnaire is to gather some basic information about your home blood pressure monitor. There are also a few questions about you. This information will help me to confirm your eligibility to take part in this interview study. At the end of this questionnaire, you will be asked to confirm that you would be interested in taking part in an interview about how you use your blood pressure monitor. We ask you provide your contact details so that if you are eligible and if you would like to take part, the researcher can contact you to arrange a convenient time. Please, note that all this information will be held and processed in the strictest confidence and in accordance with the Data Protection Act (1998). Only the researcher conducting this study will know your name. Other people involved in this project will not have access to your personal information.

Section 1: Your home blood pressure monitor

1. Do you own a home blood pressure monitor? Yes No
2. Did you buy your home blood pressure monitor yourself? Yes No

If Yes - please go to question 5

3. If you have not personally purchased your home blood pressure monitor, did another person (e.g. relative, friend) make that purchase on your behalf?

Yes No

4. If your answers in questions 2 and 3 were "NO", how did you come to own your home blood pressure monitor?

Please, briefly explain here

.....

5. When did you buy your home blood pressure monitor? Month Year

6. In general, how often do you use your home blood pressure monitor?

- At least once a day
- A few times per week (please specify how many times.....)
- About once a week
- About once every two weeks
- About once a month
- Once every two months
- Other (please specify.....)

7. What type of home blood pressure monitor do you have?

- Automatic (*or digital, these monitors have a display screen that shows the results in numerical forms*)
- Manual (*or aneroid, these monitors include arm cuff, a squeeze bulb for inflation, a stethoscope or microphone, and a medical gauge to measure the blood pressure. It is the type of monitor that most doctors use*)
- I do not know what type of blood pressure monitor it is

8. Is your home blood pressure monitor validated? (*Being validated means that it has gone through a series of tests to make sure it gives accurate and reliable results*)

- Yes
 No
 I do not know

9. What is the brand of your home blood pressure monitor?

Please specify here.....

10. What was the cost of your home blood pressure monitor?

- Less than £50
 Between £50 and £100
 More than £100

11. What would you say was the main reason for purchasing your home blood pressure monitor?

Please specify here.....

.....

.....

12. Has your healthcare professional (e.g. doctor, nurse) ever noticed any problem with your blood pressure?

Yes No

13. What was that?

Please specify here.....

.....

.....

Section 2: Your background information

1. Gender

Female

Male

2. My age in years is:

3. Currently I am:

Employed

Unemployed

Retired

Other (Please specify.....)

4. My nationality is (e.g. British, French):

5. What is your highest educational qualification?

Degree or degree equivalent and above

Higher education to less than degree level (e.g. HND)

A level/Scottish Higher/Vocational level 3 and equivalent

O level/GCSE/Vocational level 2 and equivalent

No qualifications

6. What is your marital status?

Single

Married

Divorced

Section 3: My contact details

As mentioned earlier, this questionnaire will help me make sure that the people who will be invited to take part in this research are those that are eligible and that would like be interviewed. In this last section, you are asked to provide your contact details so that the researcher can get in touch with you.

Consent

I consent to my personal details being held by the researcher conducting this study so as she will be able to contact me for inviting me to take part in the second stage of this research, which consists of an interview discussion.

At this stage I am just saying that I would like to receive more details, **I am NOT consenting to take part in the interview** and I understand that I am under no obligation to do this if I am invited to do so.

I understand that all personal data relating to research participants is held and processed in the strictest confidence, and in accordance with the Data Protection Act (1998).

Signed _____ Date _____

Name (block capitals please) _____

Adress _____

Contact phone number _____

Best time to contact _____

Thank you very much for your time!

APPENDIX C

Participant Information Sheet

Department of Information Systems & Computing

Brunel University

Study title: “Embedding home use medical technology into daily life: The case of home blood pressure monitors”

Interview Information Sheet

Dear participant,

Thank you for considering taking part in this study.

You are kindly being invited to participate in a research study conducted by Konstantina Vasileiou. Before you decide whether or not to take part, it is important to understand why the research is being done and what it will involve. **Please take time to read the following information.**

What is the purpose of the study?

The aim of this study is to gain a better understanding of how people integrate into their daily lives medical technologies which are designed to be used outside the clinical environment, such as the home. More specifically, I am interested in a) how people decide to buy a home blood pressure monitor, b) how they incorporate this device into their daily routines and b) whether the home blood pressure monitor and the practice of blood pressure measurement play any role in how people perceive and feel of themselves. Thus far, there is little appreciation in the literature of how users of home blood pressure monitors interact with and experience this kind of medical technology. Consequently, I hope that through this study I will gain better insights of users’ needs and

perceptions. The results can then be used to inform designers and manufacturers of home use medical technologies, so as these devices can be improved according to users' needs.

What will happen if I take part?

At the start of the process, you will be asked to complete a short form, asking you to consent to taking part in this study, and to provide some basic information about you such as your contact details.

Then you will be asked to discuss in a one-to-one interview your experiences of buying and using a home blood pressure monitor and of engaging with the practice of blood pressure measurement. Please note that you will not be asked questions for which there is a right or wrong answer. I am only interested in your experiences and personal views. **The interview is expected to last 60 minutes and it will be audio-recorded.**

What should I know if I take part?

It is important to be aware of and understand **your rights as a participant** in this research:

1. Your participation in this study is **entirely voluntary**
2. You have the right **to withdraw from the study at any time** during the process, without any penalty and without having to give any reason for this. Just let the researcher know about that.
3. The data you will provide will be **stored securely and will be destroyed on completion of the research.**
4. At the start of the process, you will be given a number, and **only the researcher** conducting the interview **will know your identity.**
5. Other people involved in this project will never see your name.
6. The data will be kept **strictly confidential** and will be used **exclusively for research purposes**, as part of the researcher's doctoral training

7. The researcher **will not identify you by name** in any report or scientific publication that use information obtained from this interview. Any quotes that may be used from this interview will be **anonymous**.
8. Even if you completed the study, but later on you decided that you do not want your data to be used, contact the researcher and she **will destroy immediately all records** of the information you have provided.
9. You will receive a £15 voucher on completion of the interview, as a token of our appreciation for taking part in this study.

Has an authorised body approved of this study?

This study has obtained ethical approval from the *Research Ethics Committee of Brunel University* and complies with the *Code of Ethics and Conduct* of the British Psychological Society.

Who is organising and funding this research?

This study is part of my doctoral training I am undertaking in the department of Information Systems and Computing at Brunel University, and is supervised by Dr Julie Barnett and Prof. Terry Young. This research is funded by the *Multidisciplinary Assessment of Technology Centre for Healthcare* (MATCH).

Contact details of the researcher

Please contact me for further information or questions you may have:
 E-mail address: Konstantina.Vasileiou2@brunel.ac.uk
 Mobile: 07516 09 90 34

Thank you very much for your time!

Date.....

Location.....

APPENDIX D

Participant Consent Form

Department of Information Systems & Computing

Brunel University

***“Embedding home use medical technology into daily life:
The case of home blood pressure monitors”***

Consent Form

Researcher’s name: Konstantina Vasileiou
Time:
Time:
Location:

Participant ID/Data record number	
--	--

Please, read carefully each of the statements below and circle the option (YES or NO) that best describes your view.

1. I volunteer to take part in this study conducted by Konstantina Vasileiou, PhD student at Brunel University	YES	NO
2. I understand the purpose of the present study and the process of my participation	YES	NO
3. I was provided with enough information and sufficient time to understand the aim and the process of the present study and all my questions were answered to my satisfaction	YES	NO

4. I am aware of my right to withdraw from the study at any time without penalty and without having to give reason for this	YES	NO
5. I am aware of and agree to the interview being audio-recorded	YES	NO
6. I understand that the researcher will not identify me by name in any report or scientific publication that use information obtained from this interview, and that my confidentiality in this study will remain secure	YES	NO
7. I am aware of and agree to being compensated for my participation in this study with a £15 voucher on completion of the interview	YES	NO
8. I have read and understood all the documents provided to me, and I voluntarily agree to take part in this study	YES	NO

Participant's signature	
Printed name (in capitals)	
Contact number	
Address	
E-mail	

Researcher's signature.....

APPENDIX E

Participant Debriefing Letter

Department of Information Systems & Computing

Brunel University

Study title: “Embedding home use medical technology into daily life: the case of home blood pressure monitors”

Debriefing Letter

Dear participant,

First of all, I would like to thank you very much for taking part in this study!

This letter aims to give you some more information about this study.

My general research area lies in the domain of medical technology and more specifically in the medical devices that were used to be used by doctors and healthcare professionals, but now increasingly are used by people at their homes. I am interested in examining users’ perceptions and needs when interacting with such medical devices in order to gain useful insights from their point of view. These results then can help designers and manufacturers of home use medical devices to improve their products.

In this study, I am focusing on home blood pressure monitors and I am using this device as an example of home use medical technology. Home blood pressure monitors are widely used, as a recent study in the UK showed (around 10% of the population), and are often bought “over-the-counter”, that is, from a shop or online. Hypertension on the other hand affects a very high percentage of the population. About 25% of people in this country have high blood pressure and thus it is very likely that many will use this technology to monitor their blood pressure levels. For these

reasons, I consider that it is important to understand in more depth peoples' views about home blood pressure monitors.

Thus far, research has examined the clinical and cost effectiveness of home blood pressure monitors, as well as people's satisfaction. The evidence is encouraging and shows that home blood pressure monitors are related to positive health impacts and high levels of users' satisfaction. However, we know very little about the detail of how people use it and how they feel about this. This is what this study tries to answer and the method of interviewing was thought to be the most appropriate for getting this information.

If you have any further questions please contact me:

E-mail address: Konstantina.Vasileiou2@brunel.ac.uk

Mobile: 07516 09 90 34

The researcher: Konstantina Vasileiou

APPENDIX F

Interview Protocol

Section I. Issues around the purchase and ownership of the Home Blood Pressure Monitor (HBPM) were examined in this section.

1. Please, tell me a little bit about why you decided to buy a home blood pressure monitor (HBPM)

Prompt: What would you say were the main triggers for you to buy a HBPM?

Prompt: Did you instigate this or your doctor?

2. How long ago did you buy your HBPM?

3. Did you have any reservations about buying a HBPM, at the time?

4. Thinking back at the time, do you remember in what ways you had searched for your BPM?

Prompt: Did you ask advice from your doctor about this product?

Prompt: Did you search information on the internet?

5. What were the factors that you took into account in order to make your purchase?

Prompt: What made you choose the one you did?

Prompt: Was the cost of the product important for you?

Prompt: Did you prefer any specific type of HBPM (automatic/manual)?

Prompt: Did the brand play any role in your purchase?

6. If I asked you to think about your HBPM, what do you like about it?

7. What don't you like about your HBPM?

Prompt: Do you have any difficulty when you use it? Or is it generally easy in use?

Prompt: Do you feel confident when you use it?

Prompt: If a designer asked you, as a user of this device, to recommend any changes in the features of your HBPM, what would be those changes?

Section II. Issues around the storage/display of the device within the home environment and carriage outside this were explored in this section.

1. Are there any times that you take your HBPM with you, outside the home?

Prompt: If yes - When does this happen?

Prompt: If yes - In what places do you usually take your HBMP?

2. Where do you usually keep or store you HBPM within your home?

Prompt: Do you keep it out or do you put it away?

Section III. Patterns of device use were examined in this section.

1. How often do you use this machine and why?
2. Is there any particular time of the day?
3. Are there times that you may forget to measure your blood pressure?
4. How many readings are you taking every time you measure your blood pressure?

Prompt: For example, some people say that they are taking two readings. Is this something that you also do?

5. Do you keep a record of your readings?
6. Is it ever inconvenient for you?

Prompt: Does this cause any inconvenience to you at the expense of something else? Or is it generally well-embedded in your life?

Prompt: Are you taking a certain physical position in order to measure your blood pressure?

Prompt: Is this easy for you or do you have difficulties?

Prompt: Do you ever encounter disruptions in your home when you are measuring your blood pressure?

Section IV. In this section it was investigated whether participants discussed with other people that they owned and were using a HBPM.

1. Do other people know that you measure your blood pressure? For example, your friends or family?
2. Is it important for you that other people know / do not know?
3. Why?

Section V. The implications of home monitoring on the relationship with healthcare professionals were examined in this section.

1. Would you say that the practice of measuring your blood pressure at home has changed in any way your relationship with your doctor?

Prompt: For example, some people say that they go more often to their doctor, while others less often. What would you say that happens in your case?

2. [If HBPM was bought without medical prompt] Have you discussed with your doctor that you are measuring your blood pressure?

Prompt: [If not] Why?

3. [If HBPM was bought after medical prompt] Do you generally discuss your readings with your doctor?

Section VI. The way people made sense of home readings and the actions they were taking as a result of this were explored here.

Now I would like us to focus on the readings you are taking from your monitor. Specifically, I am interested in how you make sense of the readings you get.

1. How and when do you know that your blood pressure is normal?
2. When would you be concerned about the readings you are getting?

Prompt: What would you worry you?

3. What do you usually do when your readings are not so good?
4. How do you know that your readings are trustworthy?

Prompt: How do you know that your monitor tells you the truth?

Section VII. The potential impact of home monitoring on images of self and on health management was explored here.

1. If I asked you to think back before you had bought and started using your HBPM, did you have any specific thoughts about the device or the way you would use it?

Prompt: How did you expect at that time that this experience would look like?

Prompt: Did your monitor meet your expectations?

2. More generally, would you say that having this machine and measuring your blood pressure, has changed the way you feel about yourself or your health?

Prompt: For example, some people say that they have more control over their health. What is your view?

APPENDIX G

Data extraction form

Thread 1

Name of Forum	
Title of thread	
Sequence of topics within which thread was found	
Internet link	
Country where forum was created	
Dates during which discussion was developed	
Number of posts	
Number of participants	
Online community information	

[] within brackets my own interventions/guesses that help to convey the meaning of the post.

No	Date	Participant	Post content
1			
2			
3			
4			
5			
6			
...			
n			

APPENDIX H

Forums focusing on health conditions							
Forum #	Health condition	Forum Name	Thread title	N of postings	N of participants	Dates	Country
1	Diabetes	Diabetes.co.uk	How accurate are blood pressure monitors?	23	14	14 Sep 2011 – 21 Oct 2013	UK
2	Diabetes	DiabetesSupport.co.uk	Home blood pressure monitors - case proven	19	10	5 Oct 2010 – 8 Oct 2010	UK
3	Diabetes	Diabetes Daily	Home Blood Pressure Monitor	10	9	23 Jun 2012 – 24 Jun 2012	USA
4	Diabetes	Diabetes Daily	Monitoring Blood Pressure	9	4	7 Sep 2006 – 9 Sep 2006	USA
5	Diabetes	DiabetesForum.com	Home Blood Pressure Monitor?	16	11	31 Jul 2013 – 1 Aug 2013	USA
6	Anxiety disorders	No more panic	never buy home blood pressure monitors	23	18	16 Jun 2011 – 29 Jul 2011	UK
7	Anxiety disorders	No more panic	Blood Pressure Monitoring at Home	17	9	04 Jun 2005 – 22 Oct 2005	UK
8	Anxiety disorders	PanicSurvivor.com	Blood pressure monitor	3	3	25 Jun 2009 – 25 Jun 2009	USA
9	Heart disease	ValveReplacement.org	Home Blood Pressure Monitor recommendations?	12	10	20 Jan 2011 – 25 Jan 2011	USA
10	Renal disease	KidneyPatientGuide.org.uk	Blood Pressure Monitors	12	8	4 May 2009 – 7 May 2009	UK
Forums focusing on sport activities & fitness							
Forum #	Activity	Forum Name	Thread title	N of postings	N of participants	Dates	Country
11	Running	FellRunner.org.uk	Home blood pressure monitors	11	9	20 Jan 2012 – 27 Mar 2012	UK
12	Cycling	BikeForums.net	Home Blood Pressure Monitor	37	24	17 Aug 2007 – 22 Aug 2007	USA
13	Bodybuilding	EliteFitness.com	Home Blood pressure monitor	12	8	10 Mar 2004 – 10 Mar 2004	USA
14	Bodybuilding	UGBodybulding.com	Blood pressure monitors	16	9	9 Oct 2013 – 13 Feb 2014	USA
15	Bodybuilding	UK-Muscle.co.uk	Best & Cheapest Blood Pressure Monitors?	6	5	16 Jul 2012 – 16 Jul 2012	UK
16	Fitness training	Traning.fitness.com	Blood pressure monitor	7	6	25 Aug 2007 – 22 Sep 2007	USA
Forums focusing on health and well-being							
Forum #	Forum Focus	Forum Name	Thread title	N of postings	N of participants	Dates	Country
17	Offers nutrition, health, and fitness tools & support	sparkpeople.com	Home Blood Pressure Monitor	13	8	8 Mar 2010 – 27 Mar 2010	USA
18	Online health community that assists with the exchange of information around health	ehealth.forum.com	Blood pressure monitors	2	2	29 May 2004 – 24 Jul 2004	USA
19	Complementary therapy resource for professionals offering and people seeking natural health solutions	healthy.pages.com	24 hour blood pressure monitor	9	5	1 Nov 2012 – 14 Jun 2013	UK
20	A friendly community of dieters doing 'The Fast Diet', a form of intermittent fasting for weight loss & various health benefits	The 5:2 fast diet forum	Blood Pressure Readings	7	6	25 Oct 2013 – 2 Nov 2013	UK

Forums focusing on aspects of a woman's life							
Forum #	Forum focus	Forum Name	Thread title	N of postings	N of participants	Dates	Country
21	Targets pregnant women	PregnancyForum.co.uk	Home Blood pressure monitor	11	5	13 Dec 2005 – 16 Dec 2005	UK
22	Targets new mothers & and women who intend to become mothers	Emmasdiary.co.uk	bought a blood pressure monitor and done my own reading!!!!	3	2	21 Mar 2006 – 22 Mar 2006	UK
23	Targets grandmothers	Grannynet.co.uk	Blood pressure monitoring	26	13	19 May 2012 – 20 May 2012	UK
24	Targets 35+ women	womanandhome.com	Blood pressure monitors	12	10	22 Oct 2009 – 24 Oct 2009	UK
25	Targets 35+ women	womanandhome.com	Blood pressure monitors	13	11	11 Feb 2009 – 12 Feb 2009	UK
Forums focusing on technology							
Forum #	Forum focus	Forum Name	Thread title	N of postings	N of participants	Dates	Country
26	Serves the needs of readers looking for reviews on PC components, smartphones, tablets, pre-built desktops, notebooks, Macs and enterprise/cloud computing technologies	Anandtech.com	Home blood pressure monitors	25	10	29 Oct 2012 – 31 Oct 2012	USA
27	Digital Spy focus on news and conversation about entertainment, technology and the media.	digitalspy.co.uk	Blood pressure monitor (for home use) recommendations.	14	9	24 Sep 2011 – 24 Sep 2011	UK
28	Both an internet community where people discuss Audio-Visual home consumer electronics and a resource of AV products, technology, movie and gaming news, reviews and articles	avforums.com	Anyone use a home blood pressure monitor?	65	18	30 July 2013 - 14 Jan 2014	USA
29	Addresses PC community - computer & lifestyle discussion topics	overclockers.co.uk	Spec me a blood pressure	13	10	28 Mar 2007 – 28 Mar 2007	UK
Forums focusing on financial issues							
Forum #	Forum focus	Forum Name	Thread title	N of postings	N of participants	Dates	Country
30	Provides money saving guides, tips, tools and techniques	MoneySavingExpert.com	Digital Blood Pressure Monitor	33	17	26 Dec 2006 – 10 Mar 2011	UK
31	A non-commercial investing forum	Bogleheads.org	Accurate home blood pressure monitor?	35	25	8 Sep 2010 – 14 Sep 2010	USA
Miscellaneous							
Forum #	Forum focus	Forum Name	Thread title	N of postings	N of participants	Dates	Country
32	Forum for pilots	Professional Pilots Rumour Network (pprune.org)	Home blood pressure monitors...any good.	35	25	1 Dec 2012 – 3 Dec 2012	Not clear
33	Discussions about gardening & home	Gardenweb.com	What Blood Pressure Cuff to Purchase?	15	13	20 Aug 2013 – 21 Aug 2013	USA
34	A source for the latest celebrity news, celebrity pics, TV show spoilers, movie reviews, make-up tips and fashion advice	jib.yuku.com	Are wrist blood pressure monitors accurate?	12	7	30 Oct 2012 – 30 Oct 2012	USA
35	Forum for those interested in visiting, living, or working in Thailand	thaivisa.com	Home Blood Pressure Monitor	12	8	18 Oct 2010 – 24 Oct 2011	Not clear

APPENDIX I

E-mail inviting employees to participate in ethnographic interviews

Dear [Name of employee]

You are being invited to kindly take part in my PhD research that I am conducting as part of my internship in ComX. Specifically, I am inviting you to discuss with me, in the context of an interview, aspects of your work that are relevant to the needs of people who use a home blood pressure monitor.

Please find attached:

1. The participant information sheet which will give you more information about the study and the process of the interview
2. The informed consent that you would need to sign and agree to if you are willing to take part.
3. An outline of the areas/questions I would like us to discuss.

I would really appreciate if you could take some time to read these documents and let me know if you would be willing to take part in my research.

Please do not hesitate to contact me if you have any questions or enquiries.

Thank you very much for your time

APPENDIX J

PARTICIPANT INFORMATION SHEET

TITLE OF STUDY

“Exploring the medical device manufacturer’s efforts to understand and take into account the needs of users of medical technology: An ethnographic approach using the case of home blood pressure monitors”

Dear [name of the employee],

You are being invited to kindly participate in my study which I conduct in the context of my PhD research. Please take your time to read the following information that will help you to understand why I am doing this study and what it involves. Please contact me if you have any questions or enquiries.

WHAT IS THE CONTEXT AND THE AIM OF THIS STUDY?

As part of my internship in ComX, I am conducting ethnographic research. The aim of this is to explore the ways through which the medical device manufacturer attempts to understand its end-user and to incorporate their needs into the medical technology. I am focusing on home blood pressures monitor as an example of home medical technology.

I am using three ways to collect relevant information to help me achieve the aim of this research:

- **Participant observation:** essentially this is achieved through my participation in the “2nd channel project” whereby I have the opportunity to observe and support the day-to-day activities, mostly those that are linked to user needs research.
- **Documentary analysis:** I am going to analyse Instruction Manuals of home blood pressure monitors as well as other available documents in an effort to look at the ways your organisation understands its user.
- **Qualitative interviews with ComX employees:** this is the last method of data collection that I am using and it is that part of my research in which I am inviting you to take part.

WHAT AM I ASKED TO DO IF I TAKE PART IN THE INTERVIEW?

Initially, I will ask you to read and sign the participant informed consent (please find it attached as a separate form in this email). Then I would like us to discuss your views on the ways you are using – as a medical device manufacturer and from the stand point of the department you are working in – to understand your customers who use ComX blood pressure monitors. Although I will use an interview protocol to guide me through our discussion (please find attached the areas/questions I would like us to discuss) I want to keep the interview quite open and flexible to those things you might want to bring in the discussion. In this sense, the interview will be loosely structured. I estimate that the interview would last **approximately 1 hour** and I would like to **audio-record our discussion**. In academic research we routinely ask our participants to record the interviews because in this way we ensure the precision of the data we collect (rather than reproducing what we remember that the participant said).

WHAT SHOULD I KNOW IF I TAKE PART?

It is important to be aware of, and understand the conditions under which you are invited to take part in this research. Please have a look at these terms and contact me if you have any questions.

1. Your participation in this interview is **entirely voluntary**. The fact that ComX invited my internship and has granted me with permission to approach you as a potential interview participant does not oblige you to be interviewed.
2. The interview data will be kept **strictly confidential between you and me**. This means that neither ComX nor my University (or anyone else) will have access to your interview. ComX has agreed to this condition and it is also an essential requirement for ethical conduct of research.
3. You have **the right to withdraw** from the study at any time during the process, without any implication, and without having to give any reason for this. Just let me know.
4. Even if we did the interview and later on ahead of its publication you decided that you do not want your transcript to be used in my research, you can say so and I will exclude your interview from my research, and destroy the data.

5. I will transcribe myself the interview and I will provide you with a copy of the transcript if you wish so. Once you are happy with the transcript I will destroy the audio-file.

6. I will destroy the paper-based transcript of your interview when the publication process (PhD thesis and scientific articles) will be completed.

7. I will use your interview data **exclusively for research purposes**, as part of my doctoral training.

8. I will never identify you by name in any report (i.e. PhD thesis) or scientific publication that use information obtained from this interview. Any quotes that I may use from your interview will be anonymous and non-attributable.

WHO HAS APPROVED OF THIS STUDY?

ComX has granted me with organisational permission to approach and invite you to take part in this interview. This study also adheres to the Code of Ethics and Conduct of the British Psychological Society.

WHO IS ORGANISING AND FUNDING THIS STUDY?

This research is funded by, and organised within, the *Multidisciplinary Assessment of Technology Centre for Healthcare* (MATCH) <http://www.match.ac.uk/>. This is the research project I am working in and sponsors my doctoral training. Prof Julie Barnett and Prof Terry Young are supervising my research.

FURTHER ENQUIRIES

Please contact me for any questions/enquiries you might have.

E-mail: [My e-mail address in the organisation] or Konstantina.Vasileiou2@brunel.ac.uk

Mobile: 0652 36 50 40

If you have any scientific enquiries, you can contact either me or my supervisor Prof Julie Barnett: Julie.Barnett@brunel.ac.uk

APPENDIX K

PARTICIPANT INFORMED CONSENT

TITLE OF STUDY

“Exploring the medical device manufacturer’s efforts to understand and take into account the needs of users of medical technology: An ethnographic approach using the case of home blood pressure monitors”

Researcher’s name:	Konstantina Vasileiou
Date:	
Time:	
Location:	ComX Offices in the Netherlands

Please read carefully each of the statements below and circle the option (YES on NO) that best describes your view.

1. I volunteer to take part in this study conducted by Konstantina Vasileiou, PhD student at Brunel University and currently intern in ComX, the Netherlands	YES	NO
2. I understand the purpose of this study and the process of my participation	YES	NO
3. I was provided with enough information and sufficient time to understand the aim of the study, and all my questions were answered to my satisfaction	YES	NO
4. I am aware of, and agree to the interview being audio-recorded	YES	NO
5. I understand that the researcher will not identify me by name in any report or scientific publication that use	YES	NO

information from this interview, and that my anonymity and confidentiality will remain secure		
6. I am aware of my right to withdraw from the study <ul style="list-style-type: none"> • At any time – even after I will have conducted the interview • Without any implication • And without having to give a reason for this 	YES	NO
7. I agree to the use of non-attributable direct quotes from this interview when the study is written up and published (PhD thesis & scientific articles)	YES	NO
8. I would like to be provided with a copy of my transcribed interview and make amendments/comments if I wish to do so	YES	NO
9. I have read and understood all the documents provided to me, and I voluntarily agree to take part in this study	YES	NO

Participant's signature	
Participant's name	
Contact number	
Address	
E-mail	

Researcher's signature	
-------------------------------	--

APPENDIX L

Typical protocol of ethnographic interviews

AREAS OF DISCUSSION/QUESTIONS

SECTION A: CONTEXTUALISING THE INTERVIEW

To put the interview into a framework that was relevant to the participant's organisational position and department, the interview started with a few questions about the participant as an employee.

Examples of questions:

- Could you please tell me a little bit about your organisational position and your role in the company?
- How long have you been working in ComX?
- What are the medical devices that you are responsible for?

SECTION B: QUESTIONS ABOUT THE WAYS THE MANUFACTURER TRIES TO UNDERSTAND AND ADDRESS USER NEEDS CONSIDERATIONS

Area of discussion 1: Approaches to capture and understand the end-user

Examples of questions:

- In what ways are you trying to understand the needs or requirements of users of home BPMs?

A. Prompts related to User & market research

- I have noticed that one way of accessing your end-users is through research. Would you say that this is a standard practice in ComX?

B. Prompts related to organisational experience and knowledge

- Do you have certain practices that promote the sharing of organisational knowledge about your users/customers across people in ComX?
- If yes, what are they?
- What is your view on them? Do they help to spread the user knowledge in the organization?
- New employees might bring new insights in the organisation about how to approach and understand your end-user. Would you say that ComX tries to accommodate this 'fresh' look at things? In other words, is there flexibility in doing things differently if you believe that this would help you to understand your user better?
- Do you think that people in different departments have different models or ideas about your users/customers or emphasize different things?
- If yes, could you please give me an example that comes to your mind?
- Why do you think that this happens?
- Does this create any challenges?

C. Prompts related to after-sales information from users

- Are you trying to get any sort of after-sales feedback from your customers?
- If yes, what specific things are you doing?
- How do you utilise this information?
- Do you think there are ways in which this information could be made more valuable?
- Some organisations use the complaints that may get from customers as a useful source of information in their effort to improve their products or services. Would you say that ComX adopts a similar approach?
- How do you routinely manage complaints from customers?

D. Prompts related to social media

- Do you use social media as a source of information from or for your customers?
- If yes, how does this work for you?
- Is it useful?

Area of discussion 2: Accommodation of users' cultural differences

Examples of questions:

- ComX is a company that sells products all over the world. Do you find that people in different countries have different BPM requirements or preferences?
- How do you try to accommodate cultural differences in home blood pressure monitors?
- For example, we know that French people prefer wrist BPMs while in all other countries upper arm BPMs is the first choice. Why do you think that this happens?

Area of discussion 3: Taking into account doctors and lay people's requirements

Examples of questions:

- I know that many ComX BPMs purchases are made after a doctor's recommendation. To what extent are the views of the medical world taken into account when you design and manufacture a BPM for home use?
- Does accommodating both the doctor's and end-user needs/requirements create any challenges for the manufacturer?

Area of discussion 4: Potential barriers in accommodating user needs

- Are there times that it is difficult to fully incorporate certain users' needs into the technology?
- What are the constraints/barriers to this?
- Do you have any particular example in your mind?
- Have you come across a case where certain needs or preferences of customers might conflict each other?
- If yes, how do you try to manage these contradictions?

SECTION C: QUESTIONS BASED ON MY EXPERIENCE WHILE WORKING IN THE MEDICAL DEVICE DEVELOPMENT PROJECT

Examples of questions:

- What is your role in the project?
- What are the phases of this project?
- How did you decide initially to start this project?
- I noticed during the kick-off meeting that you did not want to limit designers in their thinking about the monitor and that you wanted them to feel free to design something in lines with the results of the consumer research. Is that a fair comment?
- If so, why have you adopted this approach?
- The engineers from the global headquarters will also brief the designers from a technology point of view. Could the briefing from engineers potentially put up restrictions in designing the monitor according to the consumer research?
- You have mentioned that projects like this may not always be completed because of several risk assessments and decisions made throughout the process. What things could potentially stop this project?
- Are certain reasons more 'legitimate' than others according to your opinion?
- From a user perspective, what kind of evidence/information would make you to decide to stop this project?

APPENDIX M

List of documents

#	Documents	Access
1	<i>Instruction Manual Checklist</i> (i.e. a checklist ensuring that the user instruction manual conforms to regulatory requirements)	Made available by the organisation
2	<i>User Instruction Manuals</i>	Publicly available
3	<i>Product development project research materials</i> (i.e. research proposal; screening and main questionnaire; research results)	Made available by the organisation
4	<i>Pre-concept user experience research materials</i> (i.e. research proposal; interview protocol; research results)	Made available by the organisation
5	<i>Display and pack evaluation study materials</i> (i.e. experimental materials; questionnaire; study results)	Made available by the organisation
6	<i>Cuff usability study materials</i> (i.e. study design and flow; questionnaire)	Made available by the organisation
7	<i>The story of the Ohasama study</i> (i.e. brochure around the establishment of home BP thresholds)	Made available by the organisation
8	<i>Product Technology After Sales Support Overview</i> (i.e. training material)	Made available by the organisation
9	<i>Ideation Pre-phase</i> (i.e. proposed design directions based on pre-concept user experience research)	Made available by the organisation
10	<i>Organisation's Integrated Report 2013</i>	Publicly available
11	<i>Product catalogue 2013</i>	Made available by the organisation