Autonomy as lived: An empirical-ethical analysis of patient autonomy in the clinical context of individuals engaged with self-testing technology

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A thesis presented to Dublin City University for the degree of Doctor of Philosophy

September 2014

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DECLARATION OF AUTHORSHIP

I hereby certify that this material, which I now submit for assessment on the programme of study leading to the award of Doctor of Philosophy is entirely my own work, and that I have exercised reasonable care to ensure that the work is original, and does not to the best of my knowledge breach any law of copyright, and has not been taken from the work of others save and to the extent that such work has been cited and acknowledged within the text of my work.

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ACKNOWLEDGEMENTS

To my supervisors Dr. Dónal O'Mathúna and Professor Anne Scott: thank you for your academic guidance, invaluable philosophical insight and kind support throughout the entire process. Thank you to the patients and healthcare professionals who agreed to participate in the study, despite the busyness of their everyday lives and challenging clinical work environments. Thank you to the Director and staff of the Biomedical Diagnostics Institute for their assistance, particularly the education and outreach team and the study participants.[1] A sincere thank you to the gatekeepers who facilitated access to all research sites. For anonymity reasons I have not named you here. I would also like to express my gratitude to the many phenomenologists, ethicists and other academics, who willingly gave of their time and expertise to assist me in my work. I have noted your contributions within the thesis. My time as a visiting student to the Hastings Bioethics Centre in New York deserves special mention, both for the time it afforded for concentrated study and the inspiration gleaned from the vibrant academic community.

To my colleagues, and current and previous managers, within the Department of Nursing and Health Care Sciences at The Institute of Technology Tralee: thank you for your support, patience and friendship throughout the process. A special thank you to my critical readers, friends and accompanying thinkers: Ashley, Brigid, Deirdre, Denise, Emer, Mary, Sheila and Tom. I will always remember the kindness and practical assistance of those who 'rallied to the cause' in the final few days. Thanks to Siobhan Murphy for assistance with the graphic representation of findings. Thank you to Kathryn and Paul for opening their home to a sometimes-weary PhD student. It was much appreciated. To family members and friends who supported me in so many ways over the last number of years, your friendship, encouragement, interest and welcome distractions made all the difference. In addition to those already noted, a particular mention to my siblings, Katherine, Margaret, Bertie and their families is warranted. Thank you Katherine for the calming Crinnie walks and Margaret for all the early morning phone calls! Special thanks also to Ann-Marie, Brid-Ann, Elaine, Miriam, Nora, Sinead and Trina – a constant support network. A final note of gratitude to my wonderful parents, Jim and Sheila, who always remember my achievements, but forget they taught me the most important things in life: love, friendship, laughter and the value of education and hard work. I look forward to more of a balance in all these things ….

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[1] The Institute is named here with permission.

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ABSTRACT

Autonomy as lived: An empirical-ethical analysis of patient autonomy in the clinical context of individuals engaged with self-testing technology

Anna-Marie Greaney

Aim/Background: This study examines the meaning of patient autonomy in healthcare in the clinical context of individuals engaged with self-testing technology. Patient autonomy has gained increased prominence in healthcare ethics, policy and practice in recent decades. This poses challenges when autonomy competes with other moral principles. The proliferation of self-testing technology provides a contextualised example of this ideological shift. The philosophical assumption underpinning these technologies is that they facilitate greater autonomy through self-management. This study explores that assumption and the wider reverence to autonomy in healthcare.

Methodology: Heideggerian phenomenology provides an overarching philosophy for the research. The study adopts an empirical ethics research design, which integrates philosophical analysis and empirical enquiry in a cyclical fashion. Ethical analysis precedes and follows empirical investigation. Interpretive phenomenology is utilised to elicit the lived experience of autonomy among 12 individuals with diabetes engaged in the self-testing process. The perspectives of prominent stakeholders such as healthcare professionals and scientific community members are also sought. Data is analysed collectively in accordance with a hermeneutic approach.

Findings/Recommendations: The study illuminates the ethical principle of autonomy in a practical context. Findings reveal an understanding of *Autonomy as lived: The interdependent phenomenon of autonomy in self-testing* whereby the patient experience of autonomy is underpinned by three inter-reliant relationships - *Relationship with device, Relationship with illness* and *Relationship with healthcare provider*. Findings suggest that autonomy is a contextualised, relational process, which exists as a continuum and occurs within constraints. The concept of 'negotiated autonomy' is suggested as a means to operationalise *Autonomy as lived* within the patient/healthcare professional relationship. Findings have implications for bioethicists, policy-makers, healthcare professionals and patients when conceptualising and operationalising autonomy. The study also highlights the benefit of dialogue among the scientific community regarding the social and ethical dimensions of emerging technologies.

GLOSSARY OF CORE CLINICAL/TECHNOLOGICAL TERMS

Diabetes Mellitus: A chronic disease of the endocrine system characterised by deficient insulin production (**type 1 diabetes**) or ineffective use of available insulin (**type 2 diabetes**). This results in an inability to control blood glucose levels. Prolonged raised blood glucose levels can cause long-term complications such as damage to blood vessels, the heart, kidneys and eyes.

Glycaemic control: The extent to which target blood glucose levels are achieved

HbA1c: Glycosylated Haemoglobin.
Blood glucose levels can also be monitored by means of HbA1c or glycosylated haemoglobin. This measurement is taken at a clinic visit and gives a record of blood glucose levels over a period of time. Current NICE quality standards for diabetes in adults (2011) suggest that a target HbA1c value of between 48 mmol/mol and 58 mmol/mol. This corresponds to between 6.5% and 7.5% in previous value terms. Participants in this study frequently refer to the percentage value.

Hyperglycaemia: Raised blood glucose levels

Hypoglycaemia: Reduced blood glucose levels

Insulin: A hormone produced naturally in the body to regulate blood glucose levels. Can be given in synthetic form as a pharmacological agent to treat diabetes.

Oral hypoglycaemics: Oral medication given to individuals with type 2 diabetes (still producing insulin) to reduce blood glucose levels

Point of care testing: A method of carrying out a complete diagnostic test near to the patient as opposed to within the traditional environment of a clinical laboratory.[2]

Self-testing device: Any device intended by the manufacturer to be able to be used by laypersons in a home environment (Irish Medicines Board 2004, p.6).

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[2] The term is used differently within the literature. Some texts refer to point of care devices in a clinically supervised context only, while others include self-tests for home use as point of care devices. For clarity purposes, this study distinguishes between point of care devices intended for use under clinical supervision, and those that are utilised as self-tests for personal use outside of the clinical environment.

LIST OF ABBREVIATIONS

ABA	An Bord Altranais (The Irish Nursing Board)
ADA	American Diabetes Association
BDI	Biomedical Diagnostics Institute
DAFNE	Dose adjusting for normal eating (A structured education programme for individuals with type 1 diabetes)
DoH	Department of Health (Ireland) (Unless otherwise stated)
DoHC	Department of Health and Children Ireland (Former title of DoH)
EAGD	Expert Advisory Group for Diabetes (Ireland)
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
HTA	Health Technology Assessment
IDF	International Diabetes Federation
IMB	Irish Medicines Board
IMDA	Irish Medical Devices Association
NICE	National Institute for Health and Care Excellence (UK)
NMBI	Nursing and Midwifery Board of Ireland (formerly ABA)
RCT	Randomised Controlled Trial
SMBG	Self-monitoring of Blood Glucose
WHO	World Health Organisation

Thinking takes us beyond known ways,

into the clearing,
of un-formed understanding.

It is of ourselves, in ourselves and beyond ourselves.
Uniquely our own, common to us all.
private, precious
Only to be deemed worthy
When the knowing is "said"

The world of method/methodology
can confine thinking to pre-made boxes
with no escape

In the open place
trees show themselves
light shines
and in both seeing and not-seeing
thinking comes
up welling within.

(Smythe 2005)

SECTION 1: PRE-UNDERSTANDINGS

CHAPTER 1: ORIENTATION TO THE STUDY

Not only is Dasein woven together with the world – all parts of the world are fused into a colossal web of meaning in which everything refers to everything else.

(Harman 2007, p.63)

1.1 Introduction to the study: Why autonomy and self-testing?

This study is about the lived experience of patient autonomy in healthcare. Autonomy has gained significant popularity as a core ethical principle in healthcare ethics over the last five decades. Current Irish healthcare policy encourages greater patient participation at all levels (Department of Health and Children (DoHC) 2008a, DoHC 2008b, Department of Health (DoH) 2012a, Health Service Executive (HSE) 2013). Self-determination and autonomy are central features of codes of professional conduct for the nursing and medical professions (Irish Medical Council 2009, An Bord Altranais (ABA) 2000, Nursing and Midwifery Board of Ireland (NMBI) 2013).

Recent technological developments have dovetailed with an increasing emphasis on patient autonomy in healthcare practice (Moreno 2007). One particular microcosm of this phenomenon is the medical devices industry, particularly with products that enable self-testing in a non-clinical environment. The premise which underpins the movement towards using self-testing devices, and is noted in associated marketing strategies, is that they assist individuals to be more autonomous in the assessment and management of their health (Ryan et al. 2010). While patient autonomy is widely accepted in a westernised context as a paramount ethical principle (Kapp 2007, Gillon 2003), which would render self-testing a moral good, there is a growing counter argument in the literature. It is suggested that an over-zealous adherence to patient autonomy may allow individuals to be disadvantaged by their own choices, create unnecessary confusion and provide a means whereby healthcare professionals abdicate, either intentionally or otherwise, their own professional responsibilities (Gaylin and Jennings 1996, Downie 1998, Seedhouse 1998, Scott et al. 2003a, Kukla 2005, Tauber 2005,

Whitney and McCullough 2007, Harnett and Greaney 2008, Mol 2008, Greaney et al. 2012). I refer to the autonomy debate as the 'autonomy conundrum' to signify the 'problem' that this creates both philosophically and practically. Essentially, the autonomy conundrum refers to the extent to which autonomy should triumph over other ethical principles. Despite the presence of the autonomy conundrum, healthcare policy and practice (albeit some divergence in the national consent policy (HSE 2013) continue to progress a care agenda, which principally assumes that an advanced model of patient autonomy is a 'good' thing. This study explores this assumption through an ethical and empirical analysis of autonomy in healthcare practice.

While patient autonomy is a common theme in ethical discourse, there is a dearth of empirical work, which examines the lived experience of adopting more autonomous roles. This research seeks to address this gap. The study combines ethical analysis with empirical investigation to examine how patients experience autonomy in their daily lives, and the implications of this for healthcare professionals. The specific patient cohort encompasses individuals with diabetes who utilise technological devices to self-test their blood glucose levels. In order to illuminate the context in which the patient experience occurs, the views of healthcare professionals and those who develop potential self-testing technologies are also sought within the empirical component of the study. McMillan and Hope's (2008) model of empirical ethics, which integrates ethical analysis and empirical enquiry in a cyclical fashion, is utilised to underpin the study design. Interpretive, or hermeneutic, phenomenology informs the research approach (Heidegger 1927/1962, Smythe et al. 2008). Heideggerian phenomenology, while a philosophical method, is also an empirical methodology (Adams 2010) and therefore provides a suitable theoretical basis for both philosophical and empirical work. A phenomenologically orientated hermeneutic approach is utilised to facilitate collaboration between the empirical investigation and ethical analysis (Rehmann-Sutter et al. 2012).

On a stylistic level, the research is presented within this thesis in a linear fashion to provide clarity for the reader and conform to academic convention. However, it is important to note that in reality, as is the nature of interpretive phenomenology, the process was a much more iterative one involving constant movement between reading, writing, reflection, data collection and moments of uncertainty (Smythe et al. 2008).

A reflective journal, maintained throughout the research process, but more diligently during the analysis stage, acts as testament to the iterative processes I engaged in and the challenges involved. A selection of journal entries is included as Appendix A: Analysis journal extracts.

The terms 'patient' or 'individual with diabetes' are used throughout as opposed to the often more recently cited term, 'service-user'. I believe that the term patient is appropriate as its traditional inference denotes an individual in need of care, and avoids a more pronounced link with the market place that 'service-user' suggests. I use the terms 'philosophical analysis' and 'ethical analysis' interchangeably. I acknowledge that philosophical deliberation extends beyond ethical analysis; nonetheless, ethical analysis always incorporates moral philosophy. The literature pertaining to empirical bioethics refers predominantly to 'medical ethics'. I interpret, and utilise, this term in a looser context to incorporate all players in the healthcare environment who experience ethical problems in their daily activities.

1.2 Study aim

To examine and contextualise the meaning of patient autonomy in healthcare practice through an empirical and ethical analysis of autonomy among individuals engaged with self-testing technology

1.3 The research context: The hermeneutic circle of understanding

This study is concerned with the lived experience of autonomy among individuals engaged with self-testing technology. This engagement occurs within a wider context. The appreciation of the context, or situatedness, in which experience occurs is fundamental to an interpretive phenomenological approach, and the underlying Heideggerian philosophy (1927/1962). In accordance with Heideggerian phenomenology, all human experience is interpreted within a hermeneutic circle of understanding (Cohen et al. 2000). The hermeneutic circle is infused with the situational, cultural and historical context in which experiences occur and the presuppositions, or fore-structures, which the researcher brings to the interpretive process. This section sets out the context in which the participants in this study,

diagnosed with diabetes, relate their experiences of autonomy within the self-testing process. The hermeneutic circle, or "colossal web of meaning" (Harman 2007, p.63), in which the patient experience of autonomy is interpreted in this study is infused with a variety of factors. These factors incorporate the various settings in which the research takes place. The various factors within the hermeneutic circle are presented in Figure 1 and summarised below.

Figure 1: The hermeneutic circle in which the patient experience of autonomy occurs
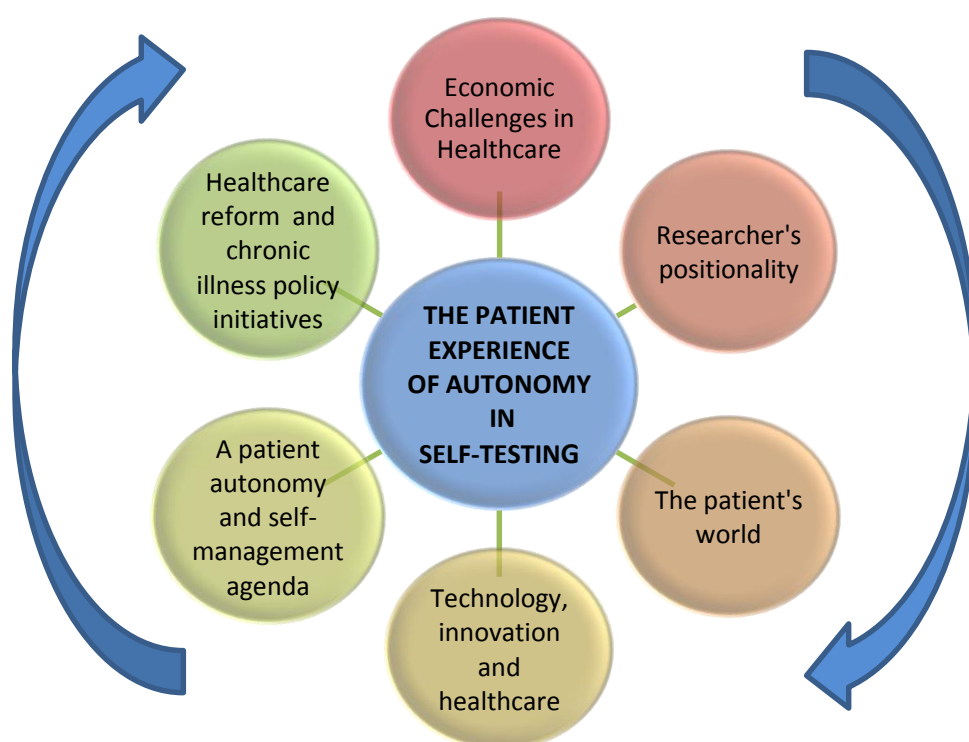
1.3.1 Economic challenges in healthcare

Data collection occurs at a time of immense fiscal pressure in the Irish economy (September 2011-December 2012). The patient experience of autonomy in self-testing, and other stakeholder perspectives, are recounted at a time when Ireland had lost its economic sovereignty through commitment to a European Union/International Monetary Fund programme of deficit reduction. Ireland exited the programme in December 2013, but the most recent Organisation for Economic Cooperation and Development (OECD) report *Health at a Glance* (2013) outlines the impact on health

spending of austerity measures. Health spending in Ireland decreased by 6.6% per capita between 2009 and 2011. This decrease was in stark contrast to the growth rates of 7% from 2000 to 2009. Less healthcare spending potentially influences patients' experiences of the healthcare system in terms of available personnel and services.

1.3.2 Healthcare reform and chronic illness policy initiatives

Prior to the emergence of the economic recession, Ireland had commenced a health reform programme designed to re-orientate health services towards a primary care model, which would involve reconfiguration of acute hospitals; integrated care strategies; the development of primary care teams and centres; and a structured response to chronic illness prevention and management (HSE 2008a). O'Connor (2013, p.40) notes, however, that the development of primary care has been "slow and tortuous" thus limiting the overall progress of healthcare reform. While over 500 primary care teams have been formed, O'Connor refers to a lack of evidence to suggest that these teams are entrenched in the everyday lives of patients in a meaningful way. It is difficult to speculate as to how reforms might have progressed in the absence of fiscal difficulties; however, it is reasonable to suppose that the reduction in health spending has curtailed progress. The development of an integrated model of care remains a core focus of reform in the Irish health service, particularly in the context of chronic illness (DoH 2012a). Healthcare professionals interviewed in this study were primarily working within tertiary hospitals, but did have some primary care responsibilities within out-reach clinics.

Chronic, or non-communicable, diseases represent a significant portion of the global health burden. Diabetes is often perceived to epitomise the challenge of chronic illness. Over 377 million people worldwide are diagnosed with diabetes. It has been estimated that diabetes related deaths will increase by two thirds during the period 2008 to 2030 (World Health Organisation (WHO) 2012). The WHO call for an integrated approach in the prevention and management of chronic diseases (WHO 2009), is mirrored in the recommendations of the Expert Advisory Group for Diabetes in Ireland (EAGD) (HSE 2008b).

1.3.3 A patient autonomy and self-management agenda

The debate regarding the primacy of autonomy as an ethical principle in the bioethics literature often translates in a clinical practice context to concerns regarding the efficacy and morality of self-management programmes (Redman 2005, Newbould et. al 2006). A growing patient autonomy agenda is evident in an Irish context as outlined in the opening section of this chapter. This mirrors international trends whereby patient autonomy has gained increased prominence in healthcare ethics, policy and practice over the last number of decades. Redman (2005) examines the ethics of preparation for self-management programmes with a particular focus on the moral requirement to provide sufficient patient support. Redman (2005, p.262) highlights "a strong programme of self-management" as a component of patient autonomy. Self-management training is recognised as a core dimension of integrated care in diabetes, of which self-monitoring of blood glucose levels forms an important component (EAGD 2008).

1.3.4 Technology, innovation and healthcare

The growing emphasis on technology in healthcare is also a significant factor that infuses the socio-cultural environment in which the patient experience of autonomy in self-testing occurs. Self-testing devices provide a specific example of an advancing technological approach to healthcare delivery. Technology in this study is defined as the practical application of scientific discoveries. This accords with contemporary dictionary definitions but also offers a coherent basis for more philosophical discussion (Oxford Dictionary 2010). Ihde (2006) maintains that we cannot properly understand our current situation in the world without an understanding of technological issues. The most recent strategic framework for the reform of the health service in Ireland (DoH 2012a) emphasises technology as a core component of the reform agenda. Members of the scientific community involved in technological innovation in diagnostics, were among the participants in this study.

The Biomedical Diagnostics Institute (BDI) at Dublin City University, from where this cohort of participants was recruited, is Science Foundation Ireland funded CSET

(Centre for Science, Education and Technology).[3] The Institute, founded in 2005, represents a clinical, academic and business partnership engaged in the development of point-of-care biomedical diagnostic devices. It's "vision is to transform healthcare by pioneering advances in the science and technology of diagnostics and by translating these advances into clinical use" (BDI 2013). The Institute's initial scientific expertise in core competencies has now been developed to include innovative clinical diagnostic platforms in oncology, infectious diseases and cardiovascular disease. The Institute has an active research community of post-graduate researchers. In addition to developing excellence in research, the Institute seeks to impart societal and economic benefits, stimulate interest in science among students at all levels and enhance the public's understanding of science. This PhD project began as a collaborative enterprise between the Education and Outreach Unit at BDI and the School of Nursing and Human Sciences at Dublin City University. The resulting *Diagnostics and Society* group "aims to integrate ethical and social scientific research methodologies with BDI research programmes". The current study seeks to address this dimension of BDI activity.

Researchers within BDI are operating at the proof of concept and early validation phase of technological development in diagnostic devices. This information is significant to explain the context in which the scientific community expressed their views. The participants interviewed develop diagnostic devices that are currently intended for use in a near-patient, point-of-care setting, as opposed to unsupervised self-testing. In this sense, the clinician is the end-user around which the device is devised. The individual views of the BDI participants are however relevant in the context of self-testing devices. While the scientists interviewed do not have specific expertise in 'self-testing', their expertise in diagnostics has the potential to shape innovation in this area. The purpose of the focus group with BDI participants was to elicit participants' views regarding self-testing and patient autonomy in light of the patient data. This enabled some insight into the vision for self-testing technology/patient autonomy espoused by individuals who are in a position to advance diagnostic technologies. The study was never at any point an exploratory study of BDI,

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[3] For a link to the Institutes website and additional detail regarding its objectives, collaborators, activities, outputs and governance structures see www.bdi.ie.

its personnel or its activities. In this light, it is important to note that any views expressed by the interviewees in this study are their personal views, and do not reflect those of the BDI Partner Institutions, Industry Collaborators or the finding body, Science Foundation Ireland.

1.3.5 The patient's world

The patient's unique experience of illness and her wider individual life course also represents a major influence on the experience of autonomy in self-testing, and is a core dimension of the hermeneutic circle. The relevance of the situated personal story is central to the phenomenological approach adopted within this study (Heidegger 1927/1962, Johnson 2000, Smythe et al. 2008). It is acknowledged that an individual's broader life context will influence her perception of illness and coping style (Karademas et al. 2009). The participants in this study are collectively presented as individuals with diabetes, yet individually they experience this diagnosis in a myriad of ways dependent on their own life stories.

1.3.6 Researcher's positionality

The researcher's perspective, or positionality, with regard to the research problem, is central to understanding in an interpretive study. Drawing on the phenomenological perspectives of Heidegger (1927/1962) and Gadamer (1960/2003), Ironside (2005) suggests that the phenomenological researcher is already engaged with the research problem. For Heidegger, there is a certain 'giveness' in the world as it presents itself to us whereby some things are more salient than others (Heidegger 1927/1962). Put more simply, some aspects of the world are already illuminated for us as individuals. While we may appear to select a phenomenon for empirical investigation, in reality it calls to us.

I have been concerned with expressions of autonomy in a healthcare context from a multi-stakeholder perspective over the last decade (Greaney 2002, Harnett and Greaney 2008, Greaney et al. 2012). A number of experiences in my professional life, as a nurse, nurse educator and bioethics student have invoked and sustained my interest in this field. On a more personal level, experiences of ill health among family members have prompted reflection related to the reality, complexity and occasional burden of

patient choice. The challenges involved in balancing respect for autonomy with a responsibility to care 'in the best way' are also pertinent in our everyday interactions with those we love. The opportunity to engage in PhD studies related to the ethics of self-testing devices provided an ideal context in which to explore these issues at a more advanced level of scholarship. The autonomy conundrum represents an ongoing dimension of my thinking as an individual, family member, nurse, nurse educator, ethicist and bioethics researcher.

The role of the researcher, particularly at the point of interpretation, is a central concept in Heideggerian hermeneutic research (Koch 1994, Laverty 2003, Smythe 2005). In contrast to Husserlian descriptive phenomenology, the researcher does not seek to 'bracket' or set aside her own presuppositions (Laverty 2003). The researcher's perspective is central to the interpretive process. Therefore, proponents of this methodology recommend that the researcher outline some detail of her personal perspective at the outset and maintain a degree of reflexivity as she progresses through the research process (Crist and Tanner 2003, Smythe 2005, Adams 2010).

Koch and Harrington (1998) present reflexivity as a means to support the establishment of rigour in qualitative research. In a reflexive approach, the researcher is engaged in ongoing self-critique and self-appraisal to bring transparency to 'what is going on' within the research process. Ongoing reflexivity assists the researcher to move beyond her own frame of reference to understand more fully the perspective of the other. The reflective journal maintained during the course of this study assisted this reflexivity. In the early stages of the research, I wrote a detailed reflective account exploring personal pre-suppositions regarding patient autonomy and self-testing. This account was available for review throughout the course of the study to ensure that my own position did not engulf the participants' voices.

1.4 Thesis structure

The study is presented in three sections. Each section consists of a series of chapters, which collectively describe the research process in a liner fashion. **SECTION 1** contains two chapters, the first of which outlines the pre-understandings that existed prior to data collection and the initial process of ethical analysis. The use of the term

pre-understandings is deliberate, as it reflects the researcher's already engaged relationship with the research problem that is central to Heideggerian phenomenology. **Chapter 1** introduces the study, explains the rationale for the research, outlines the aim of the study and sets the research context. The research context includes the personal perspective and pre-suppositions, which the researcher brings to the research study. **Chapter 2** presents the literature review. The literature review traces the autonomy conundrum from the wider bioethics debate to the self-testing context, and concludes with the more specific phenomenon of self-testing among the diabetic population. In addition to the 'traditional' empirical literature review, the chapter also incorporates the initial ethical analysis within the study, which explores the nature of patient autonomy and choice in healthcare, in the specific context of self-testing devices. This analysis was subsequently developed and published. The published paper is presented as Appendix B. Section 1 concludes with a justification for the research study and a brief overview of the methodological processes chosen.

SECTION 2 presents the research strategy in a series of two chapters. **Chapter 3** outlines the philosophical and theoretical underpinnings of the study. These include; the field of empirical bioethics, the philosophy of technology discourse, Health Technology Assessment, hermeneutics and Heideggerian phenomenology. This section also justifies the suitability of Heideggerian phenomenology to address the research problem. **Chapter 4** outlines how these more abstract concepts have been incorporated within the research methodology. The chapter describes the participant profile, the specific research settings, data collection tools, the process of analysis and the ethical procedures and systems of rigour employed.

SECTION 3 outlines the new empirical and philosophical understandings, which the research study brings to the meaning of autonomy in a specific healthcare context. This section is comprised of 3 chapters. **Chapter 5** presents the empirical study findings – an understanding of *Autonomy as lived.* The chapter outlines *The interdependent phenomenon of autonomy in self-testing*, as the meaning of autonomy in the specific healthcare context of engagement with self-testing devices. Autonomy is presented as contextual, related to one's existential existence and reliant on a number of interdependent relationships. The chapter presents three central thematic understandings: *Relationship with device; Relationship with illness; and Relationship*

with healthcare provider. Each theme is discussed individually in accordance with a number of sub-themes, which collectively present the overall phenomenon of *Autonomy as lived*. **Chapter 6** discusses the contribution of the research study in both normative and pragmatic terms, in light of the existing literature. The initial ethical analysis of autonomy outlined in chapter 2 is revisited. A means of operationalising *Autonomy as lived* in practice is explored. Pragmatic considerations regarding, the use of technology in healthcare, the merits of self-management programmes and self-monitoring in diabetes are explored. **Chapter 7** concludes the study, discusses some limitations and outlines a number of recommendations for bioethics, healthcare policy and clinical practice based on the discussion within the previous chapter. The chapter closes with a summary and presents a possible future research agenda, which will enable further illumination of the understandings presented in this study. This summary, in one sense the end of the study, yet also a possible new beginning, is congruent with the 'open' nature of interpretive phenomenology and the cyclical model of empirical bioethics employed in the study.

CHAPTER 2: LITERATURE REVIEW: PATIENT AUTONOMY AND SELF-TESTING DEVICES

There is no one place for the literature to be cited within a research report. It rather comes-along as a dialogical partner, supporting, building, challenging, showing.

(Smythe and Spence 2012, p.21).

2.1 Introduction: The literature review in interpretive phenomenology

This chapter presents the literature review, which informs the study design and concludes with a more detailed justification for the proposed research. It also delineates how the literature review in hermeneutic research differs from quantitative and other qualitative approaches. In interpretive phenomenology, the relationship with the literature is ongoing and reflective as the quotation above suggests.

Trafford and Lesham (2008) define the literature as a corpus of knowledge, which the researcher utilises to progress all stages of the research process. This is particularly true in hermeneutic phenomenology where the literature plays a very significant role in the interpretive and discussion phases of the research study (Smythe and Spence 2012). Smythe and Spence outline the uniqueness of the literature in hermeneutic research and challenge the prevailing view in academia that there is only one approach to literature searching. The authors contend that the hermeneutic researcher is on a constant journey with the literature, involving a "reading, searching, intuiting, thinking, talking, writing, letting-come process by which they discern what matters" (p.14). The literature is essential to the development of thinking at the interpretive and discussion phases. As ideas evolve, new sources of literature are sought. In this way the boundaries of the corpus are constantly extended.

This review presents an initial synthesis of the literature pertaining to the relationship between patient autonomy and self-testing devices. The review begins with the literature regarding patient autonomy, and presents the historical basis and dimensions of the debate concerning the primacy of patient autonomy in healthcare practice. As

the review proceeds it becomes more focused, whereby the autonomy issue is linked specifically to the self-testing milieu and finally to self-monitoring among the diabetic population. Other literature sourced is integrated within the chapters which follow, thus explicating how the literature acts as a "dialogical partner" in the research process, as Smythe and Spence (2012, p.21) suggest.[4]

2.2 Patient autonomy in contemporary healthcare practice: The 'autonomy conundrum'

The word autonomy is derived from the Greek, whereby 'autos' refers to the self and 'nomos' to laws. In this original sense autonomy referred to a political system shared by a group of citizens. A city in ancient Greece had 'autonomia' when its people were in a position to make their own laws (Dworkin 1988). O'Neill (2002) explains that the concept of 'individual' autonomy is generally attributed to Kantian autonomy whereby individuals, as opposed to societies, become the locus of autonomy. While autonomy is often interpreted inconsistently in healthcare (Keenan 1999, Aveyard 2000, Slowther 2007), there is an understanding in the more general lexicon that 'autonomy' is concerned with 'self-governance', 'self-rule' and 'independence' (Oxford English Dictionary 2010). In short, the general interpretation is that as an autonomous individual, 'I decide what happens to me'.

Ashley (2012) draws on the philosophical literature to present a succinct overview of personal autonomy and delineates four distinct models: proceduralist, substantivist, internalist and externalist. The four models are presented on an axis whereby internalist and externalist accounts cross-cut the other two. An image of this axis is attached as Appendix D: Personal autonomy - a conceptual axis. Essentially, proceduralist accounts of autonomy relate to the 'process' of decision making. This is the understanding of autonomy generally used in determining capacity in law (Government of Ireland 2001). Proceduralist autonomy is normatively neutral and not dependent on the 'content' of decisions. This understanding of autonomy coincides with a liberal philosophy of non-interference with the choices of others. Substantivist accounts of autonomy take issue with the neutrality of proceduralist accounts, and

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[4] A more detailed account of the literature review process is presented as Appendix C.

propose that the 'type' of choices made are significant in determining autonomy. In this sense, adherence to a certain set of criteria in the decision-making process is not necessarily described as an autonomous decision. Internalist and externalist accounts relate to the extent to which autonomy is understood as dependent on an individual's internal reflective and evaluative capacities alone or also reliant on external enabling conditions. Ashley (2012, p.22) also refers to relational autonomy which exists as "add-on, as opposed to alternative, to the procedural and substantive models". Relational autonomy is described as "an 'umbrella term', insofar as it comprises a range of accounts that adopt different views concerning the conception of the 'self' in question and the role social relations play in the development and exercise of autonomy" (Ashley 2012, p.19).[5]

Autonomy, as an ethical principle, has gained particular prominence in healthcare since the introduction of the four-principle approach to medical ethics by Beauchamp and Childress in *Principles of Biomedical Ethics* (1979). The publication is now in its seventh edition (Beauchamp and Childress 2013). The principle-based approach represents a mid-range theory of ethical decision-making. The four principles are autonomy, beneficence, non-maleficence and justice. While there is a continuing debate about the merit of this approach (Holm 1995, Düwell 2006, Huxtable 2013), the principles have endured as a core foundation of bioethics, particularly in an American context. Acknowledging the ambiguity associated with autonomy Beauchamp and Childress (2013, p.101) offer the following, widely quoted definition:

> At a minimum, personal autonomy encompasses self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice, such as adequate understanding.

Patient participation in healthcare has increased significantly over the last forty years. Complex social developments have replaced a tradition of medical dominance with a

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[5] Ashley is a researcher affiliated with the Essex Autonomy Project, a research unit and knowledge-exchange forum based in the Department of Philosophy and Art History at Essex University. The initiative is funded by the Arts and Humanities Research Council in the UK. Its central activities include clarifying the philosophical nature of autonomy, and assisting healthcare professionals to navigate the legislative framework of autonomy in a practical context. The various activities/outputs of the project have provided a significant source of information and reflection throughout the PhD process. Further detail on the project will be presented as the review proceeds.

culture of patient autonomy (Rothman 2001).[6] Willis (2006) presents an historical treatise of the decline of medical dominance and lists neo-liberalism, economic rationalism, a growth in consumerism and associated litigation, and the industrialisation of medicine as reasons for this change. Modern American bioethics[7] has also contributed significantly to this change where the principle of autonomy has gained increased prominence as the leading ethical principle underpinning healthcare delivery (Moreno 2007). Moreno refers to "an autonomy-driven bioethics" (p.417) in the US fuelled by several social events including the blatant disregard for the rights of participants in the Tuskegee Syphilis experiment, the emergence of the Belmont Report detailing ethical principles for research, and the influential Roe v Wade decision in 1972 with respect to women's reproductive rights and the legalisation of abortion. Paternalistic models of care have now been replaced by greater patient participation across the caring spectrum (Eldh et al. 2006).

Contemporary professional codes of conduct, healthcare ethics texts and policy documents provide some empirical evidence of this shift towards greater patient autonomy. Gillon's (2003) proposal that autonomy should be upheld as the first principle has gained momentum in healthcare ethics. The code of conduct for the nursing and midwifery profession in Ireland is currently under review. The most recent draft edition of the code (Nursing and Midwifery Board of Ireland (NMBI) 2013) places significant emphasis on patient autonomy, self-determination and freedom to choose, albeit in the context of appropriate capacity. The Irish Medical Council's (2009) most recent direction to its members, while acknowledging some exceptions, asserts the patient's right to control what happens to her in accordance with her autonomy. One particular medical ethics textbook outlines autonomy as the "primary consideration in patient centred treatment" (Schwartz et al. 2002 p.8).

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[6] There is some scepticism regarding the extent to which this new 'ethos' is reflected in each patient interaction. However, the overall policy context and the general healthcare rhetoric have embraced this change.

[7] The term bioethics is described by O'Neill (2002, p.1) as a "meeting ground", as opposed to a discipline, for those who debate "the ethical, legal, and social questions raised by advances in medicine, science and biotechnology". A historical account of the emergence of bioethics is found in Reich, W.T. 1994. The word bioethics; its birth and legacies of those who shaped it. *Journal of Medical Ethics* 4, pp. 319-335.

Current healthcare policy in Ireland, similar to other states, reflects this paradigm shift and denotes a move towards the more autonomous patient. A recent national policy for consent in the health services in Ireland outlines the importance of patient autonomy in treatment decisions (HSE 2013). Self-management is acknowledged as a significant factor contributing to increased patient autonomy (Redman 2005).[8] A number of recent policy documents refer to greater patient participation in care and care decisions e.g. *National Strategy for Service User Involvement in the Irish Health Service* (DoHC 2008a), *Tackling chronic disease: A policy framework for the management of chronic diseases* (DoHC 2008b), *The Health Service Transformation Programme* (HSE 2008a) and *Future Health* (DoH 2012a). These policy initiatives reflect international trends in many respects, led by the World Health Organisation, which recommends a greater emphasis on self-management as part of a multi-sectoral approach towards the prevention and management of non-communicable diseases (WHO 2008).

2.2.1 The autonomy conundrum: philosophical perspectives

The suitability of the primacy of autonomy as an ethical principle has been afforded great attention in the bioethics literature. On the one hand, there is support for the supremacy of autonomy (Gillon 2003), while an opposing school of thought suggests that other principles such as beneficence and justice are unsuitably underdeveloped (Holm 1995). An over-zealous adherence to patient autonomy may allow individuals to be disadvantaged by their own choices, misrepresent the reality of healthcare ethics, create unnecessary confusion and provide a means whereby healthcare professionals abdicate, either intentionally or otherwise, their own professional and caring responsibilities (Holm 1997, O'Neill 1997, Downie 1998, Seedhouse 1998, O'Neill 2002, Scott et al. 2003a, Kapp 2007, Whitney and McCullough 2007, Harnett and Greaney 2008, Mol 2008, Agledahl et al. 2011, Greaney et el. 2012). I refer to this disquiet regarding the value of greater patient autonomy in healthcare as the 'autonomy conundrum'. Both the philosophical and empirical literature supports the degree of contemporary interest in this conundrum.

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[8] The relationship between self-management an autonomy is further explored as the literature review, and subsequent research project, evolves.

O'Neill (1997) recommends caution in moving towards a culture of greater patient autonomy, asserting that it fails to acknowledge the special caring relationship that exists in healthcare. The tensions that exist between patient autonomy and professional responsibility are also recognised by others (Gaylin and Jennings 1996, Downie 1998, Kukla 2005, Tauber 2005, Mol 2008). Kapp (2007, p.99) discusses patient autonomy in the particular context of informed consent and presents what he refers to as "realists' critiques" of the concept (p.99). Such critiques include barriers to shared decision-making in the practical sense due to the patient's inability to comprehend complex clinical information. It is also noted that patients may not want to be involved in their own care despite a growing trend in social policy, healthcare ethics and clinical guidelines, which suggest that they should.

Gillon's (2003) specific adherence to autonomy as a paramount principle in healthcare practice, which can encompass the other bioethical principles, has been rejected by Callahan (2003) in favour of communitarianism and by Dawson and Garrard (2006) on the basis that it rejects the prima facia nature of the principles. In accordance with this 'prima facie' approach, Ross (1930) explains that one principle might triumph over others in specific situations. Using the healthcare context as an example, the principle of beneficence may triumph over autonomy when patient welfare is at stake.

Seedhouse (1998) makes a distinction between creating and respecting autonomy. He contends that one may promote autonomy without actual adherence to it. In this sense, denial of autonomy at certain points in a patient's illness trajectory may actually maximise their potential to develop greater autonomy at a later point. Seedhouse refers to the mental health setting particularly and notes that recovery may be promoted by not granting patients all their choices. Scott et al. (2003a) raise similar themes and cite the work of Carson (1995) to lend weight to the 'vacuous' notion of autonomy which focuses on the negative right to non-interference, and may subsequently lead to abandonment of ill patients. The distinction between autonomy and freedom is a recurring theme in the philosophical literature and is central to this debate. The underlying premise in advancing the autonomy principle seems to be that autonomy is synonymous with freedom, or, that autonomy is dependent on freedom to choose (Kukla 2005). Philosophical analysis suggests that this is not necessarily the case.

Dworkin, in his seminal treatise on autonomy (1988) refers to freedom as liberty and suggests that the terms liberty and autonomy should always be distinguished. He proposes that "autonomy is a richer notion than liberty" and relates to "the idea of being a subject, of being more than a passive spectator of one's desires and feelings" (Dworkin 1988 p.107). Dworkin contends that the perception "of autonomy that insists upon substantial independence is not one that has claim to our respect" (p.21). For Dworkin, the notion of freedom, or liberty is not an absolute pre-requisite for autonomy. To focus on the freedom issue is to subscribe to a negative autonomy, whereby autonomy is synonymous with self-governance and the absence of constraints. Conversely, positive theories of autonomy encompass a more relational model characterised by caring and interaction with healthcare professionals (Moser et al. 2007). The distinction between positive and negative perceptions of autonomy is generally attributed to the work of Berlin (1969). In *Two Concepts of Liberty,* Berlin (1969) distinguishes between positive liberty, which is concerned with self-mastery, and negative liberty associated with non-interference by others. The autonomy conundrum, for the most part, is associated with situations where autonomy is correlated with negative liberty, and a subsequent reliance on non-interference.

Mol (2008) equates extended autonomy in healthcare with a model of enhanced patient choice and contends that more choice does not necessarily lead to better care, but may merely fuel the free-market and support commercial interests. Mol outlines the logic of care and the logic of choice as opposing structures, with conflicting value systems, and puts forward a number of interesting arguments in support of this claim. At the outset, she explains that care is a process of interaction and intervention, whereas within the 'logic of choice' care becomes a product. Mol (p.30) takes issue with this consumerism, which has "emancipated" patients into "citizens" and claims that this is not a model conducive to good healthcare. Mol believes that viewing patients as citizens simply does not work. In accordance with her analysis, patients can only be citizens with the "healthy" parts of their bodies. Citizenship signifies control, freedom and civilisation, meaning that our bodily functions and passions are kept under control. These are abilities not always associated with the ill patient.

The logic of choice emancipates patients from a previous model of medical dominance but, in accordance with Mol's thesis, something is lost in this process. Choice,

consumerism and citizenship may not result in better healthcare. Mol's position reflects an increasing criticism of a consumer-based and autonomy-driven culture in healthcare (Moreno 2007, Callahan 2009, Agledahl et al. 2011). Agledahl et al. (2011) note that respect for autonomy has been interpreted in a healthcare context as meaning respect for one's autonomous choices. The authors argue that adhering to patient choice misrepresents the reality of healthcare practice, and denotes an inappropriate application of the doctrine of informed consent from research ethics to the wider patient care context. The analysis goes on to explain that choices in healthcare occur over time and may be presented to patients in an arbitrary fashion, which takes account of professional expertise and the realistic constraints of the healthcare environment.

There is evidence of a wider recognition of the significance of the autonomy conundrum in current healthcare practice and the need to address the issue. The Essex Autonomy Project within the Department of Philosophy and Art History at Essex University is a research unit and knowledge exchange forum, which engages with these issues. The aim of the project is to "clarify the ideal of self-determination in history, theory and practice, both for its own sake, and in order to provide guidance to those who must apply this notion" (Essex Autonomy Project 2013)[9]. The specific relevance of the autonomy conundrum for healthcare professionals is evident in this extract:

> Traces of our contemporary confusion over these matters can be found in recent legal cases. One influential decision invokes the "absolute right to refuse to consent to medical treatment for any reason, rational or irrational, or for no reason at all." A second insists that "the patient's right of choice exists whether the reasons for making that choice are rational, irrational, unknown or even non-existent." The very grandeur of these pronouncements is due testimony to our deep commitment to the ideal of autonomous judgment, but it should be clear that they also produce a host of difficulties for the practitioner who sets out to implement them. (Essex Autonomy Project 2013)

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[9] A more detailed account of the activities of this research centre and a link to its comprehensive resources is available at http://autonomy.essex.ac.uk/

2.2.2 The autonomy conundrum: empirical perspectives

While much of the literature is philosophical and discursive, a growing body of empirical work explores patient autonomy in patient/healthcare provider interaction. Empirical work has demonstrated that patients value autonomy in interaction with healthcare professionals. Oliveira et al. (2012) undertook a systematic review and meta-analysis of previous studies, which investigated the relationship between interaction styles of clinicians and patient satisfaction. The analysis concluded that styles which valued patient autonomy (including involving, supporting and facilitating patients) yielded greater patient satisfaction.

Hill et al.'s (2013) study supports this conclusion. The study found a positive correlation between patients' perceived autonomy support, and visit satisfaction, among 55 patients at a women's clinic in Texas. The study also examined patients' preferences for autonomy utilising the Autonomy Preference Index (API). The API is a validated six-item self-report tool used to investigate patient preferences in decision-making during the consultation process (Ende et al. 1989). It is significant that patients' preferences for autonomy within Hill et al.'s study were significantly lower, depending on whether they were asked about autonomy preferences in general, or, in relation to specific scenarios. The researchers surmise that this is not necessarily contradictory, but that patients may exercise their autonomy by deferring decision-making to their doctors. Having the autonomy not to be more involved in decision-making in some instances, may be positively evaluated as autonomy support and result in satisfaction with the consultation process.

Additional empirical studies lend further support to the proposal that patients may not necessarily want to assume absolute autonomy in their interactions with healthcare professionals, but value a shared decision-making approach (Scott et al. 2003b, Levinson et al. 2005, Doherty and Doherty 2005, Hamann et al. 2007, Madsen et al. 2007, Schildmann et al. 2013). A large-scale quantitative study using a survey design in Toronto investigated patients' preferences for participation in decision-making at three levels: seeking information, discussing options and making the final decision (Levinson et al. 2005). The sample was stratified to ensure representation from the wider population. Results showed that while 96% of patients surveyed preferred to be

offered choices and asked their opinions, 52% displayed a preference for leaving the final decision to their doctors. The researchers also used regression analysis to explore the relationship between various demographic variables. Results indicated that healthier people, women and those with a higher level of education sought a more active role in decision-making. In contrast, older adults and ethnic minorities preferred to leave the ultimate decision-making to their physicians.

These findings reflect those highlighted by Hamann et al. (2007) with a German, albeit smaller, sample. The researchers used the API scale to assess the desire to take an active role in the decision-making process among patients in six different clinical groups. In findings similar to the Toronto study, the respondents expressed a desire to be involved but not to assume complete control. Females, younger patients and the better educated accounted for a small, but statistically significant, preference for a more active role in decision-making. Qualitative studies also indicate similar results. In separate studies, Madsen et al. (2007) and Schildmann et al. (2013) explored the decision-making preferences of patients diagnosed with cancer. While Madsen et al. explored the patient experience of consenting to participate in a clinical trial, Schildmann et al.'s study explored decision-making in a more generic sense. Both studies concluded that autonomy and personal decision-making were not priorities for patients at all times in the care environment, and that physician trust was highly valued. Participants in Madsen et al.'s study noted the stresses and loneliness associated with the decision-making process.

The importance of shared decision-making is similarly supported by Randers and Mattiasson (2004) in the context of the older adult. The authors investigated the relationship between autonomy and integrity in interactions between older adults and healthcare workers, using a participant observer methodology. In their analysis, which draws on Collopy's thesis on autonomy, the authors refer to the loss of "decisional autonomy", a loss that has to be supplied for the patient by others (Randers and Mattiason, p.66). A shared approach to decision-making is instigated in response to the patient's vulnerability. The authors conclude that substitution of the patient's autonomy may ultimately protect her integrity and recommend that nurses seek the model of autonomy, which will best meet the context in which the patient encounter occurs. This study is distinctive as it utilises more qualitative methodologies to explore

the autonomy conundrum in healthcare. In addition, the research includes healthcare professionals as participants when investigating the autonomy issue.

As reflected in Randers and Mattiasson's findings (2004), empirical work shows that healthcare professionals do not necessarily prioritise autonomy in all interactions with patients. The tensions that patient autonomy creates for healthcare professionals are also evident in empirical studies that may not seek to explore autonomy at the outset, but nonetheless, autonomy-related concerns emerge as interactions between patients and healthcare professionals are explored. Holm (1997) undertook a grounded theory study of the moral problems experienced by doctors and nurses in practice. He coined the term "protective responsibility" to encompass the sense of professional obligation expressed by participants as they recounted the manner in which they approached moral problems (1997, p.127). 'Protective responsibility' relates to the healthcare professional's awareness of the vulnerability of the patient by virtue of their ill-health, and the significance of non-maleficence in the ethical decision-making process. The decision-making process did not involve an over-zealous adherence to patient autonomy, but rather an appreciation that professionals play an important role in decision-making in the context of client care.

Chiovitti (2008) also utilised grounded theory to explore the meaning of caring among 17 nurses engaged with patents in a psychiatric setting. The findings revealed similar concerns among healthcare professionals. Chiovitti concluded that caring was expressed through the psychological process of 'protective empowering' as a core category. Protective empowering involved six individual categories of care interventions. While nurses sought to empower patients to become more actively involved in their health, considerations of patient safety were also significant.

2.2.3 The autonomy conundrum and freedom to choose in healthcare: Emerging ethical analysis

The exposure to the philosophical and empirical literature to this point suggests the need for more considered ethical analysis of the nature of autonomy in healthcare. This stage of enquiry is integral to the model of empirical bioethics applied within the study design, whereby ethical analysis precedes empirical work (McMillan and Hope 2008).

It appears, based on the review thus far, that autonomy is misunderstood in healthcare, or at least interpreted in a very narrow context. The literature suggests that dominant interpretations of autonomy in healthcare are problematic, as they are based on an inappropriate reverence to an isolated, negative autonomy, and fail to realise the relational nature of human existence.[10]

A number of understandings have been established through the exploration of the autonomy conundrum to this point. (1) Healthcare ethics and recent social policy documents uphold patient autonomy as a paramount ethical principle. (2) This model of autonomy goes beyond merely encouraging participation as autonomy is increasingly portrayed as an individualised freedom to choose. (3) This policy 'shift' and its practical consequences are problematic for healthcare professionals who endeavour to reconcile respect for patient autonomy with their professional responsibilities and a competing caring logic. (4) It is also reasonable to suggest at this point, based on empirical evidence, that patients do not always necessarily embrace this policy shift, and on occasion prefer healthcare professionals to take a greater role in the decision-making process. I propose therefore, that this model of patient autonomy does not provide a suitable benchmark for healthcare policy, or professionals, because (a) it represents a one-dimensional, sometimes misguided, perception of autonomy associated with the absence of constraints and (b) it denies important considerations of relationality, care and responsibility, which may better serve patients. I shall address both these points separately.

(a) It appears that the model of autonomy, which pervades current healthcare policy, is based on a misguided understanding of Kantian philosophy whereby autonomy is equated with non-interference. There is a wider acknowledgement of the manner in which Kant's metaphysic of morality is misinterpreted in healthcare (Baron 1995, O'Neill 2002, Paley 2002, Heubel and Biller-Andorno 2005). In *Groundwork of the*

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[10] This emerging analysis, explored within the supervision process, prompted a more in-depth philosophical review of autonomy in the earlier stages of the PhD process. The work, which ensued, resulted in a published paper on the nature of autonomy and choice in healthcare, within the specific context of self-testing devices. This paper is available for review as Appendix C: Published autonomy paper. A brief summary is offered here to lend greater comprehensiveness to the literature review process. This analysis was revisited as the empirical work proceeded. Ethical analysis and empirical work converge in the discussion chapter where the initial argument presented here is revisited and developed in light of empirical work.

Metaphysic of Morality Kant outlines an a priori metaphysic of morality (1998). Kant's *Autonomy of the Will* is often inappropriately interpreted as an approach to morality where an individual acts solely on principles that are self-embodied and not influenced by external entities. However, in reality Kant does not subscribe to an isolated autonomy but rather an 'autonomy of principles' associated with duty towards others (O'Neill 2002). Critiques of an individualistic interpretation of Kantian autonomy also note that Kant's *Formula of Humanity* and *Law of Universality* are more indicative of the need to engage with the 'other' than an isolated freedom of choice (Paley 2002, Heubel and Biller-Andorno 2005).

(b) A relational understanding of autonomy proposes that our interactions with others are significant in expressions of autonomy (Meyers 1989, Christman 2004). This is particularly relevant in the context of the relationship between patient and healthcare provider, yet also the patient relationship with significant others. The concepts of care and responsibility, implicit within the healthcare professional's role, suggest an incompatibility with negative accounts of autonomy and the need for greater interaction in the decision-making process (Downie 1998, Holm 1997, Olsen 2003, Hofmann and Lysdahl 2008, Mol 2008, Chiovitti 2008). At this point in the review, it appears that an alternative construction of autonomy may best serve healthcare practice and patients.

> If autonomy can exist in the presence of some constraining factors, then an anti-paternalistic healthcare philosophy, which seeks to advance autonomy by promoting individual freedom to choose, is fundamentally flawed. (Greaney et al. 2012, p.386).

2.2.4 The autonomy conundrum in healthcare: concluding comments
In conclusion, the dominance of patient autonomy in healthcare is questioned on the grounds that an advanced individualistic paradigm is not necessarily congruent with a number of core issues in healthcare: the relational nature of human existence; positive patient outcomes; patient preferences or meeting professional responsibilities. Philosophical and empirical literature has collectively informed this debate and suggests the need for an alternative construction of autonomy.

The empirical studies described above primarily adopt quantitative designs. Such methodologies, particularly where survey designs are employed, allow for larger sample sizes, more reliable statistical analysis and therefore more generalisable findings. However, there are some difficulties with this approach. The studies, for the most part, do not explore the actual reasons for patients' preferences in the context of care delivery. In addition, while Scott et al. (2003b) investigated nurses' perceptions of the extent to which patients were offered choices, in general, aside from Randers and Mattiasson's (2004) research, the studies reviewed explored patient preferences for decision-making and participation in care in isolation from the social context in which those preferences occurred. Hill et al.'s study (2013) suggests that patient preferences for autonomy may vary, depending on the specific context in which decisions are made. Studies generally do not seek to investigate the impact of a more active role in decision-making on overall patient welfare, or seek to elicit the patient's actual experience of adopting a more autonomous role. While the studies do not refer specifically to the practice of self-testing, they do help to illuminate the debate regarding the merits of increased patient participation in healthcare. Further research is required to explore patients' perceptions of adopting a more autonomous role in decision-making and other aspects of their care.

2.3 Self-testing technology as a microcosm of the autonomy conundrum in contemporary healthcare practice

The self-testing context represents a specific microcosm of the wider autonomy conundrum in healthcare. The availability of self-testing technology potentially maximises the patient's opportunity to assume a more autonomous role and become a more active participant in her care. Self-testing devices are marketed as a means to encourage patient participation in healthcare, and improve overall health outcomes through the early diagnosis of disease (Simplicity Health 2009). The association between self-testing and patient autonomy has international significance. A Dutch study by Ronda et al. (2009) note that self-testing devices 'fit' with the current emphasis on consumer autonomy and self-management within healthcare. Ryan et al. (2010) draw a comparable association in the UK, while Moreno (2007) identifies self-testing as a specific example of the relationship between patient autonomy and consumerism in the United States.

Recent developments in healthcare technology have heralded a profusion of self-testing devices. The Irish Medicines Board (IMB) defines self-testing devices as "any device intended by the manufacturer to be able to be used by lay persons in a home environment" (IMB 2004, p.6). The literature review reveals minimal empirical evidence to date with regard to prevalence of self-testing and the overall range of tests available. A Dutch study (Ronda et al. 2009) explores the use of self-testing technologies among internet users. 16% of 12,529 participants from an internet sample indicated previous use of a self-test with an approximate average of 2.1 tests per participant. The ten most frequently used tests were for: diabetes, cholesterol, allergies, urinary infection, HIV infection, anaemia, ovulation, chlamydia, glandular fever and hepatitis. Ryan et al. (2006) identified 104 unique tests associated with 24 different conditions in a systematic internet search in the UK. In a follow-up study 13% of respondents indicated use of self-testing devices after pregnancy tests, deemed to be routine, were excluded (Ryan et al. 2010).

Caven (1987) presents an account of the various social, legal and ethical issues associated with self-testing devices at a time when pregnancy testing kits and blood glucose monitors were the only available devices. The author raises concerns related to the impact of self-testing, and an associated self-care model, on patient well-being, healthcare costs and the nature of the patient/healthcare professional relationship. As the availability of self-testing devices increases, so too does debate regarding their clinical value (Ianchulev 2005, Heneghan et al. 2006, Towfigh et al. 2008, Farmer et al. 2009a, Paxton 2009, Malanda et al. 2012), cost-effectiveness (Simon et al. 2008, Clar et al. 2010), psychosocial impact (Kachroo 2006, Kalb 2008, French et al. 2008), legal status (Gevers 1999) and moral significance in the context of patient autonomy (Levitt 2001, Modra 2006, O'Lynn 2007, Kearns et al. 2010, Greaney et al. 2012). While self-tests can offer convenience, privacy and a sense of empowerment to those who use them (Ryan et al. 2010, Gubala et al. 2011) there is also the possibility of harm due to false positives and false negatives, unnecessary costs, the absence of a healthcare professional to offer a broader analysis of test findings (Burger and Kass 2009) and an increasing population of the 'worried well' (Ryan et al 2010).

2.3.1 Self-testing technology and patient autonomy

A dominant debate regarding the moral value of self-testing diagnostic devices centres on their role in advancing an individualistic and empowerment paradigm in healthcare delivery, which replaces a previously more stringently controlled and professional-led healthcare system. Much of this debate exists within the bioethics literature. The ability to self-diagnose without, or with reduced, professional support is seen as an example of extended patient autonomy and questioned on this basis (Modra 2006, O'Lynn 2007, Kearns et al. 2010, Greaney et al. 2012). There are particular ethical concerns identified in the context of direct-to-consumer genetic testing (Nuffield Council on Bioethics 2010), screening tests (Raffle 2001, Burger and Kass 2009) and HIV testing systems (Kachroo 2006). The commercial incentive to progress home testing systems, despite possible ethical issues, is also acknowledged in the literature. Whellams (2008) claims that the eagerness to attain Federal Drug Administration (FDA) approval for home-based HIV testing in the United States was disproportionate to consumer demand, and motivated more by the desire to maximise commercial benefit.

Kearns et al. (2010) acknowledge the potential benefits of diagnostic self-testing devices, yet raise some ethical concerns, which have relevance for the autonomy conundrum. The authors debate the autonomous and relational dimensions of the individual and propose that while diagnostic self-testing tools can advance individual autonomy through independent testing and decision-making, the results obtained have implications for one's "relational responsibilities" (p.3). The paper explains this position in the context of a man who uses a home testing kit to discover that he is infertile. Does he have a moral obligation to share these results with his partner and thus fulfil his relational responsibilities? The authors raise further contextual issues with regard to home testing and utilise the work of Charles Taylor to highlight that diagnostic self-testing is not something that occurs in a vacuum but rather holds great significance for those who experience the diagnosis. The paper offers an important dimension to the debate as it suggests that diagnostic self-testing cannot be viewed in isolation from the associated contextual issues.

While empirical studies do not specifically explore patient autonomy in the self-testing context, there is some reference to the concept in the findings of studies to date.

Grispen et al. (2011) undertook a cross-sectional internet survey in the Netherlands exploring psychosocial determinants of self-testing with three specific devices. The study found that self-efficacy was significantly associated with self-testing among those engaged in cholesterol, glucose and HIV testing. Similarly Ryan et al.'s study (2010) exploring motivations for self-testing concluded that, in addition to other factors, members of the public self-tested in accordance with their general attitudes to their own health. Some participants believed self-testing was an empowering process and engaged in self-testing to enable them to make more autonomous decisions about their health. However, the researchers note that some participants suggested a degree of caution with regard to self-testing. It is acknowledged that self-testing can be an overzealous activity engaged in by the 'worried well'. This sentiment is expressed quite well by one of the participants in Ryan's study (2010, p.580):

> *So long as you don't start reading into everything and turn yourself into a hypochondriac because that's what can happen, isn't it really ... I think I've agreed that I would do some self-testing, so long as you're, you've got to be careful, haven't you?*

The profusion of self-testing technology also has the potential to alter the relationship between healthcare provider and patient (Caven 1987, Mol 2000, Willems 2000). This reflects a wider acknowledgement of the impact of technology on healthcare practice (Reiser 2009). Mol (2000) notes the glucose monitor as a particular technological device which can potentially facilitate greater patient independence but also has a wider effect on the relationship between patient and healthcare professional. In accordance with Mol's analysis; "diagnostic devices actively intervene in the situations in which they are put to use" (Mol 2000, p 9). The extent to which those who develop self-testing devices appreciate the potential ethical and psychosocial outcomes of technology is not well explored. In *Ethics on the Laboratory Floor,* van der Burg and Swierstra (2013) recommend that ethicists and social scientists engage with scientists in the laboratory setting. The purpose of this engagement is to encourage reflection on technological innovation and potentially co-shape emerging technologies. This particular approach is relatively new; however, philosophical reflection on technology is not a new phenomenon.

Philosophical deliberations on technology and its impacts have occurred throughout history. These discussions have been collectively presented within a particular discourse known as the philosophy of technology (Mitcham 1990/2003). The philosophy of technology recognises the importance of technology as a non-neutral entity which shapes the way we live in the world (Scharff and Dusek 2003). Similarly, a more multi-disciplinary discourse, referred to as Science and Technology Studies (STS) notes the role of technology in enabling human action and its important impact on social structures (Sismondo 2010). Health Technology Assessment (HTA) is an emerging research discipline within healthcare, which seeks to explore the cost-effectiveness of new technologies in accordance with their clinical efficacy. The significance of these discourses will be developed in the chapter that follows as the theoretical underpinnings of the study are explored.

2.4 Self-testing technology and patient autonomy in diabetes management
2.4.1 Self-testing technology and diabetes management

Self-testing had inception in the diabetic population (Free and Free 1984). Due to the considerably evolved tradition of self-testing in this client group, a review of the literature in this context offers a significant evidence base to inform the self-testing and patient autonomy debate. Diabetes, or diabetes mellitus, is a chronic endocrine disorder characterised by an inability of the pancreas to produce sufficient insulin (type 1 diabetes), or effectively utilise available insulin (type 2 diabetes) (WHO 2013). Insulin is the hormone, which regulates blood glucose levels in the body. In the absence of sufficient insulin, hyperglycaemia (raised blood glucose levels) results causing damage to blood vessels with potential long-term complications. Self-testing of blood glucose levels, associated interpretation, and subsequent self-management is recognised as a means of maintaining 'in-range' blood glucose levels (Wallymahmed 2013). Self-testing is most frequently referred to as self-monitoring, or self-monitoring of blood glucose (SMBG), in the diabetes literature. Blood glucose levels can also be monitored by means of HbA1c or glycosylated haemoglobin. This measurement is processed in the hospital laboratory and gives a record of blood glucose levels over a three-month period.[11]

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[11] Current NICE quality standards for diabetes in adults (2011) suggest a target HbA1c value of between 48 mmol/mol and 58 mmol/mol.[11] This reflects the current guidance from the American Diabetes Association (2013), albeit acknowledging some nuances in specific patient contexts.

The early links between self-testing, diabetes care and autonomy are apparent. Patient autonomy in a healthcare context is often promoted within a model of patient empowerment. While patient empowerment is generally understood as a relatively recent phenomenon in healthcare associated with patient-centeredness and autonomy (Holström and Röing 2010), Joslin's approach to diabetes care in the early 20th century pioneered what the Joslin Diabetes Center (2012) still refer to as their model for patient empowerment. Joslin recommended the use of Benedict's urine test in his 1918 textbook, *Diabetic Manual for the Doctor and Patient* (Joslin Diabetes Center 2012).

Benedict's test uses a chemical reagent that changes colour relative to the amount of reducing sugars, or monosaccharides, in a solution. Since its introduction the range and availability of self-testing devices for diabetic patients has continued to grow (Free and Free 1984). The first disposable test for blood glucose measurement was introduced in 1964, but did not become available in wider circulation as a self-testing device until 1979 (Free and Free 1984). The technological capabilities and user-friendliness of blood glucose monitors have continued to evolve (Vashist et al. 2011). Current innovation is concerned with minimally invasive, or non-invasive, monitoring of blood glucose levels and continuous glucose monitoring systems, which can be used in association with internal insulin pumps to regulate blood glucose levels (Gubala et al. 2011, Moser at al. 2012). Regardless of the specific technologies applied, SMBG is now a widespread practice and forms a core component of overall diabetes care (American Diabetes Association (ADA) 2013).

2.4.2 Self-testing technology and diabetes management: Patient autonomy and empowerment

Historically, the purpose of self-testing in the diabetic population has its roots in greater clinical efficacy, but also in enhancing patient autonomy within an empowerment model (Joslin Diabetes Center 2012). When diabetics began to self-test their urinary glucose levels, treatment involved participating in an essentially starvation diet low in carbohydrate (Free and Free 1984). Joslin was eager that diabetics should take an active role in the management of their illness even in the

absence of a requirement to titrate medication doses (insulin or oral medication) with blood glucose levels. His general thesis was that participating in self-testing would increase patient empowerment and improve overall diabetes outcomes (Joslin Diabetes Center 2012). Self-testing may enable patients to determine their own blood glucose levels at a given point and time and modify diet, exercise and medication accordingly. This can potentially empower patients and enhance their autonomy. However, analysis of empirical studies shows that evidence, albeit limited, is inconclusive with regard to the impact of self-testing on patient empowerment.

A study exploring community nurses' reasons for advocating self-testing listed patient empowerment as a motivating factor (Abbott et al. 2007). One participant (DN6 p. 9) noted:

> *My aim is about self-empowerment and promoting self-care … the ethos of the team is to deliver care that allows patients to do as much as they can for themselves with support and guidance.*

However, the researchers note that there was no evidence to suggest that the patients had an opportunity to express their own preferences for self-care. Some participants reported that limitations existed among patients that would impede self-testing such as poor eyesight, limited dexterity, needle phobia and dementia. In addition, one community nurse suggested that making decisions based on self-monitoring was not common among patients:

> *Most of the patients I see are happy to do the testing themselves, but then wait for the nurse to make an assessment and decide what to do.* (DN7 p.10)

This study was a small-scale qualitative analysis of semi-structured interviews involving seven nurses' perceptions of the purpose and functions of self-testing in diabetes. Therefore, generalisations cannot be made from the data. However, the study raises an interesting point regarding the use of self-testing to advance patient empowerment in the apparent absence of determining the extent to which patients desire empowerment, autonomy and self-care. This points to an oxymoron of sorts, which could be referred to as 'enforced autonomy'. Davies and Elwin (2008) refer to this oxymoron, although not using the term per se, and raise a number of problems

regarding a move towards 'mandatory autonomy' in healthcare policy and practice. The authors indicate a preference for 'optional autonomy', which will encompass an understanding of restraints on individual choice and the cultural context of people's lives.

A well-publicised randomised control trial (RCT) in the UK, *The Diabetes Glycaemic Education and Monitoring* (DiGEM) study, explored the impact of SMBG on glycaemic control among individuals with type 2 diabetes not treated with insulin (Farmer et al. 2009b). The study design incorporated 40 qualitative interviews using a purposive sampling technique with a sample of the wider trial participants. Empowerment emerged as one of the three prominent themes within the study along with awareness and influence on health behaviour. The researchers take empowerment to mean increased control over healthcare. Patients commented on the convenience of the technology, which removed the need for clinic appointments, allowed them to initiate clinician follow up and inform healthcare decisions. Similarly, a study utilising survey methodology noted that 80% of participants reported a high satisfaction with SMBG and associated self-monitoring with feeling more in control of their illness (Barnard et al. 2010).

However, despite the positive accounts of self-testing within Barnard et al.'s study (2010), there were also accounts of depression, anxiety and guilt among others participants, with women reporting self-chastisement to a greater degree than men. Likewise, other patients in the DiGEM study reported a sense of failure, frustration, and discouragement when findings were high or seemed incompatible with recent lifestyle behaviours (Farmer at al. 2009b). Peel et al. (2004) also reported experiences of failure among participants when readings were counterintuitive. Similarly, a study in the UK explored the impact of replacing routine SMBG with a more intensive patient education programme and found that patients were reassured not to have to self-test regularly as testing reinforced the sick role (Harris and Cracknell 2005). Participants in the study also noted feelings of failure and poor health-related behaviour when unfavourable results were obtained. The replacement of SMBG with a more rigorous education programme resulted in improved glycaemic control in addition to the positive psychosocial outcomes.

It appears therefore as French et al. (2008)[12] suggest, that diabetics who are eager to pursue health-related behaviours can be demotivated by self-testing when the results do not accord with what they perceive to be their recent glucose-reducing behaviours. The researchers in the DiGEM study note that while the impact of small health behaviours may be more favourable in the long-term as evidenced by HbA1c results, these results are not apparent to patients who self-test on a regular basis. While the study found a statistically significant difference regarding beliefs about the severity of the consequences of diabetes among participants in the intensive monitoring group versus the less intensive or usual care groups, there was no statistically significant difference in beliefs about personal control over diabetes and the perceived effectiveness of treatment. It is therefore important to consider why healthcare professionals routinely recommend SMBG, if all it serves to do among some patients is to heighten their awareness of the severity of their illness, yet provide them with no sense of control over their situation. Despite some favourable accounts of SMBG as an empowerment tool, only 2 of the 40 patients who were interviewed in the DiGEM study expressed an absolute preference for SMBG as opposed to scheduled clinic visits and HbA1c testing. Other studies indicate more disturbing experiences among those undertaking self-monitoring of blood glucose.

Peel et al. (2007) found that female participants in their study associated SMBG with feelings of guilt and self-chastisement. A later study undertaken by Barnard et al. (2010) reported similar results among some female respondents despite more positive feedback from the wider population. *The Efficacy of Self-Monitoring of Blood Glucose in Newly Diagnosed Type 2 Diabetes Trial*, or ESMON study (O'Kane et al. 2008) found that patients assigned to the self-monitoring group scored 6% higher on the depression subscale of the well-being questionnaire. These findings raise obvious questions about the impact of self-testing on patient empowerment and autonomy, and also general well-being. O'Kane et al. (2008) acknowledge this as a recurring theme in the literature and recommend further investigation into the actual effects of SMBG on patients. The researchers surmise that these negative feelings may not necessarily be related to a sense of powerlessness, but rather associated with the strict discipline required in self-monitoring in the absence of any tangible gain.

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[12] This paper reported the qualitative findings of the DiGEM study.

It seems also that patients lacked the capacity for more autonomous roles due to a lack of education and a shared vision for self-testing. Patients reported their confusion with regard to the limited interest healthcare professionals placed in SMBG and referred to a lack of education with regard to self-testing and its purpose (Peel et al. 2007, Farmer et al. 2009b, Clar et al. 2010). Appropriate education is acknowledged to be of core importance in determining the success of point of care testing systems (Price 2003, Gubala et al. 2012), self-management programmes (Redman 2005, Murphy et al. 2011) and overall diabetes care (International Diabetes Federation (IDF) 2009, American Diabetes Association (ADA) 2013).

2.4.3 Self-testing technology and diabetes management: Clinical efficacy

The early interest in self-testing devices for blood glucose monitoring was motivated by a need to reduce perinatal mortality rates of up to 50% in infants of mothers whose diabetes was poorly controlled (Free and Free 1984). More recent emphasis centres on the role of self-monitoring in optimising blood glucose (glycaemic) control, a significant factor in reducing the long-term complications of diabetes (IDF 2011). The clinical efficacy of self-testing, as evidenced by improved glycaemic control, has an important ethical relevance here. If, as is reasonable to assume at this point, SMBG may induce negative feelings and fail to enhance patient autonomy and empowerment among some patients, the value of self-testing in terms of biomedical outcomes is of greater significance. An understanding of the overall impact of self-testing on both biochemical and psychosocial markers will assist in assessing the possible burdens of self-testing relative to its clinical value. In addition, the lack of conclusive evidence regarding the role of SMBG in improving glycaemic control lends greater credibility to the need for more qualitative analysis of its impacts and lends support to the aims of this study.

The clinical efficacy of self-monitoring of blood glucose levels in different diabetes classifications has become a predominant feature of debate and research in diabetes management over the last number of years (Klonoff 2008, International Diabetes Federation 2009, Kolb et al. 2010, ADA 2013). Available evidence is inconclusive with regard to the actual impact of SMBG on glycaemic control, particularly among

type 2 diabetics not treated with insulin.[13] Inconsistencies are evident in the findings of systematic reviews and among individual Randomised Controlled Trials (RCTs.)[14] Reviews of evidence undertaken by Welschen et al. (2005), McAndrew et al. (2007), Towfigh et al. (2008) and Alleman et al. (2009) offer support for the ongoing use of self-testing among type 2 diabetic patients not treated with insulin. However, Clar et al.'s later review (2010) concludes that the synthesised evidence did not support additional investment in SMBG for these same types of patients. Similarly, Malanda et al. (2012) fail to endorse routine blood glucose monitoring among individuals with type 2 diabetes following their review of the evidence.

An analysis of specific RCTs among type 2 diabetes not receiving insulin reveals similar conflicting results. *The Auto-Surveillance Intervention Active Study* (AISA) in France (Guerci et al. 2003) revealed a statistically significant effect on glycaemic control among individuals engaged with self-monitoring. However, the ESMON study (O'Kane et al. 2008) showed no statistical difference in glycaemic control between the self-monitoring group and those assigned to a non-monitoring control group. Similarly, the DiGEM study (Farmer et al. 2009b) found no convincing evidence to endorse routine self-monitoring in adults with type 2 diabetes not treated with insulin. Findings did not exclude the possibility of favourable clinical outcomes for certain sub-groups of patients, but the recommendations did not endorse widespread self-testing. The DiGEM study has gained considerable attention in the UK, as the associated economic analysis did not deem SMBG among type 2 diabetics, not receiving insulin, to be cost-effective based on quality adjusted life years (QUALYs) and healthcare costs (Simon et al. 2008). This analysis has been supported by subsequent HTA (Clar et al. 2010), and endorsed by recent National Health Service (NHS) guidance (NHS 2010). The recommendations suggest more prudent decision-

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[13] The need for more frequent blood glucose monitoring among individuals receiving insulin, primarily those with type 1 diabetes, is seldom disputed due to insulin's greater potential to induce hypoglycaemia.

[14] The difficulties associated with assessing the impact of SMBG on glycaemic control are acknowledged among researchers in the field. Inconclusive evidence has been attributed to methodological inconsistencies in trial design (McAndrew 2007, Kloncoff 2008) and the protocols applied within systematic reviews (Clar et al. 2010). Farmer et al. (2009b) note that it is difficult to design trials, as patients in the monitoring group require information about the testing process and interpretation of results, while the control group also require some instruction in self-care activities.

making among physicians, and propose that SMBG should only be routinely used in individuals with type 2 diabetes who are not treated with insulin, when there is an agreed goal to testing. Research pertaining to economic evaluation is ongoing and the benefit of urine testing as a replacement for blood glucose monitoring is currently being explored (Dallasso et al. 2012).

While self-monitoring has been questioned in the context of type 2 diabetes for some time, particularly among those patients not treated with insulin, more recent analysis of evidence also questions the clinical value of routine self-testing in other diabetes classifications (Kolb et al. 2010). The authors note that as SMBG is not a discrete variable, but one component in an overall diabetes management approach, the efficiency of SMBG-based management programmes for diabetes is assessed in RCTs, as opposed to SMBG itself. Kolb's basic premise is that self-testing of blood glucose levels, in any diabetes classification, should be initiated to enhance understanding of diabetes, monitor periods of poor glycaemic control, or prevent hypoglycaemic events secondary to anti-diabetic agents in susceptible patients (Kolb et al. 2010). Current clinical guidelines support a more patient specific approach to SMBG (IDF 2009, National Institute for Health and Clinical Excellence (NICE) 2011, ADA 2013). RCTs exploring SMBG versus non-monitoring are lacking for individuals treated with insulin. However, due to the greater risk of hypoglycaemia in this client group there are ethical issues in assigning any patient to a non-testing group.

2.4.4 Self-testing technology and autonomy in diabetes management: Concluding comments

In conclusion, the evidence to date is inconclusive with regard to the impact of blood glucose monitoring on glycaemic control, as a marker of clinical efficacy, or on patients' perceptions of autonomy, empowerment and overall well-being. The cost-effectiveness of SMBG is also a matter of debate. The impact of SMBG on patient empowerment reflects the wider debate regarding self-testing and patient autonomy. There is limited qualitative data exploring the psycho-social impact of self-management on diabetic patients with regard to the adoption of this more autonomous role. Research focuses predominantly on the clinical efficacy of SMBG within RCTs as evidenced by changes in glycaemic control. The emergence of some recent qualitative data associates SMBG with expressions of empowerment, yet also

experiences of guilt, frustration and depression. There is evidence of frustration among patients when self-monitoring is not adequately supported by healthcare professionals. This raises obvious questions about healthcare professionals' perceptions of their roles in self-monitoring. However, only one study reviewed to date explored this dimension (Abbot et al. 2007). Peel et al. (2007) note the failure to illicit the views of healthcare professionals as a limitation of their study. It is also apparent from the literature that methodological problems exist in the design of RCTs investigating the impact of SMBG on glycaemic control and that self-testers are not a homogenous group.

2.5 Conclusions from the literature and justification for proposed research

There is considerable emphasis on patient autonomy within contemporary healthcare practice. This is supported by the prevailing policy context and a tendency to exalt autonomy as the most important ethical principle. While a greater emphasis on patient autonomy may have some intrinsic moral value, the empirical and philosophical evidence explored suggests this is not necessarily always congruent with positive patient outcomes or meeting one's professional responsibilities. This model of patient autonomy is often associated with increased patient choice, which does not reflect the reality of the healthcare environment and the arbitrary nature of choice. The prevailing understanding of autonomy in healthcare is rooted in a misguided understanding of Kantian philosophy whereby a negative understanding of autonomy translates to an isolated decision-making process. Ethical analysis to this point suggests that a relational understanding of autonomy may be more congruent with the reality of patient choice, the shifting healthcare needs of patients and the professional responsibilities of their caregivers.

Available evidence suggests that self-testing is now a relatively prevalent activity. Individuals can test for a range of diseases and conditions without leaving their homes. The predominant discussion regarding the moral worth of self-testing devices centres on their ability to facilitate greater patient autonomy within the healthcare sphere. This philosophy underpins the marketing strategies utilised by the designers and manufacturers of this technology. In this respect, self-testing represents a specific microcosm of a growing model of patient autonomy and its associated tensions. The growth in the number and use of self-testing devices reflects a significant shift from a

more paternalistic model of patient care, where investigation and diagnosis were the sole remit of healthcare professionals. While self-testing devices are associated with improved clinical outcomes and have the capacity to enhance patient autonomy within an empowerment model, criticisms of the technology also exist. It is noted that self-testing devices can cause psychological distress due to false positives, can delay treatment due to false negatives, may incur unnecessary costs and potentially influence the patient/healthcare professional relationship in unintended ways.

The literature, which questions the moral significance of self-testing devices in an autonomy context, is primarily discursive and philosophical in nature. When studies investigate the autonomy issue, they are primarily quantitative in nature and reveal little information about the actual experiences of patients when assuming more or less autonomous roles. This highlights a gap in the literature, which the researcher intends to address. Research is required to review the psychosocial implications of self-testing and the associated individualistic paradigm in healthcare from a qualitative perspective. While studies, albeit inconclusive, may reveal positive clinical outcomes of self-testing with regard to biochemical markers, research is needed which provides an insight into the actual experiences of patients who partake in self-testing.

An ethical appraisal of self-testing tools is warranted from a quality assurance perspective in accordance with Health Technology Assessment (HTA). The process of HTA is relatively new in Ireland and is led by The Health Information and Quality Authority (HIQA) (Government of Ireland 2007). HTA is a form of multi-disciplinary mode of policy analysis that explores the clinical efficacy and cost-effectiveness of health technologies (Saarni et al. 2008). It also considers the legal, ethical, social and organisational aspects of technology use. HIQA (2010) notes the need to develop HTA in an Irish context. Ethical technology assessment provides a tool to determine problematic aspects of technology at an earlier stage (Palm and Hansson 2005, Saarni et al. 2008). However, research to date had tended to focus on the clinical outcomes and cost effectiveness of technology, with limited appraisal of the social and ethical components (Sacchini et al. 2010). In accordance with emerging approaches to HTA (van der Burg and Swierstra 2013), it would be useful to engage with the scientific community who develop self-testing devices to elicit their vision for self-testing.

The diabetic population provides an ideal context in which to explore patient autonomy within the self-testing process. The evidence to date is inconclusive with regard to the impact of blood glucose monitoring on clinical efficacy, or on patients' perceptions of autonomy, empowerment and more general well-being. In addition, despite patients reporting a frustration with the level of support received from healthcare professionals, studies reveal little inclusion of healthcare professionals as participants. This literature review reveals that technology has an impact on the relationship between patients and the healthcare team and that advancing patient autonomy may pose a challenge for healthcare professionals. In this context, it would be useful to elicit the perspective of healthcare professionals in future research. The literature also notes the limits of RCTs in assessing the clinical efficacy of SMBG and the lack of homogeneity among self-testers as a group.

In conclusion, the contemporary policy context and current empirical and philosophical evidence point towards the need for an in-depth qualitative analysis of patients' experiences of autonomy and empowerment within the self-testing process to provide insight into the ethics of self-testing. This is particularly apparent in the diabetic population, where research is inconclusive regarding the clinical and psychosocial outcomes of self-monitoring. The views of healthcare professionals are also required to understand the patient experience in light of the relationships they share with the healthcare team. It would also be useful to elicit the views of those involved in the design of future self-testing devices to determine the extent to which patients' experiences of this technology accord with the vision espoused by the designers.

A combined philosophical and empirical analysis is warranted on the basis of this review. Agledahl et al. (2011) refer to the dissonance between the current focus on autonomy in bioethical discourse and the reality of choice situations in clinical practice. The authors acknowledge the valuable contribution of philosophical discussion but suggest that empirical work is essential in order to have philosophical reflections rooted in the reality of clinical practice. Similarly, Broer et al. (2010) note that autonomy is seldom explored in light of the dilemmas associated with particular conceptualisations of autonomy in practice. The authors draw on Latour's (1987) actor-network theory to suggest that autonomy cannot be defined without addressing

the actors who shape the concept. Empirical work can stem from, and inform, the philosophical debate regarding the meaning of autonomy and its application in the healthcare context. There is a prevailing assumption that patient autonomy and patient choice are good and should be maximized at all cost. This is not necessarily the case. Policy needs to be based on a sound philosophical understanding of the concepts it seeks to promote. This study seeks to contribute to that knowledge base.

SECTION 2: RESEARCH STRATEGY

CHAPTER 3: PHILOSOPHICAL AND THEORETICAL UNDERPINNINGS

If we want to understand man's existence we must listen to the language of objects. If we are describing a subject we must elaborate on the scene in which the subject reveals himself.

(van den Berg, 1972/2013)[15]

3.1 Introduction

The literature review concluded with a justification for a combined qualitative, empirical and philosophical exploration of self-testing among individuals with diabetes, to explore the actual experience of autonomy in a specific clinical context. The aim of this chapter is to examine the various theoretical and philosophical underpinnings, which support this research strategy. In this sense, this chapter acts as a bridge between the literature review and the specific research methods outlined in chapter 4. The research strategy employed merges ethical analysis with more traditional qualitative empirical methods, to explore the meaning of autonomy in a specific clinical context. The influences on the research methodology include the empirical bioethics literature, the field of Health Technology Assessment and a Heideggerian approach based on the philosophy of technology discourse, hermeneutics and interpretive phenomenology. The synergy between these various components will become more apparent as the chapter proceeds.

3.2 The 'empirical turn' in bioethics: Implications for this study

The decision to incorporate empirical research questions within this bioethical research study was motivated by the aspiration to ground normative discussion in a

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[15] Quote retrieved online as one of a selection of quotes from phenomenological thinkers. The website is dedicated to the work of Max van Manen, the phenomenologist. Available at http://www.phenomenologyonline.com/ (Accessed 24/11/2013). Van den Burg is a phenomenological psychologist. For a more detailed account of his perspective and the source of this quotation see, Van den Berg J.H. (1972, p.40) *A different existence*. Pittsburgh: Duquesne University Press.

particular patient context. This was highlighted within the literature review, where criticisms of a purely philosophical approach to patient autonomy were outlined (Broer at al. 2010, Agledahl et al. 2011). Traditionally, normative ethics involves the application of moral philosophy informed by norms, rules, and duties, to make decisions about what one ought to do. However, there has been a shift towards empirical work to support this analysis, as the bioethicist is now increasingly engaged in field work previously rooted within the realm of social scientists (Holm and Jonas 2004,[16] Widdershoven et al. 2008, Borry et al. 2008, Salloch et al. 2012, Rehmann-Sutter et al. 2012). Holm (1997) acknowledges the limitations of purely theoretical analysis and highlights the significance of the context in the analysis of bioethical problems. For Holm, (1997, p.27) moral problems are rooted in the real world of practice, therefore empirical work is important to develop moral principles which are applicable in a "less than perfect world". In empirical ethics, empirical research provides a "context-sensitive insight into certain moral practices in healthcare" which can contribute to normative deliberations (Salloch et al. 2012, p.2).

Empirical ethics can be defined as "a broad category, grasping different interpretations of combining or trying to integrate ethics and empirical research" (Borry et al. 2008 p.39). Borry et al. (2008) trace the emergence of 'empirical ethics' as an autonomous research field over a period of four decades. The term itself is not new, being used as early as 1930 to distinguish empirical and non-empirical philosophy. However, earlier roots are found in Kant's reference to moral anthropology and applied moral philosophy. Borry et al.'s paper (2008) outlines the factors, which have contributed to the recent interest in empirical bioethics. These include an appeal for evidence-based healthcare, an interest in contextualising ethical problems and the growth of clinical ethics. Arguably, the development of qualitative research methodologies within the social sciences may also be a contributing factor.

In a recently updated version of *Methods in Medical Ethics* Sugarman and Sulmasy (2010, p.17) refer to the "flourishing" of interdisciplinary work in medical ethics and list eight ways in which empirical work can contribute to medical ethics. These

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[16] The papers within this text form part of the EMPIRE project (Empirical methods in bioethics). This is a European project dedicated to uncovering ways in which bioethics can contribute to bioethical thinking in the context of biotechnology.

include, among others: purely descriptive studies about morality; studies which test behavioural adherence to established moral norms; studies which establish facts relative to moral problems,; empirical data which examines the merits of slippery slope arguments; and descriptive studies which assess the likely consequences of moral action. However, there is considerable debate regarding 'the empirical turn' in bioethics (Widdershoven et al. 2008).[17] Elements of this debate include epistemological concerns regarding the merits of an empirical approach in a discipline previously dominated by normative analysis, but also disciplinary tensions regarding the value of merging philosophical and empirical enquiry. Campbell (2003) refers to the relationship between normative and empirical ethics as contentious. In embracing empirics, bioethics researchers not only grapple with their own identities, but also face opposition from analytic philosophers concerned with the dilution of philosophical method, and social scientists protecting their position as the researchers of the empirical 'real world' dimension of ethical analysis (Hedgecoe 2004, Dunn et al. 2008, Molewijk and Firth 2009, Williamson 2010).

Most significant in the debate are the epistemiological issues. There is a fundamental epistemological question at stake regarding the relationship between normative and descriptive ethics. McMillan and Hope (2008) refer to this as the 'is-ought' problem and the associated 'naturalistic fallacy'. Essentially, the 'is-ought' problem suggests that exclusively 'is' premises cannot lead to 'ought' conclusions. The basis of the 'is-ought' problem is found in Hume's *A Treatise of Human Nature* (1739/2006) and hence also referred to as the Humean Dilemma. The standard Anglo-American interpretation, prior to debate in the 1950s, suggested that there was "no logical relation between 'is' and 'ought' judgements" (Kupperman 2005 p. 343). Searle (1964) expresses the issue in more modern terminology noting that no collection of 'descriptive' statements can entail an 'evaluative' statement without the introduction of an evaluative premise.

Salloch et al. (2012) present an account of empirical ethics, which provides the novice researcher with a sufficiently clear, yet robust guide to undertaking empirical work in the field of bioethics. While other papers concentrate on exploring the problems,

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[17] Widdershoven et al. (2008) use this term in the introduction to their text examining the growth of empirical research in psychiatry. The text provides an historical overview of the increasing degree of empirical evidence in bioethics and presents some specific empirical studies in psychiatric ethics.

Salloch et al. (2102) provide some solutions. The authors criticise studies in empirical ethics which either fail to make normative conclusions, or fail to sufficiently delineate the relationship between 'is' and 'ought' statements when normative conclusions are outlined. The authors' general thesis is that empirical studies in bioethics require "considered reference to normative research questions" to ensure quality (p.2). Recognising the underlining epistemological issues, the authors emphasise the importance of developing a meta-ethical position at the outset, which is observed throughout all phases of the research process. This meta-ethical position would justify the researcher's perspective on the nature of empirical and normative collaboration, and provide a backdrop against which empirical work proceeds and is later analysed.

A detailed account of my own meta-ethical perspective is available for review as Appendix E: 'Is-ought' paper.[18] Essentially, I adopt a position of neo-naturalism, as advocated by Stewart (2009). I argue that Hume's position is not as absolute as often portrayed; the 'is-ought' distinction does not preclude utilising empirical work in normative judgement. I propose that empirical facts can be utilised to ground ethical analysis in the concrete world of experience. This does not necessitate deriving normative conclusions directly from facts, but rather involves utilising facts in moral reflection and deliberation to arrive at ethical conclusions. Central to the argument presented within the detailed paper is that the relational autonomous agent considers the facts of the situation one 'is' in, in a societal context, in order to determine what one 'ought' to do. I suggest that complete acceptance of the 'is-ought' problem denies the process of personal reflection on fact that is implicit within moral decision-making.

This position reflects the views of others who have also grappled with these issues. Borry et al. (2004, p.48) suggest that "empirical research cannot by itself determine

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[18] This paper began as an initial review of epistemological issues related to empirical bioethics and has continued to evolve throughout the course of my studies. The attendance at a graduate studies *Philosophy of Social Science* module, under the direction of Dr. Fiachra O'Brolchán, was very helpful in providing a specific forum to explore the issues in addition to the supervision process. A meeting with Dr. Sabine Salloch, from the *Institute for Medical Ethics and History of Medicine*, Ruhr University Bochum, Germany was extremely useful in crystallising my ideas towards the end of my studies. I am grateful to both for their assistance. An earlier draft of this paper was presented at the *International Philosophy of Nursing Conference* in Dundee, September 2011. Feedback received from delegates at the conference also contributed to the development of the paper. The paper presented in Appendix E is an updated version of the paper submitted for the graduate studies module. It is intended that this paper will be developed further and submitted for publication on completion of the PhD process.

what is good or evil, right or wrong" but they do not accept the 'is-ought' distinction as "absolute" (p.51). In accordance with Borry et al.'s analysis, facts can embody normativity and inform our actions but this normativity requires legitimate construction through the application of ethical analysis. In this account of empirical bioethics both inductive and deductive reasoning is applied whereby one uses the facts gained through empirical activity but then subjects those facts to moral enquiry (p.50).

In accordance with Salloch et al.'s (2012) guidance, it is important to consider the manner in which this meta-ethical position could be incorporated within the study design, and how normative and empirical collaboration could be best achieved. McMillan and Hope (2008) present a cyclical model of integrated empirical bioethics which facilitates this process. In this model "ethical analysis and empirical data collection inform each other in an interactive cycle" (McMillan and Hope 2008, p.19). The model incorporates four interactive phases: ethical analysis, identification of empirical issues, empirical studies and generation of new data. This new data can then be subjected to further ethical analysis as the cycle continues. The model is consistent with the meta-ethical position of neo-naturalism that guides this study. McMillan and Hope acknowledge the presence of Hume's 'is-ought' problem, but note, similar to the analysis presented in Appendix E, that empirical ethics is not condemned to meta-ethical fallacies when the facts gleaned through empirical investigation are associated with a moral premise to arrive at a normative conclusion.

However, while McMillan and Hope's (2008) cyclical approach provides us with a 'process' of integration, it does not define the precise nature of empirical-normative collaboration. Rehmann-Sutter at al. (2012) outline a hermeneutic approach to empirical bioethics which provides a sound methodological basis for normative-empirical collaboration in this study. This approach is appealing as it congruent with the meta-ethical position, which guides the empirical-ethical collaboration within the study, is congruent with the interpretive, hermeneutic underpinnings of the empirical methodology and dovetails coherently with McMillan and Hope's (2008) cyclical model of empirical ethics.[19]

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[19] As my thinking progressed throughout the PhD process the synergy between McMillan and Hope's (2008) integrated model of empirical bioethics and the iterative nature of interpretive

The features of McMillan and Hope's (2008) cyclical model of empirical bioethics, and Rehmann-Sutter at al.'s (2012) phenomenologically informed hermeneutic approach to bioethics, will be explained in greater depth in chapter 4 as the research methodology is outlined in a more mechanistic format. At this point, it is sufficient to note that the study is located within the growing field of empirical ethics. McMillan and Hope (2008, p.19) suggest that three criteria are necessary to satisfy the use of the term 'empirical ethics'. (1) The project must encompass normative analysis, (2) there must be a systematic collection of data and (3) the relationship between the empirical and the normative should go beyond a linear association to involve a more cyclical relationship. This PhD study meets these criteria through a cyclically integrated empirical and ethical analysis of patient autonomy among individuals engaged with self-testing technology.

3.3 Technology, ethics and Health Technology Assessment

Health Technology Assessment (HTA) acknowledges the need for an empirical analysis of bioethical issues in technology development. HTA is "a multi-disciplinary field of policy analysis [which] studies the implications of the development, diffusion and use of health technology" (Saarni et al. 2008, p.617).[20] These implications include health-related outcomes, and financial, social and ethical concerns. The research questions relate to the patients' interactions with self-testing devices with regard to the manner in which these interactions shape expressions of autonomy, are mediated by healthcare providers and relate to the vision for self-testing espoused by the scientific community involved in the development of new technology. Theoretical discourse related to the assessment of technology is therefore particularly relevant in this study.

To date, HTA has primarily been concerned with cost-benefit analysis. Recent discussion acknowledges the need to develop a greater evidence base with regard to the social and ethical significance of technology (Sacchini et al. 2010). An ethical

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phenomenology became more apparent. Rehmann-Sutter et al.'s (2012) paper delineates this relationship quite clearly and was extremely helpful in crystallising my emerging ideas in this regard.
[20] The Health Information and Quality Authority (HIQA) hold responsibility for the development and facilitation of HTA in Ireland (Government of Ireland 2007).

component within HTA can be useful at the point at which technology is being developed to identify problematic aspects at an early stage (Palm and Hansson 2005, Saarni et al. 2008). The European network for Health Technology Assessment (EUnetHTA 2008)[21] presents a core model for the ethical assessment of technology. The model seeks to integrate ethical assessment 'within' HTA, as opposed to ethical assessment that occurs in an 'add-on' fashion. The core model suggests a series of strategies, which can bef utilised to integrate empirical and ethical analysis and avoid the epistemological problems associated with empirical ethics outlined earlier in this chapter. However, empirical research in HTA is primarily quantitative in nature. van der Burg and Swierstra (2013) acknowledge the ongoing dominant focus on the 'hard' as opposed to 'soft' impacts of technology within HTA. While hard impacts are associated with crude measurements related to cost analysis and clinical efficacy, soft impacts are concerned with more subtle consequences pertaining to how people live their lives.

In *Ethics on the Laboratory Floor* van der Burg and Swierstra (2013, p.7) outline an approach to technology assessment, rooted in the laboratory setting, which "uses moral philosophy to distinguish issues related to developing technology that demand ethical reflection, and to provide tools to enhance reflection about them among scientists and engineers". This PhD study draws on some of these tools to explore the perspectives of the scientific community engaged in the development of diagnostic technologies. van der Burg and Swierstra's (2013) approach remains rooted in the philosophy of technology discourse but represents a new frontier in this area of scholarship.

3.4 Philosophy of Technology

Prior to the advent of a more empirical dimension within HTA, or Science and Technology Studies (Sismondo 2010), the appraisal of technology has a long historical tradition in theology and philosophy (Mitcham 1990/2003). The philosophy of technology discourse, though rooted in the earliest branches of western philosophy, represents a growing contemporary field of study exploring the relationship between

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[21] The European Network for Health Technology Assessment (EUnetHTA) consists of 34 government appointed organisations within Europe who "work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries." (See www.eunethta.net). HIQA in the Irish Context is a member of this network.

humanity and technology. The philosophy of technology represents a specific field of philosophy concerned with the impacts of developing technologies on the world we inhabit and humanity's relationship with this technology. Its central tenet is that it respects technology as more than a neutral phenomenon and seeks to uncover the realities of human-technology relationships (Ihde 2006). While the tools utilised by philosophers exploring the technological world do not differ from those used by other philosophers, i.e. reason, argument and thought experiments, this field provides the researcher with a specific focal point for philosophical discussion and access to a body of philosophical literature which deals specifically with this area of specialisation.[22]

In *Three Ways of Being-With Technology* Mitcham (1990/2003) provides a succinct historical account of the philosophy of technology tradition. Mitcham aligns humanity's engagement with technology to three major movements with particular characteristics: 'ancient skepticism', 'Renaissance and Enlightenment optimism' and 'romantic ambiguity' or a sense of uneasiness. In brief, ancient skepticism refers to man's movement beyond a previous dependence on, or reverence to, God or the gods towards a tentative investment in the technological world. Renaissance and Enlightenment optimism encompasses progression towards a more favorable account of technology whereby man's social development was perceived as related to his technological pursuits. The third movement, romantic ambiguity, became prevalent in the mid-eighteenth century as the societal impact of the industrial revolution brought about a post Enlightenment more critical view of technology. Mitcham states that a sense of Romantic uneasiness towards technology may prevail in the twenty-first century whereby we aim to find a middle ground between ancient skepticism and Enlightenment optimism.

Deitrich (1995) critiques Mitcham's 'historicophilosophical' analysis. Deitrich's commentary is complementary for the most part. However, while he acknowledges the merit of Mitcham's contribution he notes that it is incomplete. He suggests that

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[22] The Philosophy of technology discourse has been prominent in my work since the 2nd year of my PhD studies. This philosophical understanding of technology has been greatly assisted by links with faculty at the *Centre for Philosophy of Technology and Engineering Sciences* (CEPTES) at the University of Twente in the Netherlands and Dr. Simone van der Burg, previously employee at Twente, now engaged as a Senior Researcher in Philosophy and Ethics of Medical Technology at IQ healthcare in Nijmegen.

Mitcham add a fourth dimension which represents a post-modern period in the philosophy of technology discourse: post-modern immersion. While 'post-modern immersion' may not be the most appropriate term, it seems reasonable to suggest, as Deitrich does, that an additional movement or classification would be required. This 'new' classification could more suitably encompass the growing body of work (including the Ethics on The Laboratory Floor approach described above) which examines emerging technologies in the laboratory, and other settings, from a combined philosophical and empirical perspective (Mol 2000, Willems 2000, van der Burg and Swierstra 2013). While empirical ethics and philosophical approaches to HTA have much in common there appears to be little engagement between the discourses.

Mitcham uses Heidegger's concept of 'being-with' technology to frame the three movements he refers to. The more contemporary philosophy of technology discourse shares a commonality in its reference to the work of Heidegger as a key influence in this field of scholarship. Martin Heidegger is acknowledged as one of the forbears of contemporary philosophy of technology discourse. *Being and Time* (BT)[23] (1926/1962) is credited with providing a pioneering account of our engagement with things as human beings (Mulhall 2005, Adams 2008). *Being and Time*, or *Sein und Zeit*, written in 1926, was largely inaccessible to the English-speaking world until the translation provided by Macquarrie and Robinson in 1962. The text is viewed on the one hand as a difficult, pretentious piece of prose, yet on the other as an intricate, influential work of philosophy (Mulhall 2005). Heideggerian philosophy of technology encompasses the earlier, classical philosophy of technology discourse in a developing body of work which is particularly dominated by North American (Mitcham 1990/2003, Ihde 2006) and more recent Dutch perspectives (Willems 2000, Verbeek 2005, Mol 2008, van der Burg 2009, Boenink 2012, van der Burg and Swierstra 2013).

Heidegger's philosophy of technology cannot be separated from his wider ontological and phenomenological perspective. Heidegger advocated a phenomenological understanding of the world in view of the *things* that inhabit it (Adams 2008).

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[23] Heidegger's *Being and Time* will be referred to as BT with the appropriate citation as per philosophical convention

Heidegger summarises his perspective in his own words in accordance with the maxim – *To the things themselves* (BT 7:28). Heidegger's ontological position articulated within *Being and Time* is that we are inextricably entwined with the world in which we live. In accordance with Heidegger's understanding of being as 'Dasein', meaning 'being-there' or 'being-in-the world' (BT 3:15), we encounter the world in a practical sense as a world of things which are 'ready-to-hand' and imbued with human meaning. Heidegger's 'being-in-the-world' is central to his understanding of human-technical relations. For Heidegger, man's engagement with technology is not merely technical but has "an immediately and intimately social dimension" (Mitcham 1990/2003, p.491).

This is apparent in Heidegger's *The Question Concerning Technology* (1954/2003). For Heidegger, technology is much more than a means to an end or a human activity. Technology is a way of revealing. In accordance with Heidegger's analysis, if we acknowledge this perspective "another whole realm for the essence of technology will open itself up to us. It is the realm of revealing, i.e., of truth" (1954/2003, p.255). In referring to technology as a way of revealing, Heidegger is explaining the process of moving from a time of concealment to unconcealment. This is Heidegger's special mode of being (Verbeek 2005). This essence of technology as revealing is referred to in Heidegger's earlier work, *Being and Time,* in the context of the hammer. For Heidegger, the hammer's significance lies in its human engagement; its 'readiness-to-hand'. It is only in functioning to hammer a nail the hammer gains meaning in the world:

> The less we just stare at the hammer-thing, and the more we seize hold of it and use it, the more primordial does our relationship to it become, and the more unveiledly is it encountered as that which it is—as equipment. The hammering itself uncovers the specific 'manipulability' of the hammer. The kind of Being which equipment possesses—in which it manifests itself in its own right—we call 'readiness-to-hand' (BT, 15:98)

Heidegger's *Dasein* or 'being-in-the world' relates to the way in which material objects gain meaning for us once used for some purpose (Harman 2007). In our 'ready-to-hand' mode, we engage with objects pre-reflectively as, for example, we drive a car or turn a key in lock. In addition to 'ready-to-hand' as a mode of being, Heidegger also refers to 'unready-to-hand' and 'present-to-hand'. The hammer, which is integrated

seamlessly in our world as equipment in use, only becomes overtly apparent to us when it ceases to work and perform its necessary function. In this sense, the hammer is 'unready-to-hand' just as the car that breaks down and the key that fails to turn. In the 'present-to-hand' mode, we become more immersed in reflection on the object and its place in our world. It is now presented to us.

I adopt Heidegger's hermeneutic and ontological phenomenology as the philosophical basis of this study and propose that Heidegger's 'being-with' technology provides a coherent platform to examine patients' relationships with self-testing technology.[24] I present Mitcham's analysis in support of this proposal:

> The being-with relationship thus disclosed through technical engagements is, for Heidegger, primarily social in character; it refers to the social character of the world that comes to light through technical practice. Such a world is not composed solely of tools and artifacts, but of tools used with others and artifacts belonging to others. Technical engagements are not just technical but have an immediately and intimately social dimension. (Mitcham 1990/2003, p.491)

However, while Heidegger's philosophy of technology remains as one of the most influential positions in the field (Scharff and Dusek 2003), it is not without its critics. In *What Things Do,* Verbeek (2005) offers a critique of Heidegger's phenomenological philosophy of technology. He groups Heidegger with other classical philosophers of technology and suggests that the overriding perception of technology as the 'greatest danger', purported by this group, does not provide a plausible contemporary philosophy of artifacts. Verbeek's main thesis is that Heidegger fails to sustain a hermeneutic existentialist philosophy of technology, as his later works display a more transcendental influence. While Verbeek (2005, p.95) acknowledges the merit of Heidegger's earlier work, *Being and Time,* as an investigation of "how actual tools and equipment constitute networks of meaning", he contends that Heidegger loses this focus as his work progresses. Verbeek maintains that the process of 'releasement', which Heidegger refers to in The Question Concerning Technology (1954/2003), represents a distancing from technology that precludes a more existentialist engagement.

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[24] Heidegger's broader phenomenological and hermeneutic perspectives will be developed as the chapter proceeds.

However, I propose that Verbeek's analysis does not act as an obstacle to the adoption of Heideggerian philosophy within this study. While Verbeek uses a brief passage from Heidegger's *Memorial Address* (1955/1966) to support his analysis of *The Question Concerning Technology,* I suggest that when reviewed in its entirety *Memorial Address* presents a more favourable account of 'releasement'. Heidegger suggests "we can affirm the unavoidable use of technical devices, and also deny them the right to dominate us, and so to warp, confuse, and lay waste our nature." (Heidegger (1955/1966, p. 54). In this sense, it seems inappropriate to suggest, as Verbeek does, that it impedes an existentially focused engagement. Rather, I propose that it supports a 'sceptical' engagement, whereby we critically reflect on all interactions with technology to determine those impacts that may otherwise go unnoticed.

Svenaeus (2013) supports this analysis of Heidegger's position. In applying Heidegger's philosophy to the specific field of medical technology, he contends that Heidegger is sometimes inappropriately dismissed as hostile towards science and technology. Similar to the interpretation of 'releasement' outlined here, Svenaeus (2013, p.5) suggests that Heidegger does not propose that we "abstain from all use of scientific technology" but rather that we "strive to make this meaning pattern of modern technology and science visible through philosophical analysis, and take measures to prevent it from becoming the all-encompassing pattern of our being-in-the-world". In this sense, Heidegger's philosophy of technology provides a particularly suitable theoretical basis for this study as it supports the examination of patient engagement with self-testing devices that is central to the research design.

3.5 Heideggerian phenomenology

Heideggerian phenomenology, also referred to as hermeneutic phenomenology or interpretive phenomenology, involves the study of pre-reflective, pre-ontological lived experience (Smythe et al. 2008, van Manen and Adams 2010). Heideggerian phenomenology is distinct from Husserlian, or descriptive, phenomenology as it explicitly recognizes that lived experience is always subject to interpretation (Laverty 2003). However, some shared understanding of phenomenology remains among those of the descriptive and interpretive traditions. Phenomenology describes things as they

appear in consciousness (Moran 1999). In accordance with van Manen (1997), a major proponent of phenomenology as a social science research method, it involves engagement with the uniqueness of the lived experience. It is concerned with a sense of wonder about the world around us and what it means to be human.

Cohen et al. (2000) (drawing on Spielberg's work) succinctly trace the development of phenomenology from the *preparatory phase* to the *German phase* and the more recent *French phase*. This also reflects Moran's (1999) account of the phenomenological discourse. Arguably, a fourth could be added, the *social science research phase*, to reflect the use of phenomenological philosophy as an empirical research methodology.

Phenomenology, as a philosophy, has its roots in the preparatory work of Brentano, the German philosopher, accredited with introducing *intentionality* to philosophy and developing the philosophy of psychology (Heumer 2012). Intentionality remains a key feature of phenomenology, whereby all human activity is orientated towards the world in a specific way (van Manen 1997). The *German phase*, with which this thesis is most concerned, relates to the work of Edmund Husserl and his student Martin Heidegger. Husserl's concept of the lifeworld (*Lebenswelt*), relating to the world of lived experience, and his eidetic reduction *(eidetics)*, referring to the process of bracketing one's preconceptions to get to the essence of phenomena, are also prevalent features of contemporary phenomenological research (van Manen 1997). Heideggerian phenomenology departs from the Husserlian tradition most notably in the move towards an existentialist, as opposed to transcendental perspective. Heidegger did not share Husserl's requirement for transcendental reduction whereby there is a need to extrapolate oneself from the phenomenon under exploration to elicit its essence free from personal biases (Lopez and Willis 2004). (These distinctions will be explored further below). Finally, the third phase, the *French phase* refers to the development of phenomenology in the work of Marcel, Sartre and Merleau-Ponty, who developed Heidegger's existentialist perspective.

Macann (1992, p.94) summarises very succinctly the similarities and differences between Husserl's and Heidegger's phenomenology:

> Nowhere is both the affinity with, and the contrast to, Husserlian phenomenology more explicitly expressed than in the passage in which Heidegger takes up the Husserlian slogan: To the things themselves! – and deploys it in a new way. For the 'things themselves' concern both Husserlian and Heideggerian phenomenology in so far as *both* ways of doing phenomenology require that we first get back to the things just as they present themselves with that *immediacy* which precludes pre-judice and pre-supposition. That Husserl arrives at immediacy through an ultimate distancing (Reduction) whereas Heidegger tries to get there through a more primordial closing of the distance (Involvement) is no more important than the fact that, in one way or another they both seek to address the fundamental dictum - To the things themselves!

In this passage, Macann (1992) refers to Heidegger's account of phenomenology in *Being and Time*. In the closing pages of his introduction to *Being and Time,* Heidegger utilises the term phenomenology to describe his work. He outlines phenomenology as the joining of the Greek terms *phenomenon* and *logos* whereby phenomenology essentially means the science of phenomena. Heidegger departs from a "Husserlian preoccupation with *eidetics*, consciousness and intentionality, in favour of an ontological and hermeneutic perspective" (van Manen and Adams 2010, p.450). Phenomenon, as defined by Heidegger, refers to "that which shows itself in itself" (BT 7:29). It is essentially the manifestation of things as they are. Phenomenology is the study of what is shown to the world and the unique manner in which it is shown. Phenomenology is primarily a philosophical method, but has evolved as a human science over time and is utilised as a qualitative research methodology in the social sciences (van Manen and Adams 2010).

The focus on the pre-ontological and hermeneutical is distinctly Heideggerian (Laverty 2003, Lopez and Willis 2004, Smythe et al. 2008). Heideggerian phenomenology is pre-ontological, or pre-reflective, in that it endeavours to capture human experience as it lived in the pre-conceptual phase. van Manen and Adams (2010, p.450) encapsulate this pre-conceptual understanding in the following extract:

> Things are not first of all phenomenon that are constituted in consciousness, rather we encounter them immediately in the world where we use them.

The phenomenologist endeavours to show our pre-conceptual engagement with objects in the world; an engagement previously unexplored. It is in this sense

Heidegger awakens us to the experiential use of the hammer, as discussed in the account of his philosophy of technology earlier in this chapter (see section 3.4).

Heidegger's phenomenology is hermeneutic, as opposed to merely descriptive, in so far as it contends that all human experience is embedded in a world of meanings. The interpretation of meaning by the researcher is a central feature of Heideggerian hermeneutic phenomenology (Koch 1994, Crist and Tanner 2003, Smythe et al. 2008). Hermeneutics has a historical tradition that extends beyond Heidegger's philosophy. The term hermeneutics came into modern lexicon in the seventeenth century as the science of biblical interpretation. However, the historical roots of hermeneutics lie in the study of literature among the ancient Greeks and the interpretation of sacred scriptures in the Jewish tradition (Crotty 2003). The term hermeneutics derives from the Greek word 'hermeneuein', meaning to interpret or understand. Hermes, the Greek God, was charged with the responsibility of explaining the messages of the gods to human beings. Hermeneutics involves the art of understanding or translating text into a manner in which it can be understood in everyday usage (Gadamer 2006). Essentially, in a research context, hermeneutics involves a focus on meaning and interpretation in the pursuit of knowledge (Speziale and Carpenter 2007). The approach is suited to the aim of this project, which seeks to elicit the meaning of autonomy as experienced by patients in the self-testing process.

3.6 Why Heideggerian phenomenology in this study?

The various tenets of Heideggerian philosophy explored to this point collectively assert its suitability as the methodology to underpin this study. Heideggerian phenomenology was chosen for five principal reasons. (1) Heidegger's phenomenological approach offers a means to elicit human experience as a unique phenomenon (Speziale and Carpenter 2007, Smythe et al. 2008, van Manen and Adams 2010). The meaning of the patient's experience of autonomy within the self-testing process is a central research question. This dimension is lacking in the qualitative and quantitative studies reviewed. This reflects a wider criticism of the dearth of research regarding the individual patient experience in current approaches to HTA (Facey et al. 2010). The significance of Heideggerian phenomenology as a

philosophical basis for expanding traditional scientific perspectives in medicine is acknowledged (Svenaeus 2013).[25]

(2) The hermeneutic nature of Heideggerian phenomenology provides a means to explore the 'context' in which the patient experience occurs. The need for a contextual understanding of autonomy and self-testing has been noted within the literature review. The limitations of a purely philosophical discourse on bioethical issues, and autonomy in particular, have been acknowledged (Hedgecoe 2004, Broer et al. 2010, Agledahl et al. 2011). Phenomenology provides a process whereby bioethical questions can be examined in the real lifeworld setting (Greenfield and Jensen 2010, Rehmann-Sutter et al. 2012). Heideggerian phenomenology was specifically chosen because of its interpretive or hermeneutic tradition in favour of the transcendental perspective of Husserl. Heidegger's *Being-the-world* or *Dasein* asserts that humans cannot extrapolate themselves from the world they live in (Lopez and Willis 2004). For Heidegger, we are always situated in a contextual world of human experience and constitute meaning in this way (Johnson 2000). It is evident from the literature review that patients' experiences of self-testing are mediated to some extent by their relationships with healthcare providers.

(3) Heidegger's philosophical approach resonates with my own views on how we construct meaning in the world. I believe that an individual's experience cannot be separated from the social context in which it occurs, and contend that as researchers we interpret experience in light of our socio-political and cultural background. The Husserlian concept of bracketing is incompatible with my personal sense of identity as a researcher. I believe that I am a social being who essentially interprets reality in light of past experience and present context. Heideggerian phenomenology acknowledges that we are always embedded in the practical world. In this sense, we

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[25] Here Svenaeus is referring to Heidegger's Zollikan Seminars. In September 1959 Heidegger began a series of seminars with psychiatrists in the Swiss town of Zollikan at the invitation of his friend, and admirer of his work, Medard Boss. Over the next decade, Heidegger explored his phenomenological philosophy and move towards meditative thinking with invited seminar guests. Central to his work at Zollikan was the exploration of the value of *Dasein* for an alternative view of the body and ill-health. Boss notes the uniqueness of these seminars in so far as they represented the engagement of individuals from a purely scientific perspective with Heideggerian philosophy. Boss later reflects on Heidegger's contribution as a means to advance the 'humanization of our world'. (Boss 1987).

can never exist in a "presuppositionless world wherein one's consciousness confers meaning on the objects one encounters" (Johnson 2000, p.136).

(4) While Heideggerian phenomenology was originally chosen because of its suitability to underpin the empirical component of the study, it later became apparent that as a philosophical method this approach also provided a suitable theoretical basis to frame the wider study design. Rehmann-Sutter at al. (2012) outline a hermeneutic approach to empirical bioethics, which provides a sound methodological basis for normative-empirical collaboration in this PhD study. This approach is appealing because of its congruence with Heideggerian phenomenology (albeit the authors base their approach on Gadamer's work primarily), but also because it supports the meta-ethical position (neo-naturalism) which guides the empirical-ethical collaboration within the study, dovetailing coherently with McMillan and Hope's (2008) cyclical model of empirical ethics. Rehmann-Sutter et al.'s (2012) approach reflects the central tenets of hermeneutic phenomenology in so far as it relies on: the situatedness of human experience; the interpretation of this experience; the significance of the hermeneutic circle in interpretation and 'meaning-making'; and the importance of resonance as a marker of rigour (Smythe et al. 2008).

(5) Finally, Heidegger's philosophy of technology discourse, which reflects his wider ontological position, is a significant theoretical influence on the study. Heidegger's understanding of our existence in a world of things provides a suitable philosophical basis for exploring patients' experiences of 'being-with' technology, and how those experiences shape expressions of autonomy.

3.7 Addressing critiques of Heideggerian phenomenology in an empirical context

Just as Heideggerian philosophy of technology has its critics, so too does the application of Heideggerian phenomenology in an empirical research context. Crotty (1996,1997), for example, presents a scathing critique of Heideggerian scholarship within nursing research. Crotty (1997) rejects the 'new' phenomenology practiced by Benner (1984) and other North American researchers as a mode of enquiry, which has lost its historical roots. In accordance with Crotty's analysis, this work is based on

symbolic interactionism and humanistic psychology, whereby one seeks to take the place of the 'other' and empathise with their experience and worldview. It is this third person account of the first person experience with which Crotty takes greatest umbrage with. For Crotty, this is a significant departure from European phenomenology, which seeks to uncover the phenomena itself and not a subjective account of experience. There have been a number of responses to Crotty's criticism.

Darbyshire et al. (1999) contend that Crotty presents a narrow existentialist account of Heideggerian philosophy, and that a subjective account of patient experience is not problematic within a nursing discipline. Similarly, Barkway (2001) suggests that this 'new' phenomenology may be appropriate in nursing as an empathetic account of phenomena may be the ultimate goal. However, it is also important to consider that Heideggerian phenomenology, in accordance with Heidegger's *Dasein*, does not seek to merely uncover an account of being. This *being* is always *being-in-the-world* or being in context. In this sense, while the phenomenologist in a nursing context may seek the subjective experience, this experience is always interpreted within the social context in which it occurs. Heideggerian phenomenology may concern itself with individual experience but the meaning of this experience will be interpreted in the wider context of the patients' lives (Johnson 2000). Smythe et al. (2008), whose ontological account of phenomenology may accord with Crotty's 'new' phenomenology, are committed to the interpretation of meaning in context. Johnson (2000) notes that Crotty's critique of Benner's work reviews a particular account of Heideggerian scholarship as presented by Dreyfus. The author notes that Dreyfus' interpretation of Heidegger is based only on the first division of *Being and Time*, which lacks the richness that could be gleaned from the second division.

However, it is important to note that Darbyshire et al. (1999), Johnson (2000) and Barkway (2001) are united in the particular attention they afford to Crotty's critique. Those responding to Crotty that his criticisms merit reflection and that nurse researchers should expand their understanding of Heideggerian scholarship prior to engaging in Heideggerian research. The details of the research strategy outlined in Chapter 4 present a series of procedural steps applied in the use of Heideggerian phenomenology in this study. These steps are undertaken to address the criticisms of the method's use in an empirical context and to ensure rigour.

3.8 Conclusion

In conclusion, a number of theoretical and philosophical perspectives are relevant in addressing the research aims. These perspectives include the emerging disciplines of empirical ethics, HTA and Ethics on The Laboratory Floor, and a more seminal Heideggerian influence in the context of the philosophy of technology discourse, hermeneutics and phenomenology. The always engaged, hermeneutic nature of Heideggerian phenomenology and its ontological understanding of our place in a world of 'things' provides a suitable theoretical framework to explore patients' experiences of autonomy in engagement with self-testing technology. Heidegger's ontological perspective is incongruent with a complete separation of what 'is' and what 'ought' to be. In this sense, there is also a synergy between the model of empirical ethics employed and the core tenets of Heideggerian phenomenology. The chapter, which follows, outlines how these philosophical and theoretical standpoints are adopted in the research strategy. While the study draws on these various methodological influences to support the research process, it also has the potential to contribute to these discourses and develop the available body of knowledge in this regard.

CHAPTER 4: METHODOLOGY

Empirical bioethics "is neither a substitute for moral philosophy nor does it merely service it – it has its own distinctive orientation and purpose"

(Holm and Irving 2004, p.133).

4.1 Introduction

This chapter explains the interactive processes of philosophical and empirical enquiry employed to address the research aim and objectives. It builds on the previous chapter as it describes the specific strategies chosen from the range of theoretical and philosophical perspectives explored. This chapter elucidates the aim and objectives of the study, the research design, the methodologies utilised, the sampling, data collection and analysis procedures and the ethical dimensions of the research process.

4.2 Research aim and objectives

Aim: To examine and contextualise the meaning of patient autonomy in healthcare practice through an empirical and ethical analysis of autonomy among individuals engaged with self-testing technology

Objectives:
1. To explore the philosophical basis of patient autonomy in healthcare
2. To develop an in-depth empirical understanding of patients' experiences of autonomy in engagement with self-testing technology
3. To ascertain the perspectives of some healthcare professionals and scientific community members regarding patient autonomy in the self-testing context
4. To develop a morally defensible pragmatic account of patient autonomy for healthcare practice
5. To contribute to the current knowledge base regarding:
    a. the application of autonomy in clinical practice
    b. the use of self-testing technology among individuals with diabetes
    c. the broader self-testing and self-management context
    d. empirical ethics and HTA methodology

4.3 The research design: A cyclical process of ethical and empirical enquiry

The research design builds on a cyclical model of empirical ethics outlined by McMillan and Hope (2008). The model provides a diagrammatic representation of normative ethics integrated with empirical data collection to address bioethical questions in practice. Figure 2 demonstrates how this model has been applied within the study.

Figure 2: Cyclical model of empirical ethics research (Adapted from McMillan and Hope 2008)

ETHICAL ANALYSIS	EMPIRICAL ISSUES
Analysis of autonomy drawing on philosophical and empirical literature *(Argument 1)* Initial analysis of autonomy revisited in light of empirical data *(Argument 2)*	1. How do patients experience autonomy in their engagement with self-testing technology? 2. How is this experience mediated by healthcare professionals? 3. How does the patient experience of autonomy relate to the vision for self-testing espoused by the scientific community?
NEW DATA Empirical data from patient, healthcare professional and scientific community interviews revealing new understandings of autonomy in self-testing	**EMPIRICAL STUDIES** *Heideggerian Phenomenological Approach* 1. Hermeneutic interviews with patients engaged in self-testing 2. Semi-structured interviews with health care professionals engaged with patients who self-test 3. Focus group with scientific community participants who have the potential to shape future innovation in self-testing through their expertise in diagnostics

The empirical ethics research design involves four interactive phases: ethical analysis, identification of empirical issues, empirical studies and generation of new data. The combined processes of deductive and inductive enquiry implicit within this design provided a strategy to address both the empirical and normative research questions within this study. As noted in the preceding chapter empirical methods can contribute to bioethics research as they provide contextual data to illuminate normative enquiry (Borry et al. 2004, Holm and Irving 2004, de Vries and Gordijn 2009, Salloch et al. 2012).

The research design can be summarised as follows. The literature review/initial ethical analysis of patient autonomy prompted a more in-depth analysis of the nature of patient autonomy. Utilising philosophical method, an argument for a relational understanding of autonomy was outlined (Argument 1). The initial ethical analysis concluded with empirical and normative/ethical questions:

Empirical Questions: How do patients experience autonomy in their engagement with self-testing technology? How is this experience mediated by healthcare professionals? How does the patient experience of autonomy relate to the vision for self-testing devices espoused by the scientific community?

Normative Questions: How may autonomy be operationalised in practice to respect both patient autonomy and patient welfare? How may we resolve the 'autonomy conundrum'?

All questions are incorporated within the research objectives. The empirical questions were addressed through empirical study. Heideggerian phenomenology was utilised to explore the contextualised patient experience of autonomy within the self-testing process among individuals with diabetes. Findings generated from the initial analysis of patient interviews were utilised to guide semi-structured interviews with experienced healthcare professionals involved in diabetes care. A focus group with the scientific community was also undertaken utilising patient data/initial analysis to formulate questions and generate discussion. The purpose of the additional data sets in this study was to assist in the interpretation of patient data. The primacy of the patient voice was protected. All data generated was collectively analysed using

hermeneutic phenomenology (Crist and Tanner 2003, Smythe et al. 2008) to reveal new understandings related to autonomy within the self-testing process.

The resulting understanding of patient experience was subjected to additional ethical analysis within an interpretive framework (Rehmann-Sutter et al. 2012) to address the normative questions. At this point ethical analysis concluded with a re-appraisal of the initial argument and the presentation of Argument 2 within the discussion chapter. This argument presents normative conclusions regarding the most appropriate way to operationalise autonomy within the healthcare setting and offers some resolution of the autonomy conundrum. McMillan and Hope (2008 p.19) note that within an empirical bioethics design interaction between the normative and the empirical can occur to the point where "the idea of a cycle gives way to a blend". This blending of philosophical and empirical work was integral to the research study and congruent with the overarching hermeneutic phenomenological approach.

4.4 Research methodology

The procedures outlined in the sections that follow primarily refer to the empirical work, as significant detail is required to explain the various processes of inquiry. However, the research study also includes philosophical enquiry as a research strategy. A synopsis of this method is included here to signify its importance in the overall design.

4.4.1 Philosophical enquiry

Philosophical enquiry is utilised throughout the research strategy. Ethical analysis is essentially moral philosophy and hermeneutic phenomenology, though developed as a social science research methodology, originated as a philosophical method (Adams 2008). Philosophical method involves exploring concepts, uncovering assumptions, identifying lines of reasoning and constructing arguments (Scott 2006). The method, or form, of philosophy cannot be separated from the content. Reichling (1996) cautions us against a quest for a definitive method as this may curb the imaginative discourse that philosophical exploration can promote. Warburton (2004) explains that philosophical method is developed by the process of 'doing' philosophy whereby the 'doer' engages in active reading, active listening, active discussion and active writing.

All these activities are implicit within this study and are integral to the hermeneutic phenomenological research approach undertaken (Crist and Tanner 2003). The data, which informed philosophical analysis in this study, was gleaned from the literature, as described in chapter 2, but also from the participants' data.

There is some debate as to the extent to which philosophical enquiry can be considered an actual research method or a form of scholarship (Edgerton 1988). However, philosophical method is gaining greater prominence as a method within nursing research (Edgerton 1988, Pask 2003, Gray 2004, Scott 2006) and has also been utilised by other disciplines (Reichling 1996). There are suggested means to apply rigour in philosophical method. Gray suggests that the internal and external consistency of arguments can be assessed. Similarly, Reichling (1996, p.119) proposes that the merit of philosophical method can be adjudicated by the criteria of "consistency, coherence and correspondence". This perspective is congruent with Rehmann-Sutter's appeal to reasoned argument when merging empirical work with normative analysis. The authors contend that conclusions "acquire normative force insofar as they are insightful and can convince others" (Rehmann-Sutter at al. 2012, p.445). To this send, the study endeavours to exhibit coherency and consistency in argumentation.

4.4.2 Heideggerian hermeneutic phenomenology

Heideggerian phenomenology is applied in this study in accordance with the interpretive tradition employed by Smythe et al. (2008) and Crist and Tanner (2003).[26] Smythe et al.'s phenomenology embodies the essence of Heideggerian phenomenology as both hermeneutic and interpretive. Smythe et al. (2008) view the research process as a journey of thinking where the ontologic takes precedence over the ontic. While this study also draws on van Manen's (1997) and Adam's phenomenological perspective (2010), their work is not adopted in its entirety as the focus on phenomenological reduction suggests less of an interpretive dimension.[27]

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[26] The previous chapter explores the central tenets of Heideggerian phenomenology and delineates its suitability to underpin the research approach (see sections 3.4-3.7). This chapter addresses its practical application within the study.

[27] Speziale and Carpenter (2007) refer to van Manen's approach as descriptive phenomenology. Other phenomenologists describe van Manen's phenomenology as hermeneutic phenomenology yet note that it combines features of descriptive and interpretive approaches (Cohen et al. 2000, Finlay 2009).

Therefore, while the broader steps of the research process were adopted from van Manen's (1997) approach, the analysis stage is primarily modelled on a process outlined by Crist and Tanner which points towards a more hermeneutic approach (2003). Crist and Tanner's process will be explained in association with the overview of the analysis process below.

Heideggerian phenomenology is concerned with individual experience yet also the social context in which it occurs. As Smythe et al. assert (2008, p.1392), "to remove a story from its rich textual background is to remove meaning and thus the possibility of understanding the experience as it is lived, for we can only ever live in a context of time, place and situational influences". For this reason, the views of other stakeholders were sought in order to assist in illuminating the patient experience. The Heideggerian concept of temporality suggests that we always exist in relation, as "the standpoint of humans is always to be involved in the practical world of experience" (Johnson 2000, p.136).

Human experience in this study is mediated by the patients' relationships with self-testing technology, but also by their relationships with the healthcare professionals with whom they interact. The literature review highlights that the role of healthcare professionals is significant in terms of how patients understand and value the self-testing process. Peel et al. (2007) note the absence of healthcare professionals' views as a limitation in their study. Semi-structured interviews with healthcare professionals took place after the patient interviews. Interview questions were based on the initial themes emerging from patient interviews, in addition to findings from the literature review. Similarly, members of the scientific community were interviewed in order to interpret the patient experience, in light of the vision for self-testing devices expressed by individuals with the potential to shape innovation in this area. Interview questions for this group were also based on the emerging analysis from patient data.[28]

van Manen (1997) and van Manen and Adams (2010) outline a series of steps within the process of hermeneutical phenomenological research. These steps have been

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[28] I am grateful to Dr. Pam Ironside at the Institute for Heideggerian Phenomenology, for assisting my thinking in this regard.

incorporated within the empirical study as part of the overall research design. Step 3 has been added to include the contextual dimension involving other stakeholders as noted above. The various steps are as follows:

1. *Orientating to the phenomenon*: This involves being intentional about the inquiry, immersing oneself in the literature regarding the phenomenon and examining any pre-conceptions.

2. *Collecting lived experience descriptions:* This refers to the data collection procedures undertaken in order to elicit accounts of human experience.

3. *Collecting the views of other stakeholders engaged with the patient experience:* This is a distinctive addition to this study, which is undertaken to assist in interpreting the patient experience in light of the wider context.

4. *Reading philosophical literature to cultivate interest in the phenomenon:* In this phase access to the literature is ongoing throughout the research process

5. *Reflecting phenomenologically*: This involves engaging in the process of hermeneutic analysis to capture the meaning of human experience

6. *Returning to participants*: The process can begin again as the participants may be re-interviewed to deepen the understanding of the phenomenon following initial analysis. (One participant in this study was re-interviewed in accordance with this criterion.)

4.5 Research setting, sample and recruitment procedures

The empirical research took place in the Republic of Ireland. The research setting included the outpatient departments of two hospitals to gain access to diabetic patients and healthcare professionals associated with their care. Additional details of these settings are not provided here to protect their anonymity. The research setting also incorporated a scientific institute: The Biomedical Diagnostic Institute (BDI) at Dublin City University. BDI is a multidisciplinary research centre engaged in the development of point-of-care biomedical diagnostic devices for the clinical setting, but with potential extension to the home environment at a future point.[29] Collectively these research sites represent a significant component of the wider context in which the patient experience occurs. On receipt of ethical approval, gatekeeper/access approval

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[29] The Institute has waived its anonymity.

was obtained in all three sites in accordance with the relevant organisations approved procedures.[30] Ethical approval procedures are detailed below.

Strict homogeneity of sampling is not a key issue in establishing rigour in hermeneutic phenomenology (de Witt and Ploeg 2006). The prime motivation in sampling is that participants have experienced the phenomenon under investigation (Crist and Tanner 2003, van Manen and Adams 2010). For this reason, purposive sampling was employed in this study. In accordance with this sampling strategy, the patient participants were selected based on their previous experience of self-monitoring of blood glucose levels. Despite the small sample sizes required in this study, two clinical facilities were selected to add greater anonymity to the research findings.

The sample sizes in Heideggerian phenomenology are relatively small due to the focus on collecting information-rich data from participants (Connelly 2010). For this reason Speziale and Carpenter (2007) suggest that 12-14 participants are generally sufficient to elicit the essence of the experience under review. Twelve patients were interviewed. A detailed patient participant profile is included as Table 2 in the findings chapter (see section 5.2). One patient was re-interviewed to deepen the understanding of the phenomenon, as her particular circumstances indicated merit in re-examining her experience of autonomy at a later point. Sampling is deemed complete when interpretations are clear and new findings fail to appear (Benner 1984). In light of this criteria, a sample size of twelve participants was deemed sufficient within the supervision process, to elicit an understanding of the phenomenon of autonomy in self-testing. Patients were recruited from the outpatient departments of both hospitals. This included the physician clinics or the smaller diabetic nurse specialist clinics. The inclusion criteria for patients were that they should:

➢ Be engaged in self-testing of blood glucose levels
➢ Be over eighteen years of age
➢ Have a diagnosis of type 1 or type 2 diabetes mellitus
➢ Speak conversational English

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[30] Copies of gatekeeper approval letters are not attached to preserve anonymity but are available on request.

> ➤ Have given their consent to participate

Patients who met the inclusion criteria were approached, with the assistance of the appointed gatekeeper, and provided with a written letter of invitation. Appropriate time was given to read the letter, after which I returned to address any queries. Not all patients approached agreed to participate.

Healthcare professionals were also purposively selected because of their engagement with patients who self-test. The sample size consisted of six experienced healthcare professionals who liaise with diabetic patients at the two clinical sites. Non-consultant hospital doctors, or non-specialist nurses, were not invited to participate as their level of expertise and engagement with patients could be quite different. The sample size was therefore dictated by the available personnel who met the inclusion criteria and agreed to participate. All eligible individuals were invited to attend by letter. Letters were delivered in person at the outpatient sites, or circulated by the appointed gatekeeper. The final sample incorporated two consultant endocrinologists and four diabetic nurse specialists. Healthcare professionals were interviewed within the outpatient setting.

The focus group consisted of eight personnel working in various roles related to medical diagnostics. Participants were similarly purposively selected due to their expertise in diagnostics. While the participants are currently engaged in the development of point of care devices for use in a clinical context, as individuals they have the potential to shape innovation in self-testing technology.[31] Invitation to participate was via the scientific communities group e-mail with the assistance of an appointed gatekeeper. Eight individuals agreed to participate. The sample included scientific researchers (PhD to post-doctoral level) and associated research and development personnel.[32] This facilitated a reasonably diverse perspective from across the Institute's various live projects and activities. Morgan (1996) notes that the sample size in focus groups can be appropriately determined based on their function within the overall research design. This sample size fulfilled this criterion and is compatible

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[31] For further detail regarding the specific focus of BDI activity, see section 1.3.4.
[32] Specific roles are not included to preserve anonymity.

with the numbers deemed satisfactory for focus group participation (Polit and Beck 2006).

4.6 Data collection procedures

The data collected was central to the empirical study but also to informing philosophical analysis. While this section addresses empirical data collection, the importance of the literature as data in contributing to philosophical/ethical analysis is also significant as outlined in the introduction to the chapter. Data collection with patients involved in-depth unstructured interviews with 12 diabetic patients who self-test their blood glucose levels. One interview took place in the participant's own home but all others were located in the outpatient setting. One patient was re-interviewed resulting in 13 interviews. The questioning technique for patients adopted a hermeneutic phenomenological approach involving open-ended questioning in order to elicit the patient's lived experience of self-testing. The Heideggerian perspective of *Dasein as* 'being in-the-play' requires that the interview process remains open to what may emerge (Smythe et al. 2008).

Smythe et al. draw on Gadamer's (1960/2003) perspective of a 'conversation' in preference to conducting a pre-planned interview. For Gadamer (1960/2003, p.383) "a genuine conversation is never the one that we want to conduct". The conversation approach facilitates the fostering of a more relaxed relationship between researcher and participant and gives the participant the necessary space to tell his or her story (McEldowney 2005). An open question, or the phenomenological question is posed to participants to commence the conversation and a series of cues may be used to encourage participants to elaborate on particular stories (van Manen 1997, Cohen et al. 2000). Additional questions may then evolve as the conversation proceeds and meanings emerge (Crist and Tanner 2003). The openness of questioning is essential as the researcher seeks to ascertain rich descriptions that may reveal hidden meaning, a key feature of hermeneutic phenomenology (Johnson 2000). The patient interview guide is attached as Appendix F.[33] A pilot interview was undertaken initially to assess

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[33] Some interviews required little more than the opening question depending on the conversational style of the interviewee. The detail in the guide is drafted to include possible questions that could be utilised as the interview progressed. This level of detail also facilitated a more thorough review of

my interview skills and the ability of the method to elicit the data required. I completed a self-assessment of the pilot interview in accordance with the reflexive approach noted in the introduction. The pilot was also reviewed in association with supervisors and resulted in refinement of my interviewing skills.

Semi-structured interviews with healthcare professionals took place following initial analysis of patient interviews. Individual interviews were logistically more suitable in light of the geographical spread and work commitments of participants. In addition to the literature review findings, emerging findings from initial analysis of patient interviews were utilised to formulate semi-structured interview questions for the healthcare professionals. The interview guide for healthcare professionals is attached as Appendix G.

Data was collected from the scientific community participants by means of a focus group. The focus group permitted access to a group of individuals with various levels of expertise with regard to point of care diagnostic devices.[34] There was a potential for the community to be cautious due to the fact that the researcher was not engaged with the community full time, and operates within another discipline. The focus group can facilitate a non-threatening environment which was helpful for both participants and researcher (Morgan 1996). Morgan notes that focus groups provide a means whereby the researcher can decipher the degree of consensus and diversity among the participants (1996, p.139). To this end, the group processes involved in the focus group interview were useful to elicit some sense of shared understanding of autonomy and self-testing from those individuals with the potential to shape innovation in self-testing technology, albeit not their current target end-user. The focus group format was also a useful method to facilitate focused reflection among participants. Individual participants, though present throughout discussion, were not obliged to speak at any point thereby allowing time for consideration in advance of contribution. The aims of the focus group, which support the wider study objectives, were as follows:

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planned interventions by the ethics committee. The interview guide included here is the final draft. Initial drafts were modified slightly as the interview process and researcher skill evolved.
[34] For further detail regarding the specific focus of BDI activity, see section 1.3.4.

1. To explore the scientific community's perspective on the application of self-testing devices in the patient population and associated issues regarding patient autonomy

2. To explore the extent to which the scientific community considers these issues as significant and communicate a shared perspective

3. To promote critical reflection among the group participants with regard to the 'soft' impacts of technology

The elements of good practice in focus group technique were employed as advocated by Krueger and Casey (2000) and Stewart et al. (2007). An initial pilot was undertaken to develop skill using 'mock' participants and a pseudo-research problem applicable to the group. An observer provided constructive feedback, that was used to structure and guide the actual focus group. The use of a scribe in the research focus group allowed me time to engage more fully with participants and contributed to the early analysis stage. Questions for the focus group participants were based on the literature and the emerging findings from patient interviews regarding their interaction with self-testing devices. In addition, practical scenarios, derived from the patient data, were utilised to engage the participants and encourage them to reflect on the possible outputs of current technological developments.[35] The basic premise in the application of any scenario is that individuals connect more with contextual narratives when reflecting on the world. Fiction is becoming more popular as a means to explore the intricacies involved in future technologies (O'Mathúna 2010). Following focus group participation, I invited the participants to complete a brief evaluation of their experiences via e-mail. This data was also utilised, with the participants' permission, to contribute to the study findings.[36] The focus group guide and post focus group evaluation is attached as Appendix H.

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[35] A 'Futures Workshop' delivered by Dr. Dónal O'Mathúna and Dr. Simone van der Burg at Dublin City University in November 2011 was helpful in exploring these issues. Time spent with researchers in emerging technologies at the University of Twente also contributed to the development of this aspect of the study. I am grateful to Dr. Marianne Boenink and the post-graduate students at Twente for their assistance in this regard.

[36] The focus group evaluation did not form part of the initial methodological procedures. However, in keeping with the 'in-the-play' nature of hermeneutic phenomenology it was deemed a useful strategy as the project progressed. As participants left the interview room, they began to recount their experiences of participation. I thought it useful to capture these insights with the participants' permission. As the resulting demand on participants was minimal, it was decided, in discussion with supervisors, that the brief online evaluation did not warrant additional ethical approval.

Semi-structured interviews and the focus group were recorded with participants' permission. The interplay between patient, healthcare professional and scientific community interviews is congruent with the iterative nature of hermeneutic phenomenological research (Crist and Tanner 2003, Smythe et al. 2008, Adams 2010) and the cyclical character of empirical bioethics (McMillan and Hope 2008) employed within this study design. All data contributed to the final analysis procedures.

4.7 Data analysis

4.7.1 Empirical data

The analysis process in Heideggerian phenomenology is an iterative one, which is described by the metaphor of the hermeneutic circle. Essentially parts of the text are understood in isolation yet also in terms of the whole i.e. wider transcripts (Cohen et al. 2000). It is within this hermeneutic circle that Heideggerian meditative thinking occurs. This process of enquiry allows the smallest statements to be interpreted in light of the greater cultural context (Cohen et al. 2000). The quest, as advocated by Smythe et al. (2008, p.1396) is simply to "let thinking come" as the researcher immerses herself in the data. The process of hermeneutic phenomenological enquiry involves a "journey" of thinking and continuous cyclical movement from data to reflection and reading (Smythe et al. 2008). The series of analysis journal extracts, attached as Appendix A, gives some insight into the 'journey of thinking' within this study.[37] My journey resonates with the experiences of other researchers who navigate the fluidity of analysis in hermeneutic phenomenology (Duffy 2011)[38].

Crist and Tanner (2003) acknowledge the potential challenges associated with this fluid-like approach and present a series of phases involved in the analysis process. As a novice researcher, these steps were extremely useful and were utilised in the study

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[37] Interpretive analysis of transcripts was undertaken during my time as a visiting scholar at the Hastings Bioethics Centre, New York. This provided an ideal environment for immersion in reading, writing and reflection. I also had the opportunity to present my work and have many 'phenomenological conversations' with experts in bioethics. I am grateful to all at the Hastings centre for their warm welcome and their willingness to share their expertise.

[38] Dr. Mel Duffy at Dublin City University was generous in sharing her expertise and provided valuable assistance at the analysis process. The phenomenological insights gained from Rita Glover at Dublin City University were also extremely helpful.

to guide analysis. Crist and Tanner's approach provides some structure while not conflicting with the hermeneutic vision. The interviews with healthcare professionals, and focus group with the scientific community participants, were analysed in association with the patient data and not as a separate study. Additional stakeholder data assisted in the phenomenological reflection stage of analysis which van Manen (1997) refers to. Crist and Tanner's 5 phases for analysis were adapted in this study by the introduction of phase 3a to facilitate this process. The various steps undertaken in analysis of empirical data are listed below. Appendix 1: Analysis worked example, shows how these steps were applied in the study in light of one particular thematic understanding.

All interviews were transcribed by a trusted third party and reviewed for accuracy prior to analysis. As I listened to each interview, any detail regarding the participants' para-language such as sighs, laughs or pauses etc. was noted. Field notes taken following each interview were also considered in the analysis process. Appendix J contains the interpretive guide that was used to guide the analysis of each transcript.[39] The guide incorporates the existential themes of corporeality, temporality, spatiality, and relationality in accordance with van Manen's (1997) approach. The terms refer to lived body, lived time, lived space and lived relations, respectively. These existential elements were apparent among the patients' experiences.

The phases are as follows:

Phase 1: Early Focus and Lines of Enquiry: Transcripts of initial patient interviews are discussed. This facilitates a critique of interview technique and the identification of initial lines of enquiry, which can guide subsequent interviews.

Phase 2: Central Concerns, Exemplars and Paradigm cases: Central concerns, themes or meanings emerging from individual participants are identified. Where applicable an interpretive team may be involved at this point.[40] Exemplars are

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[39] My attendance at the Heideggerian Institutes Summer School in Indiana under the direction of Dr. Pam Ironside was extremely helpful in guiding the analysis process. A presentation by Dr. Susan Crowther, of her hermeneutic approach to analysis was pivotal in guiding my approach to analysis. The work of Dr. Crowther, and her supervisor, Dr. Liz Smythe is acknowledged in Appendix I.

[40] While an interpretive team can add further insight, it is not a necessary pre-requisite for hermeneutic research (Crist and Tanner 2003).

extracts from narratives, which characterise common themes. Paradigm cases refer to salient stories that are particularly captivating in illuminating the phenomenon. Interpretive writing begins at this point consisting of a number of pages of main concerns interwoven with significant extracts from individual participant's stories. (In this study, central concerns identified from participants were used to guide interview questions for other stakeholders).

Phase 3: Shared Meanings: As individual meanings become clearer, shared meanings are then sought. An interpretive summary is drafted at this point to identify links between meanings identified within and across participants' narratives. Initial drafts are re-written and phenomenological reflection is ongoing.

Phase 3a: Shared meanings in context: This phase incorporates analysis of data from other stakeholders identifying salience with the shared meanings/themes established from patient data. Stakeholder data is utilised to illuminate the 'meaning' of patient experience in light of the associated context.

*Phase 4: Final Interpretations***:** There may further interviews at this point to follow lines of enquiry identified in shared meanings. Phenomenological writing are reflection are ongoing. In-depth interpretations of central concerns and summaries are produced.

*Phase 5: Dissemination of the Interpretatio*n: Final reports are refined and work is disseminated. An audit trail of activities up to this point is maintained.

4.7.2 Ethical Analysis

Ethical reflection was ongoing throughout the study. The formal process of ethical analysis continued once empirical data analysis was complete in accordance with McMillan and Hope's cyclical model (2008). The findings from analysis of patient and other stakeholder data were subjected to interpretive analysis as advocated by Rehmann-Sutter et al. (2012). The ethical questions identified in the initial ethical analysis were revisited in light of the empirical data. The findings, which emerge from the qualitative data, can contribute to normative judgements through the process of reasoned argument, as outlined within the methodological processes identified earlier in this chapter.

4.8 Rigour

The issue of rigour in interpretive research is a key consideration as the fluid-like nature of data collection and analysis raises questions about the accuracy of findings. de Witt and Ploeg (2006) contend that there is need for expressions of rigour that are particular to the nature of hermeneutic phenomenological research. Many terms have been used as expressions of rigour in an interpretive context, including, 'resonance', 'atunement' (Smythe et al. 2008), 'trustworthiness' and 'authenticity' (Lincoln and Guba 1986), 'openness', 'balanced integration', 'concreteness' and 'actualization' (de Witt and Ploeg 2006) and 'credibility', 'fittingness', 'auditability' and 'confirmability' (Sandelowski 1993). Despite the difference in terminology, there is a shared understanding that the researcher is obliged to demonstrate the legitimacy of findings. Rigour should be integral to the entire research process and not merely a discrete dimension that emerges at the analysis stage. Those who defend Heideggerian phenomenology in a nursing/healthcare context note that nurse researchers should expand their understanding of Heideggerian scholarship to engage accurately with Heideggerian research (Darbyshire et al. 1999, Johnson 2000, Barkway 2001). Draucker (1999) proposes Heideggerian phenomenology researchers should; outline their pre-understandings of the phenomena under exploration; demonstrate the convergence of their own understanding and the participant's experience; outline the interpretive processes within the research and utilise Heidegger's philosophy not merely as method but to enrich findings. These processes were applied in this study.

Smith (1998) outlines a number of practical expressions of rigour in his hermeneutic study of problem drinkers. These dimensions of rigour are adopted within this study with one exception (see Table I: Features of rigour in hermeneutic research): I do not incorporate participant validation or member checking. McConnell-Henry et al. (2011) contend that member checking diminishes rigour in interpretive research. The patient experience, in accordance with Heideggerian phenomenology, is temporally situated and is interpreted in light of that temporality. Returning to the participant to validate interpretations is a futile exercise as their account of the phenomenon may be quite different if asked to verify it at a later stage. However, if there are significant changes then returning for an alternative account of the phenomenon may be appropriate to elicit a new understanding, in order to further illuminate the phenomenon under

investigation (Crist and Tanner 2003, Smythe et al. 2008). One participant (Frances) was re-interviewed in accordance with these circumstances.

Table 1: Features of rigour in interpretive research (Adapted from Smith 1998)

- Trusting relationship with participant
- Thick, rich, vivid descriptions of phenomena from participants
- Accurate interview transcription
- Recognisable descriptions which offer a sense of attunement to the phenomena
- Audit trail (Facilitated by means of an analysis journal in this study)
- Reflexive journal
- Independent validation by other researchers (Facilitated through the supervision process and ongoing phenomenological conversations at the interpretive/analysis phases)
- Researcher's own narrative and theoretical perspective is evident in the research report

An additional significant feature of rigour in this study was an ongoing immersion in learning throughout the research process. Learning was related to both the phenomena under exploration and the methodology employed. This was achieved through a process of continual knowledge development and knowledge dissemination during the PhD process. Details of core aspects of these activities are included as Appendix K.

4.9 Ethical considerations

Ethical approval was obtained from the ethics committee of the Dublin City University and the clinical ethics committee of the applicable hospitals sites. A copy of the approval letter from the university is included as Appendix L.[41] The study did not require review by the Irish Medicines Board (IMB 2010). Studies involving devices that are already in use with a CE (European Conformity) mark are not subject to review by the Board if the study reflects the devices' intended use. Official gatekeeper access to all sites was sought and granted post ethical approval. All potential participants received letters/e-mails of invitation, and plain language statements regarding the purpose of the research and the procedures involved. Written consent forms were signed by all participants. Copies of this documentation are included as Appendices M-O.

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[41] The clinical committee notification is not attached to preserve anonymity.

The ethical conduct of any research project goes beyond the attainment of formal ethical approval. The research course may change as the study evolves, welfare issues for participants may arise and academic integrity may be challenged. All these potential issues require a commitment to ethical practice throughout the course of the research. To this end, the research was conducted in accordance with a series of broader frameworks for research ethics and integrity. These included the University's *Code of Good Research Practice* (Dublin City University 2008) and *Guidance to Nurses and Midwives Regarding Ethical Conduct of Nursing and Midwifery Research* (An Bord Altranais 2007).

The competing roles of 'nurse as nurse' versus 'nurse as researcher' were an important consideration throughout the study. As a registered nurse, it was important to achieve a correct balance between adherence to methodological rigour and concern for patient welfare (Eide and Kahn 2008). Following review of the pilot interview and initial participant interviews, patient information letters were simplified.[42] The non-therapeutic purpose of the interview was further clarified, and I articulated with greater clarity the protocol to be followed if a patient was deemed to be at risk. These changes necessitated an amended submission to the clinical ethics committee, which was approved prior to further patient interviews. If patients raised any queries about their diabetes management during the course of the interview, I suggested they contact the relevant healthcare professional and supported them in this regard. One patient was referred, with his permission, to the unit's psychologist in light of issues that arose in the course of the interview.

Confidentiality of all participants' data was paramount throughout. Professional obligations, which may supersede confidentiality, were explained at the beginning of the interview process. Any data collected was treated as confidential and stored appropriately in accordance with the Data Protection Act (Government of Ireland 1988). As a funded researcher, undertaking data collection within a biomedical institute, I appreciated the need to be aware of any competing commercial or political interests and remain true to the data at all stages of the research process. While the thesis critiques the wider technological sphere in healthcare, it was important that any

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[42] This was explored within the supervision process.

discussion accurately reflected the specific expertise of the scientific community participants interviewed, the prime focus of their organisations activities and the governance structures in place. To ensure respect for participants, footnotes have been included within the thesis highlighting the context in which views are expressed.

SECTION 3: NEW UNDERSTANDINGS

CHAPTER 5: AUTONOMY AS LIVED

The phenomenologically orientated researcher engages with these accounts of experiences in a way that can articulate important understandings from these experiences that may be relevant to others that can take understanding further.

(Todres 2004, p.50)

5.1 Introduction

This chapter presents a series of understandings, which reflect participants' experiences of 'being-with' self-testing technology. The patients' experiences of autonomy in this study exist within a series of interdependent relationships: relationship with the self-testing device, relationship with their illness and relationship with their healthcare provider. These understandings are collectively represented as *Autonomy as lived: The interdependent phenomenon of autonomy in self-testing*. The term 'understandings', as opposed to 'findings', is used to describe the outcomes of the research in congruence with a hermeneutic approach. Within Heideggerian phenomenology, the researcher engages hermeneutically with accounts of experience to elicit meaning and "offer new understandings to practice" (Smythe 2005, p. 225).

Draucker (1999) urges the hermeneutic phenomenologist to consider Heideggerian philosophy not only at the point of data collection, but also at the point of interpretation to enrich the study findings. Heideggerian philosophy, in addition to other philosophical works, is used to support the interpretative understandings presented in this chapter. Heidegger's account of 'technology as revealing' provides a useful construct to explain how understanding evolves. (This aspect of Heidegger's philosophy is previously explored in section 3.4). The 'revealing' nature of technology is noted explicitly in Heidegger's later work, *The Question Concerning Technology* (1954/2003). For Heidegger, technology is much more than a means to an end or a human activity. Technology reveals our ontological being. Those who have adopted Heideggerian philosophy as active proponents of hermeneutic phenomenology within nursing and other disciplines acknowledge the sense of 'revealing' that is implicit

within this method (Benner 1984, Ironside 2005, Smythe et al 2008, Diekelmann and Diekelmann 2009, van Manen and Adams 2010). Heidegger proposes that we cannot separate our ontological selves from our experiences with technology. Our lives are shaped by technology in many different ways, which become almost invisible to us as we become more immersed in a technological way of being. For example, the way that business is conducted in a modern economy is shaped by the technological capabilities that influence the mode, tone and speed of communication. Similarly, in this study, the participants' daily lives are shaped by their experiences of 'being-with' self-testing technology. Therefore, to explore patients' experiences with technology is, as it were, to unearth a channel of discovery, a peephole or conduit, into their deeper, hidden selves. In this sense, as per Heidegger's analysis (1954/2003, p.255), "Technology is a mode of revealing".

The phenomenological exploration of patients' experiences with self-testing technology in this study revealed understandings related to their wider experiences of 'being-in-the-world' with a chronic illness. Their interactions with self-testing devices have been shaped by these experiences, yet these experiences are also shaped by their engagement with self-testing devices. The participants' ontological selves are interwoven with their technological relations. Focusing on these technological relations, as a particular focus of experience, is to reveal the participants' wider ontology, their human mode of being.

5.2 Technology as revealing: *The interdependent phenomenon of autonomy in self-testing*

Figure 3 provides a diagrammatic representation of the understandings arrived at in this study. Collectively these understandings are presented as *Autonomy as lived: The interdependent phenomenon of autonomy in self-testing.* The term 'interdependent' is significant as it denotes the context dependent nature of autonomy that is central to the study's findings, and embraces the paradoxical nature of restrained autonomy in chronic illness. For these participants their experiences of 'being-with' technology are quite different in many respects, yet also reveal some shared understandings related to their personal engagement with the self-testing device.

The phenomenon is presented as an interconnected circular structure of blending colours to represent the interdependent nature of the three patient relationships: *Relationship with device*, *Relationship with Illness* and *Relationship with healthcare provider*. These relationships are not static but continue to evolve and change within the individual's lifeworld. An alteration in any relationship has the potential to impact on the patient's experience of autonomy. Each relationship is presented as a central theme consisting of a number of sub-themes, which collectively describe the various facets of the overall phenomenon. Themes are not an indication of how many times something is said but rather, "an understanding we [as researchers] have seen something that matters significantly" (Smythe et al. 2008, p.1392). The various sub-themes are not necessarily of precise 'weighting', but rather represent an essential part of the 'whole' patient experience. To extend a greater balance among the individual themes than the data suggests would be a disingenuous attempt to bring a quantitative type order that does not exist in a phenomenological study. The individual themes/sub-themes, in isolation, do little to explain the phenomenon as it exists in the world. However, collectively they "are fasteners, foci, or threads around which the phenomenological description is facilitated" (van Manen 1997, p.91).

Figure 3: Autonomy as lived: The interdependent phenomenon of autonomy in self-testing
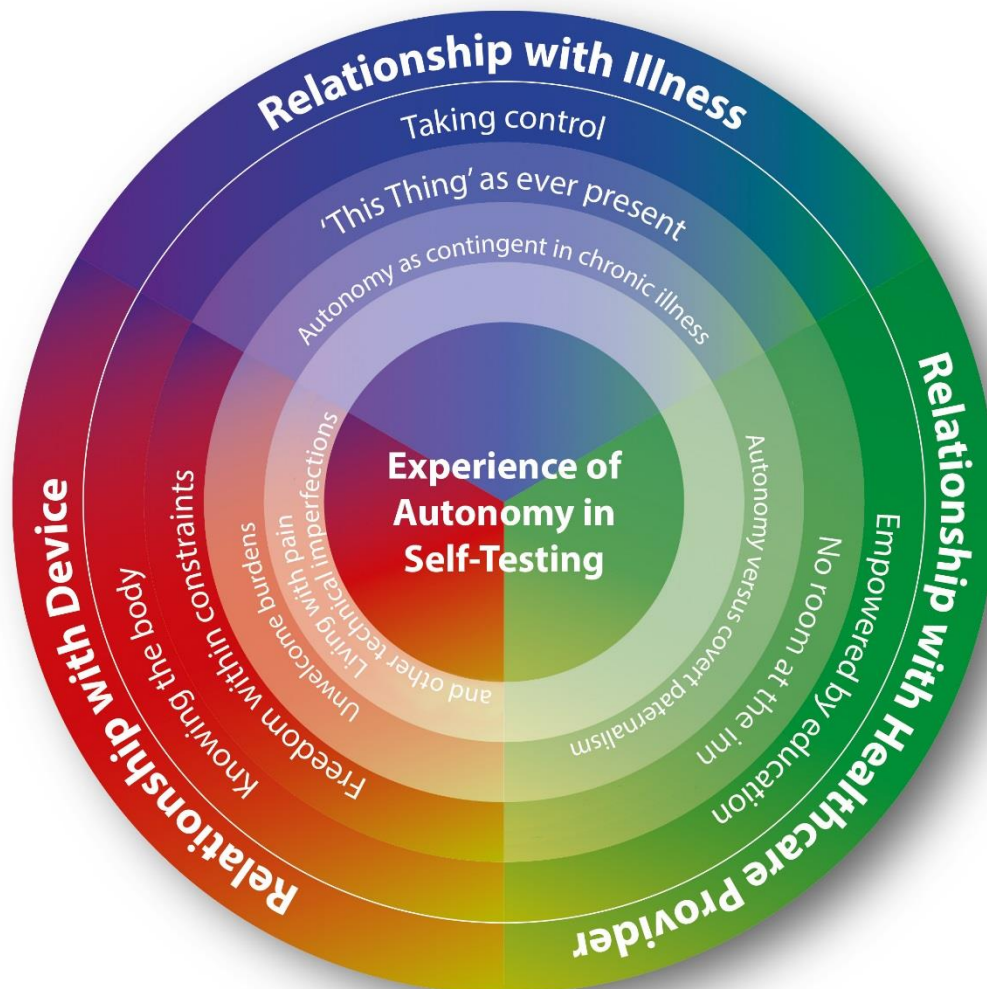
Understandings are portrayed using patient stories or shorter exemplars to elucidate meaning. Stories are not always neatly confined to one thematic structure or another. The totality of patient experience is central to the existential understanding of illness that a phenomenological approach represents. While it is possible to differentiate between the existentialist themes (corporeality, spatiality, temporality and relationality), one cannot separate them, as collectively they represent an "intricate unity which we call the lifeworld" (van Manen 1997, p.105). Therefore, elements of patient stories may be repeated to some extent, as they are salient for different reasons in the context of the various thematic threads of the overall phenomenon. The other stakeholders within this study represent a critical component of the hermeneutic circle

in which understanding occurs. Their perspectives are interwoven with the patient experience to illuminate the overall phenomenon.

Patient data is identified using a pseudonym e.g. *Ann*. When the term 'participant' is used in a general sense it refers to patient participants as they are the central focus of the study. A table of patient participants by pseudonym, with details of their diagnosis, period since diagnosis, gender and age is included below as Table 2: Patient participant profile. Age is given within a particular bracket as opposed to actual age to assist anonymity. The table also notes if the patients were receiving insulin therapy at the time of their interview, as this is often relevant to their story. As I refer to the patients by name in describing understandings, I have also added some more specific humanistic data to the biographical account of each participant. This will assist the reader in understanding the thematic aspect of the phenomenon in light of the overall patient story.

The term scientific community participant was been chosen to represent the various focus group participants. Scientific community participants are identified as *SCP1-8* and Healthcare professionals are identified as *HCP1-6*. Gender or specific role is not identified among supporting stakeholders. Despite the added dimension that this could bring to interpretation, identification of gender and position in a small purposive sampling frame could threaten anonymity. For the purpose of discussion, where necessary, all healthcare professionals will be referred to in male terms and all scientific community participants as females.

Table 2: Patient participant profile

No.	Pseudonym	Age at time of interview	Gender	type 1/type 2 diabetes	On Insulin?	Length of time diagnosed at time of interview	Story Synopsis
1	Ann	55-60	F	type 2	No	15 years	Ann enjoyed the security and sense of control that self-testing brings, but acknowledged it can be demanding on a day-to-day basis. She frequently referred to pain in her story but seemed reluctant to say self-testing was painful.
2	Betty	40-45	F	type 1	Yes	9 years	Betty appeared very much in control of her diabetes. She had previously completed a self-management programme to titrate insulin doses relative to dietary intake and still adopted this concept. While acknowledging the 'bind' that self-testing can be, the flexibility it brings was very important to her. She commented on time pressures within the healthcare 'system'.
3	Colette	55-60	F	type 2	No	4 years	Colette was very distracted on the day of interview and seemed confused by her overall diabetes management. A number of social problems were prominent in her life. She reported feeling 'down' and displayed dissatisfaction with the level of support from the healthcare team. Colette seemed to have unrealistic therapeutic expectations of our interview, which I had to correct and direct her towards appropriate support.

4	Deirdre	55-60	F	type 2	No	9 years	A sense of personal responsibility for managing her illness was quite prominent in Deirdre's narrative. She took an active role in managing her diabetes and despite acknowledging the restraining aspect of frequent self-testing, she enjoyed the freedom self-management brings, including a trip to Australia to visit family.
5	Eileen	60-65	F	type 1	Yes	6 weeks	Eileen was newly-diagnosed with diabetes and expressed some concern regarding self-testing and insulin administration in public. Eileen referred to the 'clock-watching' associated with self-testing and medication management a number of times during interview.
6	Alex	55-60	M	type 2	No	7 years	At the point of interview, Alex's pancreatic function was decreasing. Prominent in his story was his frustration with his current self-testing results and constraining factors within the healthcare system, which prevented him from taking greater control of his diabetes. Alex also questioned the value of self-testing versus HbA1c results.
7	Frances	45-50	F	type 2	No	9 years	Frances expressed various attitudes to self-testing coinciding with different points in her illness. The chronicity of her illness was quite significant for her. A follow up interview with Frances revealed a greater adaptation to her illness, self-testing, and adjustment to an alternative treatment regime. The sense of control that Frances associated with the administration of insulin and self-testing, versus oral medication, was prominent in her story.
8	Geraldine	60-65	F	type 2	No	15 years	Geraldine seemed very accepting of self-testing. It did not appear to have a hugely significant role in her life. She appeared to be managing her diabetes well with the aid of minimal self-testing.

9	Bart	55-60	M	type 1	Yes	35 years	Bart spoke very positively of self-testing and the freedom it afforded him to work full time as a taxi driver. This was not always the case but evolved over time.
10	Con	50-55	M	type 2	No (Victosa)[43]	6 years	Con spoke quite negatively about self-testing during the interview. He appeared to have significant difficulty in adjusting to a diagnosis of diabetes in addition to other previous health problems. I was concerned for Con's welfare and with his permission discussed his concerns with the diabetic nurse specialist following interview.
11	Hannah	60-65	F	type 2	No	2 months	Hannah was also newly-diagnosed with diabetes at the point of interview. She did not seem unduly perturbed by her diagnosis or the self-testing regime. However, a more careful review of her narrative revealed some lack of understanding regarding her diabetes. The lack of support from healthcare professionals during initial education is evident in her story.
12	Denis	40-45	M	type 2	Yes	6 years	Denis referred to his diagnosis of depression during his interview and the ongoing battle this presented for him, albeit acknowledging improvement. He utilised self-testing results mainly to maintain his safety as opposed to engaging in more elaborate self-management strategies.

[43]Victosa is one of the more recent non-insulin based injectables for patients with type 2 diabetes. It is a once daily injection of GLP-1, a synthetic version of a naturally occurring hormone, which encourages the beta cells in cells to release insulin. It is used in association with diet and exercise, and possibly oral hypoglycaemics to manage blood glucose levels.

5.3 Relationship with device

This facet of the interdependent phenomenon concerns the participants' relationship with the self-testing device. This relationship significantly contributes to the participants' experiences of autonomy and is presented in accordance with four sub-themes, which reflect different perceptions of the meaning of the device for the participants: (1) *Knowing the body*; (2) *Freedom within constraints; (3) Unwelcome burdens;* and *(4) Living with pain and other technical imperfections*. The device is assimilated in different ways and exists as something different for the various participants. The *'as'* structure (or the thing 'as') is a significant tenet of Heideggerian philosophy. The hermeneutic phenomenologist is concerned with the tangible reality of 'being-in-the-world'. In this context, as Ironside (2005) explains, the things of the world hold varied significance in terms of our engagement with them. There is no objective reality to be explored. The 'as' structure reflects an understanding of phenomena "as something other than fixed or atemporal notions" (Diekelmann and Diekelmann 2009, p.8). This theme presents the understandings arrived at following exploration of the patient's engagement 'with' the self-testing device as opposed to an investigation of the device itself. It is apparent that the patients engaged with the device in many different ways. For example, the device existed 'as': a window to the internal functioning of the body; a means of freedom within certain constraints; a source of unwelcome burdens and an imperfect, yet accepted, piece of technology.

5.3.1 Knowing the body

This sub-theme relates to the participants' knowledge of their bodies which results from use of the self-testing device. The device provides a window to the inner workings of their own bodies. This can have both positive and negative outcomes for patients in terms of their overall well-being and implications for autonomy. These factors will be addressed as the findings' overview proceeds. However, the 'knowing' of the body as a dimension of self-testing is salient in itself, regardless of the outcome. This 'knowing' is presented here. A number of participants refer to the self-testing device as a means to confirm what they feel is happening in their bodies. This is evident in the narrative below:

I can obviously do a test and it will just confirm the way I'm feeling. Either I'm feeling low or it's confirming that I've got a low, or I've eaten too much and it's sky high and then I dose-adjust and bring it down again ... So I can see the benefits of self-testing ... I like the reassurance of the fact that it is on the kitchen counter or is in my bag if I want to use it and see what my blood sugars are ... So it kind of helps me sometimes if I feel I've been getting a little bit lax, it kind of makes, you know, kind of makes me pull myself together. (Betty)

Betty is a type 1 diabetic, who uses her blood glucose levels to titrate her insulin dose. However, even among type 2 diabetics, who do not alter medication relative to results, the self-testing device has the same effect on their 'knowing' their own body. At three separate points in her story Deirdre, a type 2 diabetic, refers to the awareness she associates with recording her blood glucose levels:

It keeps you on your toes ... The one thing that you can go by ... It keeps me more aware ... (Deirdre)

Interestingly, Frances notes that the previous experience of testing her blood glucose levels allowed her to know her body even in the absence of self-testing. It is as if it acts as a reference point within which future symptoms can be assimilated. This is evident in the following narrative:

I'm very tired and I'm drinking a lot of water and I'm going to the bathroom and I'm totally exhausted, you know ... I have the symptoms again, I feel myself that I had say 8 or 9 or whatever like in 2002 whenever I was diagnosed. So I know myself ... I do not even have to test, I know myself if I am going low ... (Frances)

This sense of 'knowing the body' remains significant for Frances at a repeat interview 15 months later. Similarly, Bart refers to this sense of understanding his body or being 'in-tune' with it:

I'm very aware of the low feeling and possibly the high feeling as well ... if I woke in the morning and I had high blood sugars, I'd feel really desperate, I do, I can feel it in my body ... That's probably the time that I'd really feel it the most, after a night's sleep. I'd feel it in my legs; I just do not feel right having it up so high. (Bart)

This sense of 'knowing' or awareness, as articulated by the patients, is also acknowledged as significant among healthcare professionals. It appears to be one of the reasons they encourage self-testing, even among type 2 diabetic patients who do not use results to titrate medication. HCP1 sees self-testing as a measure, which keeps patients *"in-tune"* with their diabetes. HCP3 notes that for patients who do not self-test, regardless of classification, *"it's like being in the fog without fog-lights"*. HCP5 also acknowledges the role of self-testing for type 2 diabetic patients when newly diagnosed. Testing will allow patients *"to see the impact of various food stuffs on their glucose levels"* in addition to assisting physician treatment decisions.

The scientific community participants also acknowledge the role of near-patient testing, albeit under clinical supervision, in assisting patients to understand their own bodies. SCP6 refers to patient trials with a new device under development, which monitors ammonia levels, a significant marker of kidney function, among dialysis patients.[44] In the absence of a point of care device, blood results, and subsequently feedback regarding kidney function and response to therapy, are not as readily available via the standard hospital laboratory system. SCP6 relates how the device offered patients more immediate knowledge of the inner workings of their bodies:

> *… what they were happy about was that on a daily basis they could actually see how their levels were increasing or decreasing and they got a better perspective on their dialysis working in their favour, or not in their favour, so they could better understand how their kidneys were functioning, and if that meal they had last night is actually helping them, or hurting them, versus waiting a whole month and a surprise at the end of the month versus daily.* (SCP6)

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[44] Dialysis is a form of renal replacement therapy whereby patients with kidney failure have their blood filtered by a synthetic membrane to remove the toxins and fluids that are harmful to body functioning. The point of care urea monitor allows an assessment of ammonia levels and hence acts as a marker of dialysis efficacy. The development of this technology has been since publicised. Clinical trials show that ammonia results achieved from the breath monitor correlated well with results from standard laboratory tests. While the device is currently used within the dialysis unit, the institute also note the suitability of the device for possible personal monitoring and the development of future trials in liver disease. (See http://www.dcu.ie/research/highlights/2013/september/every-breath-you-take.shtml). This technology won first prize in the Universities' Annual Commercialisation of University Research Student Project Awards 2008.

This sense of 'knowing the body', in association with more frequent monitoring, is evident even outside of the diabetic population. Using the example of peak flow monitoring in patients with chronic lung disease, Willems (2000) uses Foucault's (1988) *Technologies of the Self,* to explain the sense of 'knowing' oneself that a self-testing device, in this specific context, can provide. Foucault (1988, p.18/19) explores the relationship between "care of self" and "knowledge of oneself", whereby the former was a necessary pre-requisite for the latter. Foucault (1988, p.18) uses the term, "technologies of the self" to characterise "a certain number of operations on their own bodies and souls, thoughts, conduct and way of being" which an individual engages in alone, or with assistance, "so as to transform themselves in order to attain a certain state of happiness, purity, wisdom, perfection or immortality". Willems (2000) refers to Foucault's *Technologies of the Self* at a number of points, to explain the 'self-knowing' associated with self-measurement in chronic lung disease. Central to this are the various bodily techniques involved [self-testing and observation] and the importance of writing, [documenting values obtained] as a path to self-knowledge.[45]

In current self-management practices, as Willems (2000, p.35) explains, previous techniques such as introspection have been replaced by "a material device". The ongoing use of modern technologies of the self, such as self-monitoring, results in knowing one's body: "patients gradually learn to predict peak flow values" (p.35). While patients initially rely on measurements more than on their feelings of body disturbance, after a period of time "felt disturbances become modified by previous measurements" (Willems 2000, p.23). The relevance of physiological 'felt' disturbances is learned over time through the process of self-testing, and associated written accounts of acquired values. Willems explains this in the context of one particular patient, Charles:

> In Charles' example the role of the technology in the practice of living
> with his disease shifts in the course of time. Peak flow has become a way
> of feeling for him; the correct knowledge of lung-function has become part
> of his body competencies. The device itself has acquired a different
> function from what it initially was supposed to do: it has become, just like

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[45] In *Technologies of the Self,* Foucault (1988) outlines these strategies in detail drawing on various references to self-knowing within ancient Greco-Roman philosophy and early Christian writings (see Foucault 1988, p.19). A more elaborate account of Foucault's treatise is beyond the scope here.

the techniques Foucault describes, a device to learn to understand what is going on inside him. (Willems 2000, p.33)

In this way, as Foucault explains, the care of self becomes "medical care". The patient becomes the "doctor of oneself" (Foucault 1988, p.31).[46] Interestingly, HCP2 refers specifically to self-testing as an activity which facilities patients to "*become their own doctors*". Participants in this study reacted differently to this sense of '*Knowing the body*". This depended on how the participants integrated the device and its associated ability to create an awareness of their bodies into their own lives. The two sub-themes that follow, *Freedom within constraints* and *Unwelcome burdens,* address these issues.

5.3.2 Freedom within constraints

For many of the participants in this study the device enabled them to exercise greater freedom, or control, over their lives, as it encourages and facilitates self-management. The 'knowing' of their bodies, as recounted above enabled them to self-manage their illness effectively and live their lives more freely or independently. However, what is obvious in some participants' stories is that this 'freedom' is achieved through acceptance of the constraints associated with the device. As participants recounted positive experiences of self-testing, other accounts of the device as a taskmaster, or watchdog of sorts, are also evident. Here the device demands ongoing attention from participants and may provide negative feedback. This watchdog and associated constraints are acknowledged, but accepted, as they provide patients with a means to assess and manage their diabetes. There are particular relational perspectives at play here in terms of the existential experience of illness. As participants refer to greater freedom, it is often with regard to the relational aspects of their existence, their interactions with friends, family and work colleagues.

A number of the participants relate personal stories, which support self-testing as a positive influence on their ability to live a full life with diabetes. Deirdre's experience

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[46] The use of Foucault's work in this context is acknowledged as Willems's (2000) thesis. However, Foucault's original text was consulted to establish the wider context. Therefore, primary references are utilised here.

of travelling to see her family in Australia is significant in this regard. Managing her diabetes with the aid of self-testing gave her the freedom to travel this distance:

> *I've been to Australia twice and I've been away a few times with it, so all in all I'm able to cope with it and I'm able to get on with my life.* (Deirdre)

Deirdre is specific about the role self-testing plays in this freedom: "*It helps you to live I suppose and to get on with your life*". However, Deirdre is not without reservations, she refers to the complexities associated with planning her travels as a diabetic who self-tests. Yet, despite misgivings, Deirdre prefers that the activity is available to her:

> *I'd like to say I could get up in the morning and say I do not have to do it … .You live with it, you have to live with it, you have to get your head around it, you have to get used to it.* (Deirdre)

The significance of self-testing in Deirdre's daily life is apparent in the following extract:

> [Self-testing] *is the most important part of my day at the moment. From once I test that it's within reason, and if it isn't, if I find it is climbing to 8 or 9, I cut back then straight away. That is what it's about. That's able to tell you if your blood sugar level is going up. Well then, what did you do? You know exactly what you have done so cut that out now today and watch what you're doing. That's what that's about. That's where self-testing comes in.* (Deirdre)

Deirdre sees the monitor as more than a device to test blood glucose levels. For her it is an important management tool, an incentive towards appropriate diabetes management. Deirdre is not a silent bystander in the management of her diabetes. She takes an active role in assessing the blood glucose levels, considering the possible reasons for elevation and deciding appropriate actions to resolve the issue. However, there is an element of control evident in the language, which Deirdre uses to describe the role of the device. The device keeps her "*on her toes*" and "*on the straight and narrow*". This suggests a watchdog of sorts, which exerts a restraining influence.

This *Freedom within constraints* is also apparent in Ann's story, a participant with type 2 diabetes. Similar to Deirdre, the sense of 'knowing' associated with the device acts as a mode of reassurance and a motivating tool for Ann, despite some misgivings about the process. She uses language similar to that employed by Deirdre to articulate the function of the device for her:

> *It isn't something I look forward to but it really does give me an incentive to make sure and I know how things are and I feel more secure that I know what the reading is ... I mean because you know, when you test your blood, and the reading is not right then you start taking action either maybe not eating as much or cutting out something, or making sure it comes down to a correct reading. It's the one thing that keeps me on the straight and narrow.* (Ann)

The freedom associated with self-testing in participants' lives is very evident in Bart's story:

> *... there was a period of time when I used not check it that often and I have a feeling that my blood sugars were all over the place. Up and down, in and out, one way or another, but over the past 3 or 4 years, I've been checking it 4 times a day at least and I find that I'm after hitting the stage now where I can really keep them where I want and I just find it of great benefit ...* (Bart)

Field notes reveal that Bart's enthusiasm and sense of being in control was palpable during the interview. Bart works as a taxi driver and is a type 1 diabetic. The self-testing device enables him to work full-time and plan his daily activity, including dietary needs. It appears from Bart's story that he feels empowered by the device. Bart makes specific reference to the accessibility of the device and the advantages that this brings. When asked about the possibility of ceasing self-testing and attending more regularly for clinic visits Bart notes the following:

> *Can't you see that even its disruption, disruption of the day? [Attending a clinic visit] I mean I've taken the afternoon off work now and I mean, I should be working today and if I had to visit the hospital I'd be losing a lot more time at work between one thing and another. So it's much more convenient testing it myself ...* (Bart)

Similarly, Betty speaks positively about the freedom that self-testing affords her, particularly with regard to going out to dinner with friends. Betty is a type 1 diabetic who self-tests twice a day and as she deems necessary. The device gives her the 'flexibility' to live her life and certainly seems to facilitate greater control. Betty had completed the DAFNE (dose adjusting for normal eating) programme as a newly diagnosed diabetic. Essentially, DAFNE educates individuals about type 1 diabetes and how to titrate insulin doses relative to carbohydrate intake. DAFNE facilitates a greater flexibility in dietary intake. In this way, patients are empowered to manage their diabetes less restrictively, which can have positive outcomes, both from a biomedical and psychosocial perspective (Speight et al. 2010).[47] Even though Betty no longer links with a centre that offers the DAFNE programme, the principles she learned on this course remain relevant for her in self-managing her diabetes.

However, it is apparent that this is control within certain limits. Betty recounts a number of times in her story that she finds self-testing "a bind" in some respects:

> *I find the blood testing side of it more of a bind than the actual administering of my insulin. I find it kind of, I won't say time consuming, but in day to day life when you're flitting maybe to work and you've got a quick break, by the time you get your monitor out and get your strip out and do your blood test, you know it's, I'm not very good for doing my blood testing on a regular basis for that reason. I find it just a little bit of a, a bit of mission, you know when I just want to do my insulin, eat my lunch, get my pen, dial up my insulin and away I go. So I find the blood testing more restrictive on my day-to-day planning of my day I suppose.* (Betty)

This 'bind', or time factor, associated with the device is perhaps more applicable in participants who test more regularly, and require blood glucose readings to titrate insulin levels. This is evident in Eileen's story. Eileen, albeit newly diagnosed with diabetes, refers to a recent trip to London with her daughter. Although the self-testing device enabled her to travel abroad, suggesting greater independence, it also dictated the sequence of her day. At numerous points, Eileen refers to the role of the clock in her day-to-day activities: *"I watch myself all the time, I look at the clock"*. Frances uses the term "*regimented*" specifically at four points in her narrative as she explains

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[47] For more information on DAFNE, see http://www.dafne.uk.com.

her engagement with the self-testing device. Similarly, albeit not on insulin, Alex notes that *"the routine is a bit of an issue"* when trying to manage his working day. Here again the existential dimension of illness is evident as there is a temporal significance in the patients' experiences. The regimental nature of self-testing and insulin administration leads to an alternative perception of time. This is a further example of the constraining nature of self-testing. Patients are constrained by routine requirements. Morris (2008) refers to this existential appreciation of time in the specific context of individuals with diabetes. Morris draws on the work of Heidegger and Merleau-Ponty to explain the different 'sense' of time experienced by individuals with chronic illness:

> … she or he cannot be improvident with respect to time, and cannot be heedless of time in its objective flow as measured by the clock, because she or he must always be clocking the next dose, treatment or turn of the disease. Rather than casting her or his own net of projects in a temporally improvisational way, she or he is caught in what I call a provisional time that already looks forward to the next dose as already foreseen. (Morris 2008, p.4)

This "caught in time" reflects the "bind" which Betty refers to, and encompasses some of the restrictions associated with the device, even while it facilitates greater control for participants.[48]

This sense of 'contingently being-in-control'[49] is also evident in other patient narratives, albeit to a more limited degree. Denis, a patient with type 2 diabetes, but receiving insulin therapy for greater glycaemic control, notes the role of the device in assisting him to live with his diabetes. Denis self-tests 4 times a day and refers specifically to the role of the monitor in detecting hypoglycaemia which allows him to take action to prevent deterioration: "*it would help me an awful lot … once I take it I can feel if it goes below 4 and I take something to eat*". Denis does not engage in the degree of self-management with regard to medication or dietary changes, referred to

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[48] The temporal reality of chronic illness, as an enduring presence, was significant for many of the participants in this study and will be addressed further in accordance with the theme: '*This thing' as ever present*.

[49] This articulation of 'being-in-control' is chosen specifically as it reflects the Heideggerian temporality of a sense of control that is transient and part of 'being-in-the-world', enmeshed in it, at one point in time

by other participants above. However, the monitor keeps him safe and enables him to engage in his daily activities. HCP5 notes the importance of monitoring as a safety mechanism in patients who are receiving insulin, or related therapies, with a risk of hypoglycaemia. It is interesting to note that Denis openly refers to his ongoing struggle with depression. This suggests it is possible to integrate self-testing successfully in patients' lives even in the face of adversity.

Self-testing as a means of enabling greater freedom for participants corresponds with the perspective presented by other stakeholders when they discuss the purpose of self-testing. The terms "*control*" (HCP1), "*empowering*" (HCP2), and "*self-managing*" (HCP3) are all evident among healthcare professionals' transcripts. HCP2 summarises the purpose of self-testing as "*empowering the patient into self-management*". The patient stories noted above support the role of the self-testing device in assisting patient control, empowerment and self-management and ultimately autonomy. The freedom afforded by a self-testing device is also espoused by the scientific community participants. Focus group participants in this study refer to the "*accessibility*" of a self-testing device as an important factor (SCP2) and the sense of "*partnership with the healthcare provider*" that the device can facilitate (SCP1). SCP5 refers to the "*immediate access to information*" which the device facilitates and how this can be utilised to "*evaluate their* [the users] *own state at any time*".

It is evident from the patient narratives above, and supported by the wider stakeholder context, that the self-testing devices can assist participants to assume greater control of their diabetes management. This in turn facilitates a greater degree of freedom in managing daily activities and interactions with others. In this sense, the vision for self-testing as espoused by the designers of self-testing devices is real. The participants referred to above do not see self-testing as solely an exercise in data compilation to hand to the healthcare professional. They regard the device as a tool to assist in the management of their condition and subsequently to facilitate greater control or autonomy in their daily lives. However, while the device can enable the participants to take control, it also constrains their daily lives to some extent. It is apparent that participants value the freedom that the device facilitates while also acknowledging its

restraining nature. There is a paradox here, but one that makes sense in the context of particular philosophical conceptualisations of autonomy.

There is a distinction between being free to do as one wishes and being autonomous. I suggest that the 'freedoms' which the participants enjoy are evidence of autonomy within the self-testing process. Freedom exists within constraints. Autonomy exists without absolute freedom. This crucial distinction between positive and negative freedom is often lacking in dominant perceptions of autonomy. Autonomy is often misconstrued as being synonymous with freedom; a freedom associated with the absence of restraints. Berlin's distinction between positive and negative liberty, or freedom, is helpful here. In *Two Concepts of Liberty* Berlin (1969) delineates between a sense of positive freedom, associated with self-rule or mastery, and negative freedom associated with non-interference by others. While there is evidence of self-mastery in the participants' stories, there is also evidence of constraints. The participants' freedom, or autonomy, is achieved through accepting that they have certain behaviours to adhere to in order to keep them well. The device is a "bind", an inconvenience, or a form of interference for participants that places certain demands on them, yet these demands allow them to live more independent lives.

This alternative construction of autonomy accords with Dworkin's (1998) perspective as outlined in the literature review. For Dworkin, freedom is not a pre-requisite for autonomy. Autonomy can be promoted by the denial of one's liberty. In this sense, we act on our higher order desires by deciding that certain behaviours are forbidden. The diabetic patient who subscribes to an onerous self-testing and dietary regime is one such example. Mars et al. (2008) support the theoretical basis of this paradox in a chronic illness context. The authors propose that dependence can be compatible with autonomy whereby "autonomy may be promoted by increasing people's opportunities to arrange their lives" (Mars et al 2008, p.337). The self-testing device allows participants in this study such opportunities. It allows Deirdre and Eileen the opportunity to travel, it enables Bart to operate his taxi business and it assists Betty to have dinner out with friends.

5.3.3 Unwelcome burdens

The experience of self-testing, this 'knowing' the body, does not result in favourable outcomes for all participants. For some, the device resulted in more negative experiences. These experiences are represented in this sub-theme as *Unwelcome burdens*. The 'Unwelcome burdens' outlined here are distinct from the various interferences or demands that the device imposes, which the participants accept. These burdens include feelings of uncertainty or confusion, guilt, embarrassment, distress and frustration, which the participants experience in their engagement with the device. The possibility of such burdens is also recognised by other stakeholders within the study. Their perspectives are interwoven with the participants' experience to extend understanding.

A sense of uncertainty, associated with a lack of understanding, is apparent in Colette's narrative. Colette is a patient with type 2 diabetes, diagnosed for four years at the time of interview. Colette sees the monitor merely as a tool to record blood glucose levels, not necessarily a precursor for personal decision-making. Colette does not report any difficulty with the physical process of self-testing: "*I've no problem with that.*" However, she seems to have minimal understanding of her diabetes or the current nature of her blood glucose levels: "*I can't see how my blood is so high like. That's what's worrying me the most*". This suggests an overall confusion in relation to self-testing. The recording, for the most part, is only purposeful for Colette in so far as she gathers data to give to the healthcare professional: "*I have it recorded every day. I have to put it in the book every whole day. Four times a day. I've to go back then and I show it to the doctor.*" It appears that Colette is 'self-testing' but not 'self-managing'. Colette does not understand the significance of the readings or their correlation with her diet and medication. Colette does however suggest some minor role for self-testing from a safety point of view:

> *It does help because you know what it is, whether it is up or down, do you know what I mean? Cause if you do not test it, you won't know what it is. I could be down on the floor in two minutes like; do you know what I mean*? (Colette)

Throughout her narrative, Colette refers to three recent episodes of hypoglycaemia, which suggests that her diabetes is not being managed well. The absence of self-management and lack of understanding in Colette's story may be associated with a lack of education, an inability to assimilate information given, a failure to accept any personal responsibility for her own health, or the myriad of other problems that she spoke so openly about during the course of the interview. Colette refers to housing, family, other health related issues and "*feeling down*" related to a recent bereavement. These issues will be explored as the wider aspects of the phenomenon are further outlined. For the purpose of discussion here, it is significant that for Colette, self-testing does not promote freedom and empowerment as in other participants, but creates confusion. Colette is unable to explain high readings, which appears to distress her, and liaises with healthcare professionals in order to initiate any change in management.

Colette's scenario is reflective of the type of patient for whom self-testing is not a means of enhancing autonomy. Other stakeholders in this study acknowledge that self-testing can be harmful, when results create anxiety but do not result in corrective action. HCP3 refers to this category of the patient population:

> *… patients who would be testing 7/8 times a day and not doing anything 'with' [emphasis] the reading, as in the case of the type 2 where they can't actually, they have got so hung up on this being the be all and end all of their care, that this is going to fix things when in fact it's possibly their diet they should be more focused on. … Personalities are different obviously in people, there are some people who get completely wrapped up on self-testing when they should be focusing their energies on another aspect of their care so that can be a disadvantage to some people.* (HCP3)

These sentiments very much echo the reality of Colette's story.[50] The scientific community participants, while aware of the possible role of self-testing devices in patient empowerment, are not naive to the more negative consequences that may result.

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[50] Colette's general demeanour and lack of insight into diabetes and its overall management prompted me to spend some time with her after the interview ended. I advised her to seek assistance from the diabetic nurse specialist and dietician with regard to clarifying aspects of her diabetes treatment and discussing other personal concerns with them. This was a particular example of the ethical commitment to participants throughout the research process.

Similar to healthcare professionals, they acknowledge the anxiety that can be associated with self-testing, particularly when results are not interpreted correctly:

> *I mean a patient can have a bit of a flip-out if they see something going up but medically it might be completely under the radar, it might be noise, but the patient might be worried, or the opposite, the patient might get complacent if they see something going up or down. So access to information as [SCP5] said is quite important – it does empower the patient. But maybe down the line and when a device is more accessible to a wider public, it is quite possible that the doctor, or like I said the practitioner, might have to give them levels of 'look do not freak out if this goes up'. If it goes up 20 fold let us know, if it goes up 2 fold it's just noise or the other way round ...* (SCP2)

A number of healthcare professionals refer to the use of specific blood glucose level targets to assist patients in interpreting their results and recognising 'at risk' figures. This interpretation does not seem to be understood by Colette or may not have been provided.

Some participants refer to a sense of embarrassment in their engagement with the self-testing device. Both Betty and Geraldine refer to the fact that they prefer not to test during their working day. This is not necessarily because their colleagues are unaware of their diagnosis, but rather because it results in a degree of self-exposure that may not be necessary:

> *It's [self-testing] not something you can do very discreetly and at the end of the day, you know, the whole world does not need to know, especially at work ...* (Betty)

For others, the exposure associated with self-testing is more significant in terms of the limits it places on their daily activities and interaction with others. Con refers to this explicitly. The self-testing process seems to exclude Con from some social activities:

> *I play a lot of pitch and putt and we normally have coffee, biscuits when the day is done. ... I can't because I must go home and test my blood.* (Con)

He expresses a personal preference for carrying out self-testing in private but also notes that some of his sporting companions might *"object"*. His wife, who remained

present during the interview with his permission, also noted: *"they'd be watching"*. Similarly, Eileen*,* a newly diagnosed type 1 diabetic, refers to the embarrassment associated with self-testing and injecting herself with insulin. She relates a recent conversation with her daughter, who encouraged her to have dinner in a restaurant during a recent weekend away. Eileen conceded but noted her reluctance, and the fact that she was *"hiding in a corner"* and kept her handbag in front of her during the process. HCP5 acknowledges the sense of embarrassment that can be associated with self-testing, as noted by participants in this study: *"some of them are conscious of not doing in public it means that they need to carry equipment with them every time"*.

The self-testing, and sometimes insulin administration, associated with diabetes represents an outward sign of an otherwise 'unseen' chronic illness. Vickers (2001) presents a phenomenological study of individuals who experience 'unseen' chronic illness in the work environment and the implications that this has for them. Her study offers some interesting insights to assist interpretation here. Drawing on the work of Parsons (1951) and others, Vickers (2001, p.3) asserts that ill health is problematic in a functionalist society where "any level of illness that takes the person below optimal capacity becomes a problem". Vickers' study reveals a series of harms inflicted on individuals in the work place where their capacity to function is at odds with the capitalist ideology of the modern working world. Vickers focuses on those illnesses which are unseen and do not display outward signs of ill-health. Vickers incorporates diabetes in a list of such illnesses. In making the 'unseen' seen through the process of self-testing, the participants in this study are potentially exposing themselves to the negative responses that Vickers portrays.

Con, like other participants, struggles with the chronic nature of his condition, a condition which does not result in acute visible manifestations of ill-health; it differs from his cancer and previous stroke, but is ever-present and potentially life-threatening and debilitating. Con notes, despite his obvious distress, *"I don't feel I have a condition"*. This sense of 'unseen' chronic illness, as something that is different, is also alluded to by the healthcare professionals in this study. HCP3 refers to diabetes as *"the misunderstood condition"*, while HCP2 refers to the diabetic patient as *"different but not different"*. By engaging in self-testing the participants in this study are making the

'difference' more explicit and exposing themselves, as distinct from their work colleagues or other contemporaries.

Participants also associate a certain amount of guilt and self-chastisement with self-testing. Frances refers to her reaction to a high blood glucose reading as follows:

> *First of all I'm cross. ... I would feel a little bit stressed when I see high sugars because. ... I like to be in control.* (Frances)

Frances refers to being 'cross' at two different points in her narrative. She also uses the word 'strayed' - *"I would never have strayed"* - suggesting that she associates deviance with non-compliance and high blood glucose levels. Alex's narrative also portrays a sense of self-chastisement associated with his blood sugar levels, despite adhering to medical advice:

> *I've made a lot of changes even in the last 6 months, all of which have worked. All the other benefits of doing that have come through, the weight control, the cholesterol [reduction].… They're the positives of it. Except my reading ... and my doctor is telling me that I shouldn't beat myself up about that because what's happening, they predicted would happen.* (Alex)

Willems's (2000) refers to the sense of blame that can exist within self-management programmes and the associated alteration in the patient/clinician relationship. When self-management programmes are in place, decline in one's health status can be attributed to the patient's failure to attend to certain prescribed regimes:

> Deterioration cannot solely be blamed on the disease anymore. There is some paradox in the account of the disease that is part of monitoring and self-management: on the one hand monitoring programs create and maintain an image of asthma as a treacherous and capricious disease that needs constant surveillance, while on the other hand they make people and technologies accountable whenever it is not successfully brought under control. (Willems 2000, p.30)

HCP6 supports this perspective. HCP6 recognises guilt as present among patients when sharing blood glucose results in the clinic setting. He notes that patients *"may feel abashed if they hadn't made a greater effort"*. Patients and clinicians now

"shoulder the expectation" (Willems 2000, p.30) that illness can be controlled by self-management programmes. When illness is not controlled, as exemplified by high blood glucose readings in this study, the participants can experience feelings of blame or guilt, despite the fact that the deterioration may be inevitable, due to declining pancreatic function.

An additional consequence of self-management in this regard is that the roles of patient and clinician shift. "Self-management results in a redistribution of characteristics and competencies between physicians and patients" (Willems 2000, p.30). This redistribution is an example of the 'soft' impacts[51] of technology which occur over time and are not considered at the trial stages of development. Mol (2000) articulates the unintended outcomes of technological interventions, specifically in the context of blood glucose monitoring. Echoing Willems's perspective, Mol (2000, p.48) refers to the "unexpected effects" of technologies which "generate forms of pain and pleasure which nobody predicted". Evidence of such unintended 'pain' is demonstrated among other experiences recounted in this study.

The process of self-testing can invoke greater distress for others. Con, a fifty-year-old man with type 2 diabetes refers to self-testing in primarily negative terms at the point of interview. Con reveals his 'being-with' the self-testing device in a manner that suggests the device has a debilitating impact on him. Con associates very little control with the self-testing process, albeit perhaps the role it plays in preventing more frequent hospital visits. He does not refer explicitly to the role of the device as an aid to self-management at any point in his narrative and, for the most part, he seems to be experiencing a general lack of control:

> *I used be so competitive growing up and not giving in to things and I always had a good attitude. ... I never had the attitude well, we'll give up, but this thing is getting the best of me, I feel. Through all my sicknesses, I've never had an attitude to say well you know, give up. I say well, this is part of life, what's thrown at you, you know it's better to be thrown at me than someone else. but this diabetes is getting the best of me, I think.* (Con)

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[51] Soft-impacts of technology involve more cultural issues related to "changes in our way of perceiving, acting, valuing, hoping and relating" in comparison to more 'hard' impacts related to technological hazards and economic benefits (van der Burg and Swierstra 2013, p.4).

Other negative experiences of self-testing are evident in Alex's story. Alex, a type 2 diabetic, associates a sense of frustration with monitoring and recording blood glucose levels at the point when his metabolic functioning is decreasing. For Alex, self-testing is not promoting personal freedom, but rather acting as a visual sign of his deteriorating health status. Alex relates how the self-testing serves no purpose other than *"an opportunity to frustrate [myself] even more"*.

HCP6 refers to a scenario very similar to Alex's engagement with the device:

> *If somebody is getting highs all the time ... if they are trying to do their best and it's not working out, sugars aren't improving, people might, I wouldn't say give up but might get disheartened, there are higher levels of depression in diabetes as it is a chronic illness, lack of improvements in BMs* [colloquial term for blood glucose levels based on previous manufacturer's initials] *despite them making an effort, can be disheartening.* (HCP6)

This also reflects the blame-invoking scenario as noted by Willems above.

All six healthcare professionals interviewed in the study note categories of patients for whom self-testing may not work well. HCP2 uses the word "*burden*" specifically to describe the impact of self-testing on some individuals. There is a general understanding that self-testing should be an individualised decision. This individualised approach to self-testing is evident in the following account:

> *Some people can have personality problems where there are very anxious people, if they are very elderly in some cases. If they see a high reading, it can have a huge impact on them. So I think in that case if somebody is just on diet and occasionally they have a reading of nine, but most of the time they are within target for us, that one high reading makes them very unsettled and they may restrict their food which may not be good nutritionally for them, or for their health. In that case, there is more need for community involvement or maybe just more support from the family. They may look at their overall HbA1c rather than doing frequent blood sugars, which may distress them.* (HCP4)

While there does not seem to be a formal review of the specific value of self-testing for patients, HCP2 notes that when difficulties arise "*it's all about compromise and discussion*". HCP5 refers to such discussion and notes that:

> *In some of our type 2s who are very stable, or very elderly, and not at risk of hypoglycaemia we would be quite happy if, on consultation with the patient, they were reluctant to continue testing we would be quite happy to discontinue it.* (HCP5)

HCP3 notes that the clinic endeavours to facilitate a return visit for type 2 diabetics after their initial education. This visit would ideally address the issue of self-testing, but due to limited resources, such follow-up visits do not always occur. HCP6 also notes the difficulties experienced by some patients and comments that a formal review system is "*maybe something we should look at*". In addition to HCP3, HCP4 also relates the need to discontinue self-testing for some patients:

> *We have had some people that were so distressed by readings, the occasional high reading, and it was causing them severe anxiety, and their actual status, their diabetes status was quite good, that we would actually suggest, instead of getting themselves upset, that they would attend their GP occasionally for the occasional test and have their HbA1c done and forget about the testing – it wouldn't be a huge number – a minority.* (HCP4)

However, the general philosophy among healthcare professionals interviewed in this study appears to be that self-testing is "*offered to anybody who has any type of diabetes*" (HCP3). HCP3 acknowledges the lack of a specific protocol in this regard and suggests the need for a more standardised approach:

> *There is no protocol, it's all discretionary, at the discretion of the nurse or healthcare professional the patient will meet. … It would be good to have a standard protocol or policy for maybe those who don't need to test seven or eight times a day, but still have the opportunity to test to avoid that, you know, confrontation with it down the line.* (HCP3)

However, there are real difficulties in moving towards a more policy/protocol orientated approach, as pointed out by HCP5. Despite protocols for testing in type 1 patients, patients with insulin pumps and those with gestational diabetes, a protocol for individuals with type 2 is more difficult:

> *... type 2 involves a very heterogeneous group of conditions all classed under one term. Management should be individualised so therefore we don't have any set protocol for any patient as such in relation to testing, we try to individualise their therapy according to what stage they're at …* (HCP5)

The unwelcome burdens associated with self-testing among participants in this study reflect negative feelings associated with illness in a more general sense. The sentiments of confusion, guilt, embarrassment, distress, anxiety and frustration experienced by the participants are components of what Biro (2012, p.41) refers to as the "anatomy of illness". In accordance with Biro's analysis, illness can be:

> ... represented by a series of enlarging, concentric circles set in motion by a source - disease - that keeps on repeating itself, from the body to the person to the person's standing in the world and back again. Each circle is characterized by a single felt quality: alienation. Something in my body does not feel right, I do not feel right, I do not feel like other people. This expanding sense of alienation gives rise to the constellation of feelings that make up the emotional landscape of illness: fear, anger, vulnerability, helplessness, shame, guilt, jealousy, and above all, isolation and loneliness.

However, while these emotions may be symptomatic of broader problems associated with one's illness, what is apparent in the interpretation above, and relevant to the current sub-theme under discussion, is that, for these participants, the self-testing process potentiates the emotions, or brings them to the fore. The interconnectedness of the participants' experiences of diabetes and their engagement with the self-testing device is a central feature of the wider interdependent phenomenon. This aspect of the phenomenon will be dealt with more explicitly in terms of the participants' relationships with their illness in accordance with the sub-theme: *'This Thing' as ever-present.*

The scientific community participants, as noted above, do acknowledge that negative emotions can be experienced by patients when utilising self-testing devices. Echoing the experience of Colette above, SCP1 recognises the potential for varied individual responses to the self-testing process:

But ultimately, I think if a doctor is going to put a patient on to a monitoring programme they are going to have to evaluate the patient in terms of whether that monitoring programme is going to be of use to them. And that long term use is not just going to be about the very hard biochemistry. Is it going to keep their glucose levels, their HbA1c levels down, the glucose levels in check, or is the poor so-and-so literally going to be living from one finger stick to the next and worrying about what is going on in between? In which case that can be more harmful to their long-term health than any benefit that could be derived from being on a monitoring programme. (SCP1)

However, despite this acknowledgement, it was apparent that the subjective individual response to a diagnostic device did not form part of the research process 'within' the laboratory setting. In the main, as is not unusual, because of their work at the proof of concept and early validation stage, the scientific community participants in this study were not directly engaged with patients, and were primarily concerned with clinical accuracy and reproducibility of test results. This is apparent in the following extract:

... we wouldn't actually see our patients very often, people like you [referring to the researcher] *who would, may be involved, would have more access to the patients but we do not – we would never see them. We know they are there, we know the final outcome is with the patients but we wouldn't have that much interaction with them.* (SCP3)[52]

Mindful of the problems associated with continuous access to blood values, and associated pancreatic function, by participants in this study, I asked SCP6 if any of the patients noted anything disconcerting about having continuous access to their ammonia levels (and subsequently kidney function). SCP6 responded as follows:

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[52]It is important to acknowledge that scientific researchers working in the laboratory setting are engaged in specific components of work packages, which have been agreed in accordance with the Institute's clinical, academic and scientific partnership. The clinical need for any research programme is validated in advance. The specific work focus of the scientific community participants in this study is at the early proof of concept stage as outlined in section 1.3.4. The proof of concept phase is followed by further technical validation, clinical validation and eventually end product design. Initial funding is usually designed to facilitate proof of concept studies and early validation of an innovative technology (clinical and technical). Where a device is being designed for patient use specifically, due care and consideration would be taken to ensure that it is fit for purpose, for example the ease of use of the device, meaningfulness and relevance of the data generated etc. However, while further research may be undertaken beyond the proof of concept stage, it is arguably preferable to engage with patients initially, and explore the impact that more readily available results may have on them. This debate is continued within the discussion phase of the thesis in section 6.3.4.

Not that I noticed – a lot of it was basically blood work and waiting for results to come back. Having the results almost instantly, whether they were positive or negative results, it was comforting. It is not invasive at all so you are actually monitoring biomarkers – biomarkers on the breath, which means there is little discomfort at all – it is literally blowing into a tube. (SC6)

In light of the primarily objective nature of this response, and additional data reported by the researcher relating to the physical comfort of the device, I initiated conversation about the nature of data collected and asked about the inclusion of any qualitative assessment. SC6 responded as follows:

It was mostly quantitative just because of the research perspective of the whole thing ... there was very little qualitative data from their voices and feedback from the whole thing simply because it was such an early stage of the project. It would be better, in my opinion, to have that further down the line when it is more of a regularly used device versus a six-month trial period. (SC6)

This highlights the almost exclusively quantitative and efficacy-focused nature of the assessment of diagnostic devices at clinical trial stage.

This is not to suggest that the scientific community participants were not interested in the patient perspective. Focus group participants (SCP4, SCP3, and SCP5) noted the inclusion of the patient perspective in numerous discussion fora within the scientific community:

And they [end-user applications] are definitely discussed in the review process, we've just had our Scientific Advisory Board, our Industrial Advisory Board and our Academic Advisory Board and they definitely ask those questions: 'what is the purpose of the work you do?' and I think that does apply to everybody. (SCP3)

The importance of the patient's perspective within the organisation's educational programmes was also noted.[53] It is rather that the frame of reference, within which participants assimilated the patient perspective, did not always seem to be particularly

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[53] The institute includes workshops on the social and ethical dimensions of diagnostic devices as a component of its MSc programme.

attuned to the wider affective dimensions of the diagnostic or testing process. The general assumption is that more frequent and more accessible testing, once convenient and as non-invasive as possible, is always in the patient's best interest. These sentiments are expressed by SCP1 as she outlines her vision for a connected health system of patient monitoring with the assistance of diagnostic devices:

> *That will facilitate more frequent monitoring of a person's condition. And the assumption is that that would be better for that person's health in the long-term. Because not only will you get the more frequent monitoring which of itself is probably going to be better for the patient but you get a better patient buy-in or you get a better patient adherence to management of that condition overall.* (SCP1)

While this statement most certainly appears to concur with some of the participants' stories in this study, the 'unwelcome burdens' as experienced by Colette, Con, Frances and Alex, suggest that this is not true in all cases, at all times. Interestingly, the scientific community participants acknowledge that their perspective may be unilateral in some respects and would value a challenge to their primarily scientific outlook. Following the focus group, I asked the scientific community participants to evaluate their participation (see evaluation form included in Appendix H). This response from SCP2 echoes some of the other respondents' views:

> *The experience was quite positive as many aspects of the philosophy of POC [point of care] self-diagnosis were discussed from a perspective that we would not often consider. Many of us consider our roles to be that of a developer, in that it is our remit to "make the thing work". Until the later stages of development, we may not apply much consideration to the experience of the end-user who will ultimately have the highest interaction with the device.* (SCP2)[54]

This discussion is also pertinent to the next thematic component of the phenomenon, which outlines difficulties encountered by the participants in their relationship with the device, related to its technical capabilities.

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[54] The experience of SCP2 here is not unusual in the wider context of innovation and device development. See footnote 50 above.

In light of the negative experiences recounted by participants in this study, it seems surprising that self-testing would be routinely recommended, particularly when there is an acknowledgement within the healthcare community that self-testing may not always have value. There is a general agreement among healthcare professionals in this study that, while self-testing is mandatory among individuals with type 1 diabetes and other patients receiving hypoglycaemic agents, it may have some value but is not obligatory among type 2 patients who are not receiving such pharmacological agents. HCP3 explains, similar to what much of current evidence suggests, that in type 2 patients when HbA1c is well-controlled and other physiological parameters such as cholesterol, blood pressure and lipids are satisfactory that self-testing is not an absolute requirement. Similarly, HCP5 notes that *"in type 2 diabetes patients, who are not on oral agents that have a risk of hypoglycaemia, the role is relatively limited"*. If self-testing is not necessary for physiological well-being, and may harm psychological well-being in some patients, it begs the question as to why does it continue to be routine practice for patients with type 2 diabetes.

5.3.4 Living with pain and other technical imperfections

This sub-theme addresses a number of technical difficulties that the patients experience in their engagement with the device. The patients, for the most part, are accepting of these imperfections but acknowledge their existence. Most relevant is the experience of pain, which is inevitable, as the monitoring device is invasive. Other difficulties include interrelated issues such as: the size of the device, the cumbersome nature of the component parts, and the time required to elicit a result. Collectively, these issues represent problems with the indiscreet nature of the self-testing process. Both the healthcare professionals and the scientific community participants offer some insights with regard to the technical aspects of the device, which are interwoven with the patient experience.

Pain in self-testing is noted by a number of participants in the study, but is most prominent in Ann's story. Anne's narrative represents both a denial and an acknowledgement of the problem:

You see some people have a fear of needles and that and they think it hurts but it does not hurt [raised voice]. Now initially when I started first I thought 'Oh my God Ah! [emphasis], I used to be pricking my finger and even the thought of it was desperate. When I was admitted to hospital first, and of course it was tested several times during the day, I used to nearly get sick when I'd see it [the lancet] coming. Now I do not take any notice of it and it does not hurt [raised voice]. (Ann)

In order to acquire blood for self-testing purposes patients are required to pierce their skin by use of a small needle, referred to as a 'lancet'. At four different times in the interview, Ann refers to the fact that self-testing *"does not hurt"*. However, she does refer to the fact that she *"does not like needles"* but continues to self-test because of the health implications of not adhering to the advised management programme. Ann's comments at the close of the interview refer to a need for non-invasive monitoring which would not require a blood sample:

If there was a way without actually pricking on the surface of the skin, if there was some kind of monitor that you could say just put in on, and you could, through sensors or whatever, draw the reading. (Ann)

The experience of pain is also noted by other participants. Con refers to the pain associated with self-testing as particularly problematic, in light of his previous stroke, which means he can only self-test on one hand, resulting in it *"becoming like a pin-cushion"*. Frances also acknowledges the pain factor but does not see this as a deterrent to self-testing.

HCP6 notes that many of the patients are surprised to find self-testing more painful than the actual injection of insulin, and that the experience of pain may prevent more frequent monitoring. In acknowledging the pain associated with self-testing, HCP5 notes an additional problem. As patients' fingertips become compromised due to frequent monitoring, this may affect their ability to read braille at a later stage should they develop blindness through retinopathy, which is a long-term complication of diabetes. HCP5 and HCP6 echo Anne's hope for a system of non-invasive monitoring.

The scientific community participants noted that many of the developments in diagnostics they are currently engaged with require a blood sample, and therefore, invasive monitoring. There was some acknowledgement of pain as an issue in self-testing, as SCP6 referred to the non-invasive nature of the breath-monitoring device under development. One participant noted the development of a device in another institution that would test biomarkers on saliva.

Apart from pain, participants also noted other issues regarding the device. Betty notes that the device now requires less blood to elicit a result, and that in general "*the monitors have become smaller and lighter, more user-friendly*". Denis also refers to the reduced quantity of blood now required to test. Ann refers to how the device has "*modernised*", and Frances notes the continuous reduction in testing time. However, despite Betty's acknowledgements of developments, she refers to further improvements that could be made, particularly with regard to the cumbersome nature of the device due to a number of separate parts, and the impact that this has on the ability to self-test discreetly.

The lack of discretion in the process, due to the cumbersome nature of the device, may contribute to the sense of embarrassment experienced by participants as noted earlier, and the reluctance to test in the work environment:

> *I can do a shift when I may be on a 15 minute break and to sort of get the monitor out, physically have what I need to eat in the 15 [minutes], and then administer my insulin, you know, you're on a very tight time-scale and like that, if you're in a cloak room or whatever and someone says "and what are you doing?"* (Betty)

Also referring to the time factor involved, Frances notes that she would like the monitor to be more "*instantaneous*" in producing a reading. Con notes the awkwardness of his most recent monitor. While accepting the value of a self-calibrating device, he refers to its more cumbersome nature: "*a bit awkward*" to be carrying around. Similarly, Alex also notes the size of the device, its component parts and the impact this may have on his testing regime:

I'd have gone away for the weekend and left it at home, or I've gone to work and left it at home, it's not, I mean, I don't carry a man bag or anything like that, it's not small. You know if you had something that's tidier, you know, and I believe that there's something being developed that would make it a lot easier, and maybe I wouldn't be forgetting it. (Alex)

Frances's reference to a free sample monitor in her second interview highlights her role as a discerning customer who values various aspects of the device design:

… it is very compact and it is a lovely machine and you have a little monitor – its only I'd say the thickness of your two smallest fingers it is very very sleek. But to actually test with the finger yoke is terrible! It is so sharp and I think it is at the first setting I have you would actually draw about quarter of a pint of blood; there is so much of it. It is a fabulous little monitor but to do the finger pricking you actually would die. The next time I go up and he is above now towards the end of the year I'm just going to tell him. (Frances 2)

Not all participants note difficulties with the device. Despite some acknowledgement of the *"finger pricking"* Deirdre comments: *"I do not think they could make it any easier"*. Similarly Denis, Hannah and Geraldine are quite matter of fact about their use of the device. However, it is apparent that technical aspects of the device can create difficulties for some participants, influencing the patient experience and, in some cases, the time and frequency of their testing.

When asked, the scientific community participants in this study articulated various views about the important aspects of a device from the patient perspective. In addition to a non-invasive technology, these included a *"fool proof device"* (SCP3), and a device which is professional looking from an aesthetic perspective (SCP1). SCP6 notes: *"one thing that is always overlooked is ease of use and comfort for the patient"*. It appears, with the exception of SCP6, that the focus group participants were not directly engaged with patients in a manner that could elicit this type of information. It is important to note that for the most part, the work in which focus group participants were engaged with took place within a laboratory setting that is never accessed by the patient population (see section 1.3.4). When clinical trials take place, they occur in

other centres or the hospital.[55] In the evaluation following the focus group, SCP2 notes the value of patient engagement and wider stakeholder interaction, in addressing patients' technological concerns. However, interestingly, SCP2 also notes the value of such engagement as a means to foster an appreciation of the complexities involved in technological applications.

> *I would suggest that such discussions be in two formats. The first could be similar to what we did as part of the focus group, in that we discuss our opinions and view of the application. However, I think that this would only be useful if these discussions were brought to a second level of group that would also have representation from investigators from the "flip-side" - nurses, GPs, manufacturers or perhaps patients. Here, the challenges from both sides of the POC experience could be made clear to the other. On the development side, we sometimes forget that the instrument will be used by non-technically minded persons, and on the deployment side, the difficulties of miniaturisation and speed may be explained. If there were all-inclusive discussions such as this ... from time-to-time, I would feel it would be quite a positive development.* (SCP2)

In summation, the patients in this study recounted various aspects of their individual relationships with the self-testing device, which may support or negate the experience of autonomy. Such experiences are, on some occasions, but not always, understood by the healthcare professionals or the scientific community participants. Once a device is in use, it can affect the patient's daily life in ways that were not envisaged at the point of development. The scientific community participants appreciate the importance of the patient context; however, the research processes involved at the development stage of a device will not necessarily elicit contextual information about the individual patient experience. The experience of engagement through the process of a focus group in this study suggests that interaction and reflection regarding the 'soft' impacts of technologies may benefit the scientific community participants and, ultimately, the patient experience. In addition, further interaction among all stakeholders may create a greater understanding of the complexities involved at the design stage.

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[55] The clinical partners, in accordance with the institute's governance structures have responsibility for validating the clinical need for projects and overseeing/directing appropriate clinical use of the end-product. However, the extent to which application of the end-product based on its clinical efficacy is sufficient, without a more psychosocial assessment of its effects, is a matter of debate. This point will be re-visited at the discussion stage.

5.4 Relationship with illness

This thematic component of the interdependent phenomenon concerns the participant's relationship with his or her illness. This relationship affects the experience of autonomy. The participants experienced this relationship in three distinct, yet interrelated, ways. Firstly, for some, there is evidence of accepting their diagnosis and taking ownership of the management of their health. The sub-theme *Taking control* explores this perspective. Secondly, significant among participants is that their experiences of autonomy in self-testing cannot be separated from their wider experiences of living with chronic illness and diabetes. A sense of chronicity was prominent among a number of participants as addressed in the sub-theme; *'This Thing' as ever present.* Thirdly, the illness's course, and other life events, can affect one's experience of autonomy over time. This aspect of the phenomenon is addressed by the sub-theme, *Autonomy as contingent in chronic illness*. The sub-themes within this relationship encompass various temporal and corporeal perspectives in terms of the existential experience of illness. These existential perspectives will be noted throughout, in addition to the insights from other stakeholders, to illuminate this aspect of the overall phenomenon.

5.4.1 Taking control

The issue of control, referred to throughout many narratives, is quite significant in interpreting participants' stories. This is distinct from the experience of 'being-in-control', and the sense of positive freedom or autonomy, which it affords participants, as noted in *Freedom within constraints*. Here I refer to the conscious act of 'taking control'; an acceptance of the self-testing regime and associated diabetes management. The participants who experience a sense of freedom or empowerment, associated with the self-testing device, refer specifically to accepting responsibility for their own illness. There is an obvious sense of taking ownership of their illness in their narratives. They all see self-testing as something for them, a means of taking an active role in their diabetes management. This reflects an important dimension of the interdependent phenomenon of autonomy within the self-testing process.

This sense of taking control is particularly apparent in Deirdre's narrative when she refers to the self-testing process:

> *... I'm doing something for me. ... It's up to me. ... You have to self-test and you have to able to read it and you have to be able to tell yourself if it's going up, why is it going up?... As I said it's down to you, it's down to me, it's my life. I mean, what can you do, what can you say at the end of the day? It's down to me and that's it. ... I do not think they can make it any easier than what it is; I think that the home testing as I'm doing is brilliant.*
> (Deirdre)

Deirdre is a lady in her fifties with type 2 diabetes for the last 9 years. She self-tests her blood glucose levels once a day in the morning. Deirdre's acceptance of responsibility for undertaking self-testing and managing her diabetes is evident in the extract above and was palpable all during the interview. Field notes on the day make this point and note that the interview cast self-testing in a positive light. Deirdre lives independently. Her grown up children now live away from home. Deirdre, as noted earlier, is not without criticism of the self-testing process; she refers to it as a 'nuisance' at one point, but this does not prevent her from speaking positively about its contribution to her well-being. Deirdre tests once a day and uses this reading as an ongoing marker to evaluate her health.

In a similar manner, Betty, who also expressed positive accounts of self-testing, refers to personal responsibility in her narrative. Betty refers to self-testing as an activity that is: "*more for you than for the medics*", a process that assists in "*your day to day management of your diabetes*". In the same way, Ann notes that she would "*question*" a healthcare system, which did not facilitate self-testing among diabetics as "*the ultimate responsibility is with yourself*". Geraldine's thoughts on the self-testing process are similar: "*I think it's good because at least we're able to keep control of it ourselves you know*". Geraldine, like Deirdre, self-tests once a day only, while acknowledging that perhaps more frequent testing may be useful. Even Denis, who exhibits a more limited sense of autonomy than others do, notes the following: "*I prefer to do things for myself.*"

Likewise, Bart refers to the sense of personal control that he associates with regularly checking his blood sugar levels. Bart points to a particular interaction with a healthcare provider as a turning point, which marked a shift in his thoughts about his illness from a time when he used to adopt a "harum scarum" [ad hoc] approach to his present more diligent self-management techniques:

> *I'd say, that's a long time ago now, and I was very 'harum-scarum' about it. I'd check them today and I mightn't check them for 3 or 4 days again and you know it might be the odd check every now and then, but I've definitely got into a stage now where I just can't visualise not checking them* (Bart)

With regard to his change of attitude, Bart notes: "*I do not know what frame of mind I am after coming into*". This 'frame of mind', this taking control, in association with the education received, has obvious benefits for Bart with regard to his diabetes management. In the absence of this change of attitude, and Bart's keen interest to take control of his diabetes, any amount of educational input may not have the same impact. This is a particular example of the interdependent nature of the phenomenon of autonomy in self-testing. While Bart's relationship with the device was positively assisted by the education he received from his healthcare provider, his relationship with his own illness, his taking control, allowed him to maximise the potential of that information.

The degree to which individuals feel that life events are within their control is viewed as an essential element of coping in the context of chronic illness. This characteristic is referred to as an internal locus of control. The 'locus of control' construct was developed by Rotter (1966 cited in Lange and Tiggemann 1981) and is generally understood to refer to the degree to which one considers life events to be within one's control (an internal locus of control), or dependant on fate or chance (an external locus of control). One of the healthcare professionals in this study noted that active patient management is "*integral to the management of diabetes*" as "*diabetes can only be managed if there is a full buy-in from the individual with the condition*" (HCP5). This perspective was very much echoed by other healthcare professionals. HCP6 views self-testing as a "*very important part of being in charge*". HCP3 refers specifically to the importance of patients seeing self-testing as an activity that is for their benefit, as noted

by the participants above. There is no point in patients taking recordings to please their healthcare professional or even falsifying records to achieve this end:

Taking it because they feel the nurse might like to see a whole bunch of readings, this thing of 'here are my readings, here are my numbers', and did they do anything with their insulin? No! [Emphasis] *doing it because they are trying to please the doctor or the nurse. Patients feel they are doing it for you, the nurse or the doctor, certain personalities of patients…not all patients. They are trying to please you* [emphasis] *that they have everything written down. I have seen books falsified, if you know what I mean, there couldn't be the same number practically across for a whole week in the same coloured pen.* (HCP3)

Based on their narratives Betty, Ann, Bart, Geraldine and Deirdre appear to be representative of personality types who welcome being in control, and positively take control of their illnesses. Lange and Tiggemann's (1981, p.398) synopsis of the locus of control construct accords well with the sense of control portrayed by these participants:

those individuals who have an internal locus of control have a belief that rewards follow on from, or are dependent on, their own behaviour. They believe that their actions can affect the course of their lives.

5.4.2 'This Thing' as ever present

This sub-theme is central to the interdependent nature of autonomy in self-testing revealed in this study. For some of the participants it was difficult to differentiate their experiences of self-testing from their wider experiences of living with diabetes. I suggest that it is impossible, and even epistemologically flawed, to present a phenomenological account of self-testing in diabetes without reference to the overarching experience of chronic illness. The participants' experience of chronicity is revealed here in their accounts of self-testing. There is an evident temporality in their narratives as their sense of time is shaped by the ever-present nature of chronic illness. The future-directedness with which they live their lives is also apparent as they act today to prevent future complications. The participants' spatial existence is also revealed as the presence of the self-testing device, and subsequent readings, act as a visible representation and reminder of an otherwise 'hidden' illness. It is within this

sub-theme that the ontological revealing associated with one's engagement with things is most apparent. In accordance with a Heideggerian (1954/2003) understanding of the world, our engagement with technology reveals our ontological selves. Asking participants in this study about their engagement with self-testing technology revealed much about their ontological disposition as individuals living with chronic illness.

This is most apparent in Con's story, an individual with type 2 diabetes. Con's story was briefly outlined earlier in this chapter as an example of the 'unwelcome burdens' associated with self-testing devices. Con has previously survived a cancer diagnosis, and has limited use of one hand due to a previous cardio-vascular accident. Very prevalent in Con's narrative is his struggle with a diagnosis of diabetes and its chronic nature, in light of his other healthcare problems. This struggle is interwoven with his experience of self-testing and cannot be divorced from it. As Con refers to 'this thing' in his narrative outlined below, it is impossible to decipher if he is referring to the self-testing device or his diabetes:

> *Well, when I get up it's the first thing in the drawer that's looking at me, my self-testing kit. I do not really understand. They tell me the lower my blood sugar level is the better. I do not really know I'm only going by what the nurses say. I just can't get my head round 'this thing' that I have it. There are certain times I look at the tester kit and I say well, you know if only I hadn't got it that would be one less thing.* (Con)

At another point in the interview Con notes his acceptance of other life events, but has difficulty with this diagnosis:

> *I don't regret my life, I wouldn't change it for anything, but since I had this diabetes it's really taken over. Self-testing, appointments with Doctor x, appointments with the nurse. I thought I was finished all that with the cancer and now it's back again. ... I'm being reminded every day – I have to test.* (Con)

Field notes following Con's interview refer to a concern about his general welfare and a referral, with his permission, to the diabetic nurse specialist to explore some of these issues with the diabetic support team. For Con, it appeared that his diabetes diagnosis and engagement with the device signified the 'last straw' in terms of his ill-health. This is an enduring issue for Con as he is not newly-diagnosed. He is experiencing an

ongoing difficulty in adjusting to his diagnosis, palpable in his hesitant tone and his words; *"I just can't get my head around this thing that I have it. This thing comes along and sets me back"*. Also, he seems to separate his illness from himself, referring to it in third person terms such as: as *"this thing", "this diabetes"*. The chronicity of the disease is very problematic for him:

> *I'm just fed up of all the time being ... you know, constantly worried about my health. ...Once I get over one thing it's another bad thing.* (Con)

Frances's story reveals a similar struggle with the chronicity of her condition. The ever-present nature of the illness became all consuming for her:

> *I want to just forget about this for a couple of months. I mean I would have been very good, fairly good at walking and doing exercise but you get sick of that too. It's very hard to stay focused, that's what I'm saying, you know the whole time.* (Frances)

Frances refers to discontinuing self-testing for a while, despite acknowledging the benefits of it. Again, Frances's relationship with self-testing is interlinked with her experience of chronic illness. Frances relates being "*fed up with the whole process of the testing, of being the diabetic*". Con's and Frances's experiences accord with Toombs's phenomenological account of incurable illness:

> The experience of illness is always the experience of 'having' and 'being had'. I not only have an illness it also 'has' me. (Toombs 2002, p.127)

Con, Frances (and Colette as noted earlier) refer to being consumed by their illness. There are temporal considerations at play here, related to the experience of chronicity. For Con, his illness does not have a fixed time scale, whereby if he does certain things, and accords with certain measures, he will 'recover' as in his experience of cancer and a brain injury, albeit to a lesser extent. There is no chemotherapy or rehabilitation programme that will eliminate diabetes. Previous methods of taking control do not work here: "*this diabetes is getting the best of me, I think*". Heideggerian temporality refers to the existential experience of lived time. Heidegger's concept of time involves a three-fold structure of past, present and future, referred to as Heidegger's *Care structure*. This is central to Heidegger's overall understanding of *Dasein*, as 'being-

in-the-world'. *Dasein*, *Care* and temporality are all intrinsically interwoven in Heidegger's philosophy. "For Heidegger, care is the meaning of Dasein" and "the primordial unity of the structure of care lies in temporality*"* (Dotray 2010, p.50).[56]

Time as temporality means that my existence, my human mode of being involves a non-linear fusion of my past, present and future. Reflecting this existentialist temporality, Con comes to this diagnosis with his past history of illness experience, he struggles with the present, and he seems to rebel against the ongoing, never-ending future of his diabetes. Frances notes being distressed by the ongoing nature of her illness also and the difficulty associated with keeping focused indefinitely. Colette, who seemed to understand very little about her diabetes, is caught in a whirlwind of confusion and, in some ways her struggle seems to be potentiated by her lack of understanding.

All healthcare professionals refer to the sense of anxiety that is related to self-testing when it becomes almost obsessional. This may well be the case for Con: "*when I get up it's the first thing in the drawer that's looking at me, my self-testing kit*". HCP3 notes:

> *I have seen over my career in diabetes ... there are certain personalities who cannot cope with the extra strain of it. In one instance I can think of having to take the actual glucometer off the patient, because she had become withdrawn, depressed. ... when we examined what was the causing factor it was the self-testing, it wasn't the taking of the tablet, it wasn't the diet, so you have to be mindful that it is not always beneficial to one's well-being, but obviously we have to advocate it in the event of people who need to know and we are trying to advance self-management to be able to self-care.* (HCP3)

HCP3 comments later in the narrative that this lady's difficulties subsided once self-testing was discontinued, and her type 2 diabetes was managed successfully through clinic visits and less regular HbA1c level testing. As Con does not use his self-testing

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[56] Dotray's paper provides a succinct overview of Heidegger's temporality, which was most helpful in understanding this element of Heidegger's philosophy. Within his paper, Dotray (2010) compares Heidegger's concept of time with that of McTaggart's. A thorough analysis of McTaggart's perspective, or Dotray's conclusions, is beyond the scope of this work. However, Dotray's overview of Heidegger's contribution to the philosophy of time was most beneficial.

to titrate insulin doses, discontinuing self-testing is a possibility for him. It is interesting to note that Frances's doctor prescribed oral hypoglycaemics for her diabetes, instead of insulin, due to her lack of adherence to self-testing. As her blood glucose levels could be managed without insulin, a self-testing regime would then not be as important in her management plan, thereby relieving the anxiety associated with it. This would also prevent a possible hypoglycaemic event if insulin were given without detecting low blood glucose levels. Frances notes in her narrative that during the period when she discontinued self-testing, she continued to administer the same amount of insulin every day.

For Con, Frances and Alex, it is as if the self-testing device signifies an external representation of their diabetes diagnosis and causes distress in this regard. This is an example of a more negative impact of *Knowing the body*. The extent to which participants come to 'know' the inner workings of their bodies as more 'visible' entities is relevant existentially from a temporal, spatial and corporeal perspective. Heidegger's modes of being, as discussed in chapter 3, 'ready-to-hand', 'unready-to-hand' and 'present-to-hand' are relevant here. The self-testing device brings the patient's blood glucose level and associated pancreatic function, into the 'present-to-hand' mode (Heidegger 1927/1962). Equipment that is 'ready-to-hand' is always in use for some purpose and is engaged with the user to the point of invisibility. One does not consider the lock that opens the door, or the heel of a shoe, as of any significance until they become deficient. It is in the 'unready-to-hand' mode that the world becomes apparent or 'present-at-hand':

> Cars break down; hammers fall apart or wine glasses shatter; bodily organs suddenly fail us. It is mostly in these moments that equipment becomes conspicuous and draws our attention to it. (Harman 2007, p.63)

Body function, previously existing as 'ready-to-hand', and invisible, is now 'present-at-hand' through the use of the self-testing device. In this sense the extent to which participants come to 'know' the inner workings of their bodies as more 'visible' entities is also relevant existentially from a temporal and spatial perspective. Illness states obliterate the previous "taken-for-grantedness" associated with one's body and it now becomes "the unwelcome focus of one's attention" (Toombs 2002, p.126).

Albeit welcome, or unwelcome, the experience of one's body is now central to one's sense of space. For Con, Alex and Frances, the self-testing process, as facilitated by the device, is a reminder of a diabetes diagnosis, a chronic condition. It brings to the fore decreasing pancreatic functioning, the implications of a body with diabetes and the never-ending series of tasks associated with this chronic condition.

During the focus group interview with the scientific community participants, I shared a synopsis of Con's story, anonymously, and some of his narrative. After a brief period of personal reflection on his story, the scientific community participants acknowledged the link between self-testing and the chronicity of his diagnosis for Con. This is summarised by SCP5 as follows:

> *This self-testing is one thing that he wanted to cut out of his life, to have less reminder of this constant misfortune.* (SCP5)

SCP3 also appreciated the interweaving that occurred with self-testing and illness:

> *… it's the actual disease, like every time I'm testing I'm reminded that I'm different that I have this problem.* (SCP3)

However, there was some reluctance to associate Con's experience of self-testing with his distress: "*I don't think it shows the disadvantage of the self-testing, it shows the situation in which that person has to do it*" (SCP5). There is some evidence here of a tendency to separate Con's self-testing regime from his wider experience of illness. This does not reflect the experiences of patients interviewed in this study.

HCP1 positively describes the role of self-testing in reminding patients they have diabetes. However, while this may act as a motivating factor in adopting healthier behaviours, as noted earlier, it may have more debilitating consequences for others in terms of crystallising, or revealing, the chronicity of their condition. This is central to one's sense of space. SCP2 makes the interesting associated observation that 'seeing' the result is significant:

> *I think maybe one of his problems is that he is seeing the result. You could self-test and if the device would, by whatever technology is there, send the*

result to the doctor. rather than – he seems to be obsessing about the result. (SCP2)

Another dimension to the participants' experiences of self-testing, which is interwoven with the experience of chronicity, is the awareness of the potential for long-term complications and the importance of self-testing in this regard. A number of the female participants note concerns in this regard. Frances expresses a fear of developing complications in the future and being unable to live independently:

> *I was hospitalised for the first week of it* [diabetes diagnosis] *and I saw the women inside there who were in their 60s and you know, it probably did frighten me a bit because one of the ladies, a lovely lady, she couldn't even test because she couldn't see. She kind of, you know, didn't look after herself and her son had to come in and test her and I did find that very hard. Because I don't really, if I'm not going to be in good control of it, I'm just afraid. Because I think in the long term you can't be depending on children or making people feel that, you know, I have this thing about losing my eyesight with it.* (Frances)

There are a number of long-term complications associated with type 1 and type 2 diabetes. Blood vessels, eyes (retinopathy), heart, nerve pathways (nephropathy) and kidneys (nephropathy) can all become irreversibly damaged if diabetes is poorly controlled (WHO 2012). Maintaining good glycaemic control is a key factor in preventing micro-vascular and neurological complications of diabetes (IDF 2011). Self-management, which incorporates a self-testing regime, and interpretation of results, is recognised as a means of maintaining 'in-range' blood glucose levels. Adhering to the self-testing process, and associated medication regime, is in many ways future orientated. Caution with regard to one's health today may prevent complications in the future.

Toomb's personal phenomenological account of living with multiple sclerosis offers some interesting insights here from a temporal perspective. Toombs (2002, p.129) refers to the constant "future-directedness" with which we live our lives when diagnosed with a chronic illness. One's personal sense of time is altered. Time takes on a new significance:

In our culture we think of time as a series of more or less discrete moments along a timeline of past, present and future. With the prospect of increasing debility the future assumes an inherently problematic and threatening character. So pervasive is this threat that the future engulfs the present. (Toombs 2002, p.128)

The fear of developing future complications associated with their diabetes diagnosis engulfs the present for some of the participants within this study. Toomb's analysis reflects Heidegger's concept of time as 'temporality'. As outlined previously, this is not 'clock time', in terms of how time is generally understood in common vernacular, but rather represents time as 'lived' in an existential sense. The patient experiences recounted here also reflect the sense of "*provisional time*" described by Morris (2008, p.4) whereby the chronically ill individual is submerged in a sense of time associated with the "*next dose, treatment or turn of the disease*".

The chronicity of diabetes and its never-ending nature is also noted by the healthcare professionals in the study. Interestingly, HCP3's account refers to this as a struggle for both patients and healthcare professionals:

…it's a chronic ongoing struggle, if you want to call it a struggle, that's probably the wrong word but, you have to constantly keep on top of it and you are going to constantly have the same people running into the same type of difficulties year on, year in. That's trying on the patient but it's also trying on the HCP because you may have said exactly the same thing, and gone through the exact same thing but in two years' time most likely you will doing the same thing with that same person because it's ongoing. (HCP3)

It is apparent that participants recount experiences of chronic illness when asked about engagement with self-testing devices. The participants' ontological realities are exposed in a manner that highlights the interdependent nature of autonomy in self-testing. The patients' experiences of self-testing, and subsequent presence or absence of autonomy, is interwoven with their lives as individuals with diabetes. The never-ending presence of 'this thing', 'this diabetes' shapes the participants' experience of self-testing. While for some participants, the experience may be characterised as a future-orientated concern with controlling their diabetes in the present, for others it involves a more negative perception of self-testing as a reminder of chronic illness.

The participants' experiences were not static. Their sense of chronicity and engagement with self-testing changed over time. This represents another significant aspect of the overall phenomenon that will be addressed in the section which follows.

5.4.3 Autonomy as contingent in chronic illness

This sub-theme relates to the fact that one cannot always be autonomous, despite the intention and encouragement to act in this way. This relates to corporeal concerns regarding the ill body and contextual issues related to the complexities associated with a chronic illness diagnosis, its course over time, and other life events. While some patients expressed an enthusiasm for accepting more autonomous roles associated with self-testing, this was not always realised during periods of decreasing pancreatic function. The situated nature of illness is also significant in this sub-theme. The ability to be autonomous changes over time for some participants, related to one's point in the illness trajectory[57] and other various life events. The progression from initial disequilibrium at the time of diagnosis, to later acceptance of the disease and becoming more autonomous in its management, is common across a number of participants. However, difficulties in adaptation to illness are also evident in other narratives. The stories of Alex and Frances are particularly of relevance here as their narrative displays a clear shift in their ability to 'take control' of their illness at different times. Healthcare professionals and the scientific community participants all recognise the 'individual' nature of illness and its contextual dimensions – however this recognition occurs to varying degrees.

The gradual adaptation to a diagnosis of diabetes, and associated self-testing activities, is apparent across a number of patient narratives. Deirdre, Ann, Bart and Geraldine all relate how, despite a sense of disequilibrium at the point of diagnosis, they adapted over time and began to accept a more autonomous role in the management of their illness. Ann notes how self-testing, which was initially very difficult, became "*part of everyday life.*" Here Deirdre refers specifically to her initial challenges with self-

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[57] Corbin and Strauss (1992) use the term 'trajectory' to refer to the experience of illness that occurs in the life course of individuals with chronic illness. This experience is presented as a series of stages, which are non-linear and reflect the alteration in adaptation to illness that occurs over time. It reflects the social impact of illness on the individual in addition to physical experiences.

testing, both from a psychomotor and psychological perspective and her eventual adaptation:

> *I found it very hard in the start. I found it very hard with the machine. I found it hard, I found it hard to do it because I hadn't being doing it and it was something I had to get into and for the first 12 months I really did not take it serious enough. You know, I just continued eating things that I shouldn't have been eating whereas now I wouldn't eat sweet things. I have a sweet tooth ... whereas now, I'd be more aware of that. Whereas in the start it was very, very hard. The first 12 months was very hard and I found it very hard to get into it. But now it's just second nature to me.* (Deirdre)

However, for Collette and Con, as evidenced in their stories within the sub-theme: *Unwelcome burdens*, a sense of acceptance and adaptation has not occurred as their diagnosis continues to cause distress. Colette has a number of social problems related to housing, interactions with her neighbours, which may influence her ability to adapt to her illness. For Con, his issues relate to his previous past history of illness and his associated difficulty with the chronicity of a diabetes diagnosis, which may not seem as significant, but demands ongoing attention.

Alex's story helps to illuminate the intricacies associated with autonomy in chronic illness. Alex has been diagnosed with type 2 diabetes for eight years. At this outpatient visit, where I interviewed him, he is planning to discuss deteriorating blood glucose levels with the doctor and may be commencing on insulin:

> *I know while they keep ramping up the medication, it's inevitable that I'm going to have to go on insulin and it's the fact that my pancreas is deteriorating to some extent. So the self-testing, all it is, is an opportunity at this stage to frustrate myself even more because I know damn well they [blood sugar levels] are never going to be where they should be.* (Alex)

Alex presented as a very articulate businessman, who seemed happy that someone had asked him about the self-testing process, as he had lots to say. My immediate reaction was that technology was not promoting autonomy in this specific context. The self-testing device seemed merely a tool of frustration, appearing to have no positive outcomes for Alex at the point of interview. It appears that self-testing merely tracked the progression of his diabetes - the ongoing deterioration of his pancreas. It is

apparent, from other parts of his story that Alex attempted to bring his business-like sense of order to his illness. Alex expressed a wish to rationalise schedules of testing, move to a more efficient computerised system and increase availability of necessary equipment. Alex expresses some frustration with the 'system' in this regard, particularly in the context of requiring a repeat prescription for test strips:

> *I've run out of strips and while I have a repeat prescription, the repeat prescription is there for the medication because they might want to change it. The strips and the testing strips are on it as well and really I should have a permanent supply of those. ... I've had ones and I discovered that the code was gone...I put it in and the computer strip that's on it then it won't read, because of the expiry date. ... They're small things now but they have happened and the result is I might not be able to get to a doctor for 4 days for some particular reason, I could be working, I could be away or something, so I've no testing [equipment].* (Alex)

While objectively, these initiatives may be conducive to developing a more autonomous role in illness management this will not detract from the fact that, regardless of when or how efficiently levels are recorded, his blood sugar levels continue to rise. Alex sought to be more autonomous in terms of seeking out information and organising the self-testing process but the 'system', for him, does not allow it. However, while organisational issues may prove resolvable, I suggest, based on the data above, that it is the downward spiralling nature of his blood glucose regulation that provides the greatest impediment to autonomy, and represents the source of most frustration at this point. Alex can control many things but not his decreasing metabolic function.

Frances shares similarities with Alex, in that she seems to welcome the autonomy associated with self-testing yet also struggles with it, albeit for different reasons. Frances refers to a desire to be in control at numerous points throughout her narrative. Frances has been diagnosed with type 2 diabetes for over nine years. On the day of interview, she was at the outpatient clinic to discuss having her medication regime altered from oral hypoglycaemic therapy to insulin. Frances had previously been on insulin therapy, but her consultant suggested changing to oral medication for a period of time. The decision to alter her treatment was influenced by her non-adherence to self-testing. (Administration of insulin in the absence of checking blood glucose levels

can increase the risk of hypoglycaemia and potentially prove fatal). Frances refers to a previous point in her illness when she was on insulin therapy as both a positive and negative experience. The following extract displays evidence of her taking a more autonomous role in association with self-testing:

> *... I know personally when I was on insulin I had way better control . . . it was super because I was always under 7[HbA1c level] and I did not mind doing it.* (Frances)

However, despite this positive experience, Frances refers to the chronic illness-related issues that caused her to stop self-testing for a while and lose her enthusiasm for self-management:

> *... this year hasn't been very good for me, just for no apparent reason, I just do not know why... I did test for the couple of months and then kind of some way in April May and June, I just did not bother so when my HbA1c came back at 7.7 I was nearly distraught. ... I was on insulin at that time, but I think I just got fed up of the whole thing. Even my own GP said to me, it was just like I just said; 'that's it, I'm sick of this' (*Frances)

It appears that, despite a desire for control, Frances does not experience this on a continuous basis.

I invited Frances to attend for a second interview. The second interview took place 15 months later. The purpose of the repeat interview was to explore her experience of self-testing at a later point in time when her treatment regime was altered. At the time of the initial interview, Frances anticipated meeting with her consultant and perhaps being prescribed insulin, as her blood glucose levels had deteriorated. Frances envisaged that this would work better for her and that self-testing would have more relevance. However, despite a short period on insulin and oral medication, insulin was later discontinued and Frances's medication regime was altered to include a more recent oral therapy: Januvia. Despite not remaining on insulin, as was her wish, Frances refers to self-testing in a very positive light at the second interview. Frances tests less frequently than previously, based on health care professionals' advice, relying more on quarterly HbA1c results, but has the ability to self-test when required. At this point, while Frances continues to acknowledge the lack of dietary flexibility

associated with medication-based therapy, and notes some concerns about the aftertaste from the medication, she does report the value of self-testing. The following extract synopsises the value that Frances associates with self-testing, albeit less frequently:

> *... when I had surgery last week it brought it back to me the importance of self-testing because I have been sauntering along with the last seven or eight months and I didn't have to do it because I've been fine. but when something crops up like that you have to be very vigilant and it is not so much that you want to be in control of that situation it is the fact that you know the figure that you get is telling you what way your body is.* (Frances 2)

It is evident that despite testing less regularly, the self-testing device is an important tool in Frances' overall management of her diabetes. It is also significant that in the repeat interview Frances refers to issues at the time of, and prior to, the initial interview that may have influenced her experience of self-testing and her control of her diabetes. While Frances previously referred to her struggle with the chronicity of her condition, at the second interview she also refers to "*going through the menopause*", "*different things happening and different stressors*" and the fact that younger people could "*adapt better*". This adds further support to the contingent nature of autonomy in the self-testing process, as a number of contextual factors impact on the individual experience of illness.

It seems that for Alex and Frances, regardless of a desire for control and order, which would fit quite well with increasing patient autonomy through self-testing, autonomy is not necessarily manifested throughout their experience. Alex's worsening condition, his annoyance with the healthcare system in terms of access to equipment/technology to manage his illness effectively, and Frances' sense of angst regarding the chronicity of her condition, and other contextual factors, all conspire to limit the extent to which these participants can be autonomous at various points in time. They may 'intend' to be autonomous but their temporal and corporeal experiences, as individuals living with chronic illness, impede their ability to be so at certain points.

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There is an awareness of the temporal experience of illness both among healthcare professionals and the scientific community participants interviewed in this study. Healthcare professionals acknowledge that self-testing is not a *"one-size-fits-all"* activity (HCP2), as individual nuances alter personal engagement with the self-testing process. A number of these individual circumstances have already been alluded to. Similarly, the scientific community participants note the individual nature of a self-testing regime:

> *Every device I think, whether it is going to monitor frequently, where it's going to be deployed, whether it is going to prescribe, it's a case by case basis and it is very difficult to generalise.* (SCP2)

The changing perspectives of Alex and Frances reflect theoretical work on the nature of the chronic illness experience. Corbin and Strauss (1992) outline a chronic illness trajectory framework for use by nurses in a chronic illness context. The essence of the trajectory is that chronic illness follows a particular course, or a series of stages, which are non-linear and reflect different phases in adaptation to illness in addition to clinical presentation. As well as acknowledging that the experience of chronic illness changes over time, the model also recognises the unpredictable, subjective nature of experience; trajectories are often uncertain and require the involvement of individual, family and healthcare workers to shape them.

Burton (2000, p.597) applies this theory to the stroke rehabilitation area and presents the following synopsis:

> The phases of an illness trajectory do not represent a rigid framework for the linear consideration of a patient's response to illness. Each phase, for example, may include several sub-phases which include movement in either direction along a trajectory which can be of considerable duration. This dynamism reflects the continual nature of adaptation that characterizes living with chronic illness.

Evidence of this continual adaptation and times of crisis are evident in both Frances's and Alex's narratives. While Corbin and Strauss's model (1992) refers to the stages of illness in primarily medicalised terms (e.g. pre-trajectory, stable, crisis, acute, unstable), albeit acknowledging more psychosocial influences, Roy's adaptation

model (Roy and Andrews 2008) provides more psychosocial markers of adjustment to chronic illness which lend further support to the interpretation presented here. In accordance with Roy's theory of adaptation, the person exists as a biopsychosocial being, in constant interaction with an ever-changing environment. This environment presents focal, contextual and residual stimuli. In order to cope with one's changing surroundings the individual uses a series of innate and acquired adaptation mechanisms. Roy's perspective fits well with the accounts of experience offered by Con and Colette in this study, whose ability to adapt to a diabetes diagnosis, and associated self-testing, is affected by a myriad of psychosocial factors. An inability to adapt successfully to changing environmental stimuli is also evident in both Frances's and Alex's narratives at various points in their illness trajectory. In this sense, Corbin and Strauss's (1992) trajectory of illness can be used in association with Roy's adaptation model to interpret the experience of autonomy in self-testing as contingent on a number of factors related to the individual's existential existence.

An existential understanding of the 'body as lived' can also offer some insights here, as the physical experience of illness encompasses corporeal concerns which can impact on one's experience of autonomy. Drawing on the phenomenological tradition of Husserl, Merleau-Ponty (1945/2003) outlines his account of the embodied mind in *Phenomenology of Perception*. Merleau-Ponty's central thesis is that one's body is central to individual perception and one's place in the world. There is no separate external reality for the participants in this study when one's body is dealing with the physical experience of hyperglycaemia, associated with diabetes mellitus, and the mental anguish that is often linked with chronic illness. These participants' attempts to be autonomous within this bodily existence are not always successful. The accounts of autonomy in an illness context explored by Mol (2008) and Thomasma (1984) support an understanding of autonomy that is different in illness. The patient as citizen, and associated autonomy, is a problematic concept for Mol (2008), while the ill body offers challenges to autonomy for Thomasma (1984). This phenomenological understanding of the ill body is central to the overall interpretation of *Autonomy as lived* within this study and will be revisited in the discussion chapter.

The patient narratives in this study present an understanding of autonomy in self-testing that is contingent on the individual's experience of illness and other contextual factors over time. The individual's experience of self-testing, autonomy, diabetes and other life events are continuously interwoven. The contingent nature of autonomy in self-testing represents an important facet to *The interdependent phenomenon of autonomy in self-testing*. This sense of *Autonomy as lived* has a number of corporeal and temporal dimensions.

5.5 Relationship with healthcare provider

This theme within *The interdependent phenomenon of autonomy in self-testing* encompasses three distinct, yet interwoven, aspects of the patients' interactions with their healthcare provider. The term 'healthcare provider' is used deliberately to encompass the individual healthcare professionals with whom patients interact, but also the wider healthcare 'system'. Both interactions are significant for the participants in this study. It is apparent in patients' stories that they refer to their relationships with healthcare professionals most particularly in the context of education to support self-testing. The extent and nature of education experienced by patients varied considerably. These aspects of the patients' stories are addressed in the sub-themes, *Empowered by education* and *No room at the inn* respectively. This sub-theme also addresses the degree to which autonomy is supported in interactions with healthcare professionals. While healthcare professionals use the rhetoric of autonomy, the actual 'practice' appears to be different as their stories unfold. These considerations will be addressed in the final sub-theme of this dimension: *Autonomy versus covert paternalism.*

5.5.1 Empowered by education

The role of education in assisting patients to become more autonomous in the management of their diabetes was a prominent aspect of the wider phenomenon. Some patients experienced structured education programmes that augmented their ability to self-care. Even in the absence of structured programmes, a number of patients referred to the importance of follow-up access to healthcare professionals in the outpatient setting to supplement initial education. Additional information assisted patients in

maximising the potential of the self-testing process and consequently managing their diabetes more autonomously.

Betty, the patient with type 1 diabetes, who experienced a sense of personal freedom associated with self-testing, referred to her exposure to a specific DAFNE education programme following diagnosis. As previously outlined, the DAFNE programme teaches patients to adjust their insulin relative to their food intake, thereby providing greater flexibility in dietary intake. Here Betty gives an overview of DAFNE and her exposure to it:

> *It's called dose adjusting for your food and it basically, it taught you to read labelling about carbohydrates and you know, their rule of thumb was for every like 10g of carbohydrate, you needed a unit of insulin to break that carbohydrate down. Now obviously again, there's leeway for error in that. So it basically meant that I wasn't told you know, you take 6 units in the morning, you take 4 units at lunch and you take 8 units with your dinner. I was told to adjust my insulin to what I ate.* (Betty)

Despite the lack of opportunity to up-date her skills in the DAFNE method since relocating to Ireland, Betty does utilise the essential principles learned to enable her to live more autonomously. This is evident where Betty adjusted her insulin dose to facilitate eating out with friends. For Betty, the skills in self-management learned in the DAFNE programme give her the confidence to live more independently*: "I'm not afraid, I'm not set on you take 4 units, you take 6 units ... I take what I think I should take."*

Another participant, Ann, who also speaks very positively about self-testing, noted her experience with a structured education programme for type 2 diabetics. This programme, called X-PERT, is supported by the HSE, though UK-based, and delivered in the community, primarily by dieticians. X-PERT assists patients in understanding type 2 diabetes and in developing self-management techniques with regard to dietary requirements and exercise.[58] Ann notes how her presuppositions about diabetes were altered following attendance at the programme:

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[58] For further information on X-PERT see http://www.xperthealth.org.uk/ and http://www.sicp.ie/en/PatientServices/InformationLeaflets/PDFFile_17206_en.pdf

I keep away from sweets because of the diabetes but what surprised me more than anything were the carbs [carbohydrate] like potatoes and all that, the effect they have on diabetes. (Ann)

A number of healthcare professionals refer to the structured education programmes that may be available in-house or externally. Apart from DAFNE and the X-PERT programme, there is also the DESMOND[59] programme for type 2 diabetics, an NHS devised programme, and BERGER[60], which involves an intensive overview of carbohydrate counting and insulin adjusting for type 1 diabetics (HCP3). HCP3 notes that while self-testing is an integral part of the BERGER programme, it is not a very prominent component of the type 2 DESMOND programme which focuses more on "*lifestyle choice, healthy living, activity and diet*." Healthcare professionals note that not all patients are suitable for intensive education. HCP3 notes that patients are offered places on the BERGER programme if they are "*categorised as more ready for the information*" due to its in-depth nature. HCP1 also suggests that insulin-adjusting programmes are unsuitable for some patients who may be unable to assimilate information, or may not want further insight into their diabetes.[61] There are also practical issues associated with attendance at structured education programmes. HCP1 notes the difficulty with accessing places at structured education programmes, apart from the more widely geographically available X-PERT programme. He also refers to the problem, for some patients, in getting time off work to attend these programmes (which can take place over a number of days).

Not all patients recounted attendance at specific education programmes. However, a number of patients refer to the importance of follow-up education in the outpatient setting from diabetic nurse specialists or dieticians. Alex, a type 2 diabetic refers to the initial *"information overload"* and confusion when diagnosed, and the importance of follow-on access to one key person who could explain things to him:

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[59] Further detail on DESMOND is available as follows: http://www.desmond-project.org.uk/programmes-271.html

[60] The BERGER program was created by acclaimed German diabetologist Dr Michael Berger. Many of its principles have been incorporated into the DAFNE programme.

[61] The pre-selection of candidates for structured education programmes by healthcare providers is a significant point which will be addressed later in this chapter in accordance with the theme: *Autonomy versus covert paternalism*

You're kind of bombarded with a lot of information at the start. I was hospitalised when I was diagnosed with diabetes because I did not know what was wrong with me, and there's a lot of information coming at you ... You'd probably get about ten pamphlets going through what diabetes is. But you are better off having one person; you know giving you that detail. I have [dietician's name] here who's very good at manning the diet and so on. I learned things I would never have learned in the pamphlets. (Alex)

Bart, the taxi driver, who titrated insulin doses to enable him to live more independently, also speaks very positively of the education he received from a nurse during a follow-up clinic visit. Education, and subsequent understanding in relation to carbohydrate metabolism and insulin physiology, is integral to Bart's independence as a type 1 diabetic. Bart recognises the contribution of the diabetic nurse specialist in this regard:

I was always wondering about how much insulin I should, who worked out how much insulin I should take, I always wondered about that, where that equation came from ... but I asked one of the nurses one day about it and she really gave me a real insight into it and how it was worked out and how many units of insulin, it's per your body mass and one thing and another right? ... So I, after speaking to the nurse about it and when she explained to me about, about how it was worked out with one thing and another, with the units I was taking, I just felt much more comfortable on it. (Bart)

Healthcare professionals also recognise the importance of ongoing information and availability in assisting patients with their diabetes management. HCP2 notes that education delivery is often 'piecemeal' to avoid information overload:

It's ongoing. You never sit down and say I have to decide today how much you are going to take in. If you are sitting there with a non-interested look on your face you are not going to learn a whole pile so an awful lot of the information we give is piecemeal. I might today show you how to use the glucometer the next time we might discuss the blood sugars, why they are high, why they are low. That's the way the education process works with most of the diabetics, its drip-feed really. If we were to do it all in one session it would be way too much. (HCP2)

Healthcare professionals acknowledge the importance of an individualised approach in terms of the nature and depth of information delivered, and the decision to refer

individuals for more structured education as noted above. There is a general agreement among healthcare professionals in this study that education and understanding is fundamental to the success of self-testing programmes. HCP1 notes that it is problematic when patients get varied advice about how often to test, yet are not told why. The 'why' is integral to a successful self-testing programme. This is best summarised by HCP4 in the following extract:

> *I think if somebody knows how often to test and what the targets are, and what they are aiming for in the short-term and the long-term, I think testing is a good thing.* (HCP4)

There is additional evidence of patients being empowered by education within patient narratives. The availability of blood glucose results equips patients with information to initiate discussion with their healthcare provider, and manage their diabetes in a partnership arrangement. This is not the type of relationship illustrated by Colette, as noted earlier, who continually awaits direction from a healthcare professional, but rather the type of interaction that Deirdre refers to in the following account:

> *I'm able to keep on top of it and if I do need any assistance or help I can always ring up the doctor and say "it's 12.5 today. Will I come and visit you". ... So to me I think at the end of the day, that the self-testing way is a very good way and it's a reliable way. If the person that's doing it realises that. Because at the end of the day it's your health, my health, it's up to me and it's my way of keeping check of things and I do think that it's the best way to go about it.* (Deirdre)

The results of self-testing prompt patients to contact their healthcare provider if results are high and are useful in face-to-face interaction. Many of the participants in this study refer to the use of blood glucose values in the consultation process. However, the results of self-testing can also be useful when engaging with non-specialists. The role of the device in assisting patient empowerment in this regard is endorsed by HCP4:

> [Self-testing] *empowers them to actually make choices and take action and also helps them to talk to other healthcare professionals like doctors, or like GPs who may not have a huge interest in diabetes. At least it gives them [a way]to kind of say well I'm really worried about this, because I know my target should be such and such and every day my reading is nine*

and I am really worried about it that's why I am here today. I really think it gives them a bit of power. (HCP4)

HCP4 observes that not all healthcare providers are particularly familiar with the intricacies of diabetes management. In this sense, the availability of 'hard' data achieved through the self-testing process facilitates a greater power-base, and therefore empowerment, for the patient in the patient/clinician interaction. The role of a diagnostic device in this respect is also noted by members of the scientific community. As previously noted, SCP6 has been working on clinical trials of a new device which will monitor patients' ammonia levels non-invasively. Eventhough this device is currently operated on near-patient basis under clinical supervision, SCP6 notes that patients engagement with the device *"gave them more knowledge about how to converse with their clinician"*.

This particular aspect of the educational process highlights how those interviewed viewed information as a significant factor in patient empowerment and maximising autonomy. Health care professionals can empower patients to take more control over their lives through educational initiatives, and such initiatives potentially enable patients to assume more egalitarian positions in their interactions with healthcare professionals. The wider impact of knowledge as power is significant here. Foucault's post-structural understanding of power is helpful in this regard:

> Each society has its regime of truth, its 'general politics' of truth: that is, the types of discourse which it accepts and makes function as true; the mechanisms and instances which enable one to distinguish true and false statements, the means by which each is sanctioned; the techniques and procedures accorded value in the acquisition of truth; the status of those who are charged with saying what counts as true. (Foucault 1980, p.131)

Traditionally, medicine operated within a system whereby patients sought healthcare from doctors who provided it. The emphasis on self-management programmes has altered this balance to the extent that self-management creates a shift in the competencies of doctors and patients (Willems 2000). The use of a shared language is one particular example of where this 'shifting' of competencies occurs. In discussing blood glucose values, patients now use the type of medical or scientific language previously within the realm of healthcare professionals. It also allows patients to move

beyond subjective descriptions of how they 'feel' to present more quantitative data about how they objectively 'are'. In this sense, drawing on Foucault's perspective above, the discourse which the patients now adopt allows them to engage with the 'truths' respected by the medical world and therefore potentially increase their personal power base, their autonomy, in this regard. While one may argue that healthcare professionals should pay more attention to an individual's subjective experience, the ability of patients to align subjective feelings with scientific data is helpful. This is evident in the following extract from Frances:

> *… it's just to prove to the doctors as well when I go in now that, you know, these are the results and they were all high. It proves a point for everyone. (Frances)*

As previously noted, Frances does not necessarily require 'readings' to assess her own health; "*I don't even have to test, I know myself if I am going low*". However, she does acknowledge the benefit of this 'hard' data in interactions with her doctor.

However, not all patients in this study recount empowered educational experiences which enhance self-care and autonomy. The relationship with healthcare professionals is expressed quite differently by other participants. It is apparent in some patients' stories that their level of knowledge and understanding is limited. However, this may be a feature of particular individuals; their ability to understand, and their level of engagement, and not related to the degree of education provided. SCP1 notes during the focus group interview that information itself gleaned through the self-testing process is neither "*good or bad, it's information; it is how it's used*". There is an acknowledgement among healthcare professionals that "*some patients never fully grasp the meaning of self-management*" (HCP2). This sense is shared by HCP4, who notes that there are "*some people no matter how much information you give that will not take it on board.*" This 'taking on board' is significant in terms of the wider interdependent phenomenon of autonomy as discussed earlier in the theme *Taking control*. However, even among those patients who appear to understand certain aspects of their diabetes quite well, there is also some confusion evident in their narratives about their self-testing regime.

This adds an interesting dimension to the study as a degree of disempowerment can be associated with self-testing in the absence of proper education. There are two particular issues highlighted within the study where additional information would have resulted in a greater understanding for the patient and addressed some of the associated confusion and frustration. Alex expressed his frustration with the need for manual recordings when technological advances enable the downloading of readings directly onto a computer and print-out. However, when asked about the preferred format of results, HCP5 provides a very reasonable explanation:

> *It's certainly helpful if they can bring their record with them, we prefer it written down at appropriate times so we can evaluate which time of the day, pre or post meals is most problematic and should first be targeted, so for us rather than bringing in a meter we prefer a written record of the results, some of the meters can be downloaded online and that is fine too but it's just we need to be very clear with the timings of them that they are accurate number one so we can determine which are pre and post which particular meals* (HCP 5)

HCP1 also refers to the failure of computer-based readings solely to give detail regarding the nuances of diet and other patient behaviour.

As a further example of a mismatch in patient understanding and healthcare professional perspective there is a scepticism among patients about the value that healthcare professionals actually place on blood glucose levels that are measured by self-testing. Alex summarises this as follows:

> *I've definitely picked up over the years from doctors you know, that self-testing, really those results, they're not as important as the blood test one. The blood test, it's called a, is it H?* [researcher responds HbA1c] *Yeah ... That's the one that really captures the ability of the body to deal with the glucose and all that type of thing. And so in a sense, that seems to make more sense to me as well, that if there was some maybe weekly blood test or something like that, that would probably become a more accurate, better system than maybe the ability of the self-testing glucose readings. Maybe! You know I've no medical background but I've definitely picked up, I mean I've gone to my doctor at times with readings and I've shown them to him and eh, I won't say they're dismissed, they do have some, they must have some ability but it's the blood ones themselves [HbA1c], they are the ones that he will always talk about.* (Alex)

However, healthcare professionals, albeit acknowledging the objectivity of HbA1c values, explain various reasons during interview as to why self-monitoring of blood glucose levels is important, in both patients with type 1 and type 2 diabetes. While HbA1c values are viewed as the "*gold standard*" (HCP2) there is a recognition that they are "*not perfect*" (HCP2) in all respects. Despite the more apparent need for regular monitoring in individuals with type 1 diabetes and gestational diabetes, daily blood glucose levels are deemed useful to detect: "*trends*" in blood glucose control (HCP6), "*intermittent highs*", "*dips*" (HCP3) and "*hidden hypoglycaemia*" (HCP4). HCP3 summarises various reasons for self-testing in the following extract:

> *I think you have to look at both [self-testing and HbA1c] because sometimes the HbA1c could be reflected within the normal parameters, and then on their day-to-day book, or meter, they could be quite high, we have patients today that spring to mind that we were wondering, her day-to-day readings are high but her overall test is normal, and they would be tested for other endocrine disorders, such as Addison's, Cushing's etc. etc. (HCP3)*

Despite obvious reasons for more regular testing, this appears not to have been explained to the patients in this study, or not understood by them. In this sense, patients are more disempowered than empowered, as their educational needs are not fully met. A greater understanding of the need for self-monitoring in specific patient contexts may assist the patient's 'buy-in' and contribute to a greater experience of autonomy in self-testing.

5.5.2 No room at the inn

This sub-theme refers to the insufficient access to healthcare professionals and services, which is prominent across many patients' narratives and the associated impact of this on their experience of autonomy in self-testing. For some patients, this lack of engagement with healthcare providers contributed to their confusion about diabetes and self-testing. However, for others it was merely acknowledged as an unavoidable factor in times of economic constraints. Even among those participants who seem to manage their diabetes well and use self-testing effectively, there was a sense that the health service had little time for them. *No room at the inn* emerged as a salient aspect of the wider phenomenon of autonomy in self-testing. This perspective

was supported by the healthcare professionals in the study, who frequently referred to the lack of resources available within the health service, and the associated implications for educational initiatives and other support services. An interesting dimension to this sub-theme is the associated understanding from the healthcare professionals' perspective that resources may be more readily available should self-testing technology be employed in a more selective manner.

Hannah had been diagnosed with type 2 diabetes only two months before the interview took place. The interview was recorded at her first visit to the out-patient clinic since her discharge as an in-patient. In her story, Hannah refers to her initial exposure to self-testing within the hospital setting, where a nurse showed her how to perform the test. The nurse however did not return to see her for further instruction or evaluation, which Hannah attributes to her lack of time:

> Well, I didn't know how to do it. It was Nurse x came and showed me and then even when I went home, you see I was above in the acute centre so when they sent me home, you know they didn't have the time and Nurse x was supposed to come back to me and she didn't get the time, but I figured it out for myself ... from the instructions, the books they gave me before I left the hospital. I just read through them ... it was grand, it was no problem. ...

Hannah relates that she did not receive any further teaching regarding the device from her local GP office, but was assisted by her sister who is a nurse. Field notes taken on the day noted that Hannah seemed undeterred by her diabetes and the self-testing regime, as evidenced by her narrative above. She continuously recounted her experience of self-testing in a very matter of fact manner. Hannah refers to the self-testing process as *"grand"* or *"very, very easy"* and describes the procedure in the following way: *"I get the machine and I just prick my finger and take my blood twice a day morning and evening"*.

Hannah notes how she utilises the blood sugar results to make dietary adjustments:

> ... if I'm over the top with sugar levels, I can cut back. You know if I find it's too high, I could cut back what I eat. I do not eat sweet things, well I

do, but I eat sugar-free things. But if I find I'm eating too much of them, I can cut back if the sugar level is too high. (Hannah)

However, despite her ostensibly relaxed attitude to self-testing and her utilisation of results, there is evidence in her narrative of that her diabetes is not being effectively managed. This became more apparent during further immersion in the data and ongoing interpretation. Hannah noted consistently high blood glucose readings: *"10 is the lowest and 20, 21 is [the highest] Nurse x just did it now, its high again.* Hannah appreciates that the norm is between 4 and 7 and was having her medication regime altered at the clinic on the day of interview. It may be that Hannah's blood glucose levels are fluctuating as medication is being titrated in the early stages post diagnosis. However, Hannah, by her own admission, is practically self-taught and may not be completing the self-testing procedure correctly. In addition, Hannah may not be managing her dietary intake as well as she suggests. The reference to *"sugar-free biscuits"* in her narrative suggests the use of foods labelled as 'diabetic foods', which are not recommended as they are generally high in fat and contain sugar replacements.

Colette is a patient with type 2 diabetes who was diagnosed four years at the point of interview. Colette's knowledge of her diabetes, and the role of the self-testing process to manage her illness, were both limited. Initial contact with Colette showed that she was eager to talk about her diabetes. Field notes, taken on the day, note that she seemed to have therapeutic expectations of our interview - despite having read the information leaflet.[62] At the time of interview, I thought Colette was very distracted and had little to contribute to the study. However, as I listened back to Colette's story, I realised that Colette had much to say about the experience of self-testing. Her eagerness to talk was very salient. She seemed anxious to engage in further discussion with healthcare professionals about her diabetes:

> *They have never checked out my bloods right since I got the diabetes and I have it with four years next February. … It should have been looked after,*

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[62] Following the interview with Colette, I reviewed my patient information leaflets and removed reference to my nursing qualifications. From an ethical perspective, It was decided within the supervision process that this may prevent therapeutic expectations by participants. Despite being explicit about my role as researcher, it was reasonable, as evidenced in Colette's situation that even an indication of nursing expertise may result in additional expectations.

it should have been really checked out right. I mean I do not know is it going or coming I am with the diabetes. I wonder do they, because no one has spoken to me about it only you. I mean they should take me into the hospital; they should have sorted it all out (Colette)

Similarly, the stories of distress and frustration told by Con and Alex were not communicated to health care professionals prior to the point of interview. The interview process possibly for the first time, gave these participants an opportunity to talk about their personal experience of living with self-testing and diabetes.

The core issue for Con however did not seem to be managing his diabetes, and the factually related physiological details, but rather having the diagnosis in the first place. Con was experiencing emotional problems related to his diabetes and an overall chronic illness diagnosis. The salient point here is not that those issues existed, as this has been previously explored, but rather that Con had not had an opportunity to engage in discussion about those issues at the clinic previously. While the clinic deals with blood values and medication, it may not always explore the personal stories of living with chronic illness. Once the possibility of discussion with a professional about his emotional issues was introduced to Con post-interview, he was eager to engage in this process. It is unfortunate that without the research project these issues possibly would not have come to the fore. Similarly, Alex was very eager to talk about self-testing and his wider experience of diabetes. Field notes post interview note that; *"It seemed as if Alex had been waiting for somebody to ask him about self-testing"*. This reflects the eagerness with which Colette engaged in conversation.

These stories resonate with other patient perspectives on engagement with the health services in times of chronic illness. Toombs (2002, p.130), in a personal analysis of the chronic illness experience suggests that individuals require "a genuine recognition that what is happening to them is significant not just in medical but in existential terms". As a physician, Brody (2002, p.132) makes a compelling case for the importance of the individual patient story in the clinician/patient relationship:

> As a general rule, patients will be more inclined to get better when they are provided with satisfactory explanations for what bothers them, sense

care and concern among those around them, and are helped to achieve a sense of mastery, or control over their illness and its symptoms. Patients will become worse when the illness remains mysterious and frightening, when they sense social isolation and lack of support, and when the illness is accompanied by a feeling of helplessness.

Brody acknowledges that physicians interview patients to elicit their 'history', but this is often done by asking technical and closed questions which "never hear the patient story of illness" (2002, p.134). This failure to engage more fully with the patient narrative does little, in his analysis, to address the isolation and disengagement that is central to human suffering.[63]

The need for patients to obtain psychological support, and the inadequacy of the system to provide it is acknowledged by healthcare professionals:

> *… some people will still want to come here again even though they have been through the education and that's more because there is very little psychological support for people with diabetes. A lot of the time it's around behaviour change and how to support people with behaviour change and as such we can do a certain amount for them, but we are not really trained to do the counselling aspect and I think that's a huge gap.* (HCP4)

HCP4 refers to limitations within the patient/clinician encounter and notes unrealistic expectations of what the service can actually provide:

> *I think if people have unrealistic expectations about what people can do on an individual consultation, like in every walk of life you have people who have unrealistic expectations, even when you explain how the service works and what they can expect from you, and what you can expect from them, even when you say it, they may not take that on board and we all have patients within our service who are very difficult to deal with, and I mean it's a continuous kind of circle that they go thorough and they constantly come back to us and go and it's the same issues all the time. I think that's just human life and it just shows here the same as everywhere else to be honest* (HCP4)

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[63] Brody offers some useful examples of how to adopt this narrative approach, which will be explored within the discussion chapter.

Perhaps expectations, like Colette's, for greater time with the healthcare service are unrealistic, or the service is unsatisfactory. Regardless of the specifics, there is a mismatch between what the patient wants and what the healthcare service can provide in this case. Other healthcare professionals seem more open to the need for discussion beyond clinical issues during patient engagement. HCP2 expresses her dissatisfaction with certain consultation practices:

> *The first thing they [the patients] are asked is 'Did you bring your book', no 'hello, how are you, how are things going for you'…only 'did you bring your book'. Then they look at the book and there is no discussion, only up the insulin here, or down there. There is no discussion about why it was high or what happened.….We cannot lose sight of the fact that people are people first and they are not somebody who is testing blood sugars, we have to see people as people first and diabetics after. I even hate the word diabetic because it's a person with diabetes, not a diabetic. I wouldn't like it if I walked in and the first thing the doctor said to me was 'Did you bring your book'* (HCP2)

However, even among those patients who seem to manage their diabetes quite well, and don't express a wish for greater engagement with services, their narratives revealed a sense that the healthcare system has very little time for them due to current financial constraints. Deirdre refers specifically to self-testing as a process to reduce healthcare costs:

> *I'm not costing the state anything like I would be if I wasn't self-testing and going to the clinic more often. After all, they're cutting back on everything and wouldn't that be a more expensive way of going about it? So the way I'm doing it is less expensive …* (Deirdre)

Betty also refers to time constraints within the outpatient environment and the experience of "going through a system". Acknowledging the constraints within the 'system' Betty notes her reluctance to explore issues with the team:

> *The clinic is just under the restraints of time management I suppose. As you can see from the clinic today, they're extremely busy. The volume of people that they're trying to put through in a 3-hour window, and not let anyone go home feeling that they've missed, maybe something medically, or missed an opportunity with them. They are under a lot of time restraints and time pressures so I just think the clinic isn't really … I won't say I wouldn't bring up an issue if I had [an issue of concern], I would bring up*

an issue but at the same time I wouldn't be idling with my issues, I would take it to my GP. (Betty)

Similar to HCP4's account, the lack of time to provide sufficient support to patients is acknowledged by all health care providers interviewed. HCP5 refers to the need for "*prioritisation*" within a hospital clinic system with a "*focus on more complicated patients*" while other patients are cared for in the community. However, the diabetic nurse specialists who extend their services to community-based 'outreach' clinics, also note the lack of services they can provide. It is important to note that the outreach nurse facility is not a separate service: the nurses who manage the outreach services are those who support the hospital acute and outpatient setting.[64] When asked if there was a diabetic nurse specialist relationship with all patients who attend the outpatient clinics, HCP2 commented:

> *No we couldn't see everybody. There are thousands in the county. We do outreach clinics and we see a lot of patients there also. In one area alone* [name of small town location] *I have well over 200 patients there. We now have patients starting on insulin and other treatments in the outreach clinics. … A GP might also send a patient in for our assessment. … We are very stretched and when you are that stretched you are not going to give your best service to anybody .* (HCP2)

HCP1 also refers to the difficulty with patient interaction and education in terms of the availability of time, space and privacy in a busy clinic setting. The variety of treatments available, and the diverse education required, also poses a challenge. At no point did healthcare professionals display a lack of understanding about the importance of patient education. There is an acknowledgement among those interviewed that an individualised approach to care and a gradual approach to information sharing is the best approach. However, it appears that despite the acknowledgement of the importance of individualised, ongoing support for patients, this is not necessarily forthcoming for all patients. Some feel that the system has no time for them; there is *No room at the inn.*

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[64] It is important to acknowledge that many individuals with diabetes are primarily treated in the community setting through GP practices and a growing number of primary care centres. Such sites were not the focus of this study.

An interesting dimension to this aspect of the phenomenon is that healthcare professionals, while noting the lack of resources, also acknowledge some of the waste that is associated with self-testing. The self-testing process is a costly enterprise. The economic value of self-testing is best summarised by HCP5:

> *I think it's very patient population dependent; it's cost effective in preventing type 1 patients from having a car accident. It is cost-effective in pregnant women in preventing pregnancy loss and ensuring the best possible outcome for the baby. In patients who are not on agents that have a risk of hypoglycaemia associated with them I think it would probably be hard to argue about cost-effectiveness.* (HCP5)

However, HCP5 does note that self-testing may have some value in individuals with type 2 diabetes initially, to develop an understanding of the relationship between blood glucose values and various foods and to decide on medication dosage. HCP6 supports self-testing in terms of the possible impact on reducing long-term complications, noting the economic drain that "*one complication, one small problem*" can cause. HCP1 is quite succinct in her economic assessment of self-testing:

> *It's of no economic benefit for people to be self-testing if they are not going to act on the results that they get.* (HCP1).

This echoes Colette's situation who does not appreciate the significance of results related to personal behaviour.

Interestingly, in direct response to the economic value of self-testing, HCP2 refers to the waste that arises from the availability of a never-ending choice of free monitors which results in a "*new toy*" scenario. Monitors are "*used for a period of time and then discarded*". Similarly, HCP4 notes, "*There are too many people with too many meters*". Monitors, available from marketing promotions and pharmacies, are accumulated and later discarded. While the medical device companies may distribute the monitors free of charge, the potential financial return is significant, as patients will need to use the model-specific strips on a long-term basis to utilise the monitor. HCP3 was quite vociferous about this point during interview when asked if self-testing is cost effective:

Not in all scenarios, because there is abuse, and when there's abuse there is waste and where there is waste there is overspend…Unfortunately patients are offered a meter with me today and then in 6 weeks' time they may go to the chemist and there will be another one offered, and then they might come back to clinic and there may be another one offered. I have heard of patients with seven and eight meters at home and probably strips being dispensed for each one, and each set of strips could be up to 50 Euros a bottle and we have no policing over that. I put my hand up…I think I have being saying since the start I would have a bee in my bonnet about the need for dare I say all the pharmaceutical promotion of the different monitors. (HCP3)

It is significant that self-testing may have real clinical value, but the ability to maximise that value is threatened by a non-regulated system of device distribution. There is a paradox here. HCP6 notes that the availability of free testing strips for individuals with gestational diabetes was under threat in the region, at the point of interview. As gestational diabetes is not categorised as a long-term illness patients do not qualify for free testing strips. It appears that non-specific widespread availability of self-testing in the wider diabetic patient population may restrict the availability of resources in individuals where it is most required.[65]

There was some evidence of a financial/marketing focus in data from the scientific community participants interviewed. SCP1 acknowledged the need to target new technologies specifically towards a suitable audience to assist in uptake by industry:

Getting more information on end-user applications may help to direct the development of these technologies into areas where the chances of uptake by industry are optimised, and also indicate what areas of industry the technologies should be pitched at. (SCP1)

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[65] This issue became more prevalent during the final stages of the study. An editorial in Diabetes Digest, notes that due to economic stresses, those who buy healthcare are leaning on industry to provide cheaper glucose testing strips. Kerr (2013) points to the difficulties associated with current ISO standards for testing strips, which may not be sufficient to detect potentially harmful hypoglycaemia in all cases. He suggests that in the future physicians may be charged with deciding which tests strips to utilise for individual patients, depending on the risk of hypoglycaemia. Concurrently, the European Association for the Study of Diabetes (2013) has called for greater regulation among the medical device industry in the context of blood glucose monitoring and associated devices.
(For detail see http://www.dagensdiabetes.se/home/forskning/964-medical-devices-in-diabetes-care-a-statement-on-behalf-of-the-european-association-for-the-study-of-diabetes.html)

The need to develop technologies that assist in economic growth is also apparent:

> ... obviously we are funded by [name of funding body] so they are a stakeholder they want results, they want money for the economy, for the Irish economy so hopefully we're going to create some jobs or educate the people so that they can create jobs and have an impact there. (SCP3)

Scientific community participants interviewed in this study are following a programme of work mandated by senior management in accordance with the institute's governance structures. Decisions regarding the commercial feasibility and clinical application of technologies are made at corporate level, and any government-funded programmes have been pre-approved by the funding body. However, regardless of where decisions are made the emphasis on revenue is apparent in the comments above. I do not suggest that a focus on revenue may affect the integrity of work packages, or outputs, in the context of the organisation involved in the study. The funding body which supports activity within this organisation is committed to both societal and economic impact and the research processes, previously outlined within the thesis, are committed to clinically lead projects. My point here relates to a wider issue of concern regarding direct-to-consumer marketing of self-testing devices. Government policy encourages those involved in technological innovation, particularly within the medical device industry, to maximise commercial outputs (Forfás 2012). However, the availability of such products to the wider public, in the absence of a discerning distribution pattern, may negatively affect overall healthcare costs, as evidenced in the discussion above regarding specific cost issues in self-monitoring of blood levels. In the absence of appropriate governance structures revenue could potentially take precedence over clinical efficacy and patients' best interests.[66]

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[66] There is a wider moral issue here regarding the overall spending on technology in healthcare relative to other 'goods'. For an extended discussion on these issues and an introduction to the debate see: Callahan, D. 2009. *Taming the beloved beast: How medical technology costs are destroying our healthcare system*. Princeton: Princeton University Press. In contrast to this criticism is the ongoing development of regulation, and good practice guidelines in the medical devices industry. The Irish Medical Devices Association (IMDA) unanimously adopted its Code of Ethical Business Practice at its 2012 general meeting. Adherence to the code is compulsory for IMDA members (http://www.ibec.com/Sectors/IMDA/COE.nsf/vPages/Code_of_ethics~introduction/$file/Summary.pdf). It is within the remit of individual medical device organisations to contribute to economic growth in an ethically sound way. The moral debate can be extended to include the societal benefits associated with profitable enterprise and associated job creation. The medical device industry is recognised as a significant factor in the resurgence of the Irish economy.

5.5.3 Autonomy versus covert paternalism

Also significant, in terms of patients' stories and the healthcare professional perspective, is the degree to which autonomy is actually supported. This support varied between healthcare professionals. While some use the rhetoric of autonomy, the practice appears to be different. This sub-theme also refers to the paradox that is implicit within self-testing devices: they seek to promote autonomy but may actually invoke greater paternalism in terms of imposing surveillance. The scientific community participants also offer some interesting insights in this regard. While they refer to the empowerment philosophy of self-testing technologies, the extent to which they believe patients should actually manage their own health is limited in some respects. This particular aspect of the wider phenomenon is based more on the understandings gleaned from other stakeholders, rather than the patient participants. However, these understandings represent an important aspect of the overall phenomenon as they explain why, despite the presence of a self-testing agenda, and a policy of patient empowerment through self-management practices, autonomy may not necessarily be realised.

The sense of empowerment that participants associated with educational initiatives within the sub-theme *Empowered by education* provides evidence that autonomy is supported by some healthcare professionals. The sub-theme *Freedom within constraints* also supports the degree of autonomy, albeit not absolute, that the self-testing process facilitates for patients as they exert some control over their daily lives, while living with the constraints imposed by self-testing and a diagnosis of chronic illness. However, in exploring the context in which self-testing occurs, what becomes apparent is that autonomy is not always actively encouraged by those who espouse it. The extent to which healthcare professionals support patient autonomy varies considerably.

HCP1 revealed support for patient autonomy when asked about the benefits of self-testing:

It's about keeping them [the patients] *in control, what they consider control. ... Our ideas do not mean they are everybody else's ideas about diabetes. ... They have to make the choice, we mightn't agree but...*

The remainder of the interview reveals a genuine sense of 'living' this philosophy in his interaction with patients. It is not particularly the element of 'choice' here, which signifies this statement as supporting autonomy, but rather the acknowledgement of the importance of the patient perspective. HCP1 refers to patients doing "*off the wall things*" and the associated dangers. However, there is evidence of respecting and working 'with' patients to achieve positive health related outcomes, despite their actions. HCP1 refers to a man who refused to commence insulin for type 1 diabetes, alternatively opting to ingest seeds, which he purchased over the internet. He also refers to a young girl who administered less insulin than advised, in order to prevent putting on weight. In both cases, HCP1 continued to engage with patients and advise them that they would require insulin eventually despite their refusal to comply with prescribed regimes. Eventually, both patients agreed to adopt the current evidence-based treatment for diabetes. HCP1 notes how the man who had ingested seeds for a period of time "*kept himself off insulin for another year*", albeit not in great health. He notes that he "*eventually came around because he was feeling terrible and took the insulin*". Perhaps one could argue that a year less on insulin, and his personal decision to start insulin, with the support of a healthcare professional, resulted in a greater 'buy-in' long-term than an initial enforced regime. A continuous dialogue between patient and healthcare professional resulted in good outcomes, which respected patient autonomy, healthcare professional responsibilities and patient welfare.

I asked healthcare professionals if patients taking more control of their illness ever posed a challenge for them. The tensions between supporting patient autonomy and discharging one's professional responsibilities are evident in the following response:

I suppose the only challenge I could think of is that they take it to the extremes and they are on the internet and they are listening to old wives' tales and doing all sorts of things, and while we know the guidelines and can individualise them to the said patient, sometimes the said patient thinks they know more than you know – that can be a negative aspect (HCP2)

The use of the internet among the patient population and the challenges it poses, was referred to consistently by the healthcare professionals interviewed. HCP3 refers to the "world wide web" in quite emphatic terms. The use of the word 'police' in suggesting a controlling influence is a significant choice of word in the following extract:

> *Obviously the problem now is with the WORLD WIDE WEB [emphasis], we have all sorts of enquiries about different sorts of [monitors], I had two already this morning about some meter that's on the market that I am not even aware of, it's very difficult to police it.* (HCP3)

However, there is also some understanding about the need to respect the patient's knowledge and address their concerns regarding information received through other sources:

> *I think it's very important that we respect the knowledge that patients have because they are living with it on a day to day basis and certainly a number of our insulin pump patients will probably know more about their diabetes management than we would know about it, but I don't think it's a challenge. I think we should work together to try to work for the best possible outcome, so it shouldn't be something that we feel threatened or challenged by. (HCP5)*

Maintaining engagement with patients, regardless of their choices, is also evident in the following narrative from HCP2:

> *Time, time, you let them have their rant and rave or whatever they feel they should be doing, going to somebody down the road who has plumes of smoke ... but you keep them coming back. ... It just takes people time to accept* (HCP2)

HCP2 refers to his engagement with patients as one of "*coaxing*" the patient into adopting behaviours that he believed to be in their best interest. The extent to which 'coaxing' involves support for autonomy is questionable. In addition, the language of the quotation suggests a degree of irrationality in the patient perspective.

Frances's story reveals a dialogue with her healthcare provider regarding the preferred treatment for her diabetes. Frances expressed a preference for insulin treatment in order to allow her more flexibility with her dietary intake. However, Frances's story

also reveals that she stopped self-testing for a period and administered the same dose of insulin every day. This could be detrimental to her health. For this reason, her doctor, on review of her blood glucose levels, changed her medication regime to oral medication. At the second interview Frances related how in conversation with her doctor she *"dug [her] heels in a bit"* regarding her request to go back on an insulin regime. Frances's account of her interaction with her doctor reflects a sense of 'working with' patients to which the healthcare professionals in this study refer. Despite Frances's wish to resume insulin therapy this did not occur. However, her narrative reveals an overall satisfaction with the outcome:

> *I know since I went on the medication, the last 5 to 6 months have been good. You know, there hasn't been any ups and downs because my body has got used to a lot of the medication. It takes time for the medication to work, in fairness to Dr X she said if this doesn't work you can go back on your insulin, but like she knew because of her profession, it was going to work. It was the time, like a sentence, the time you have to put into it, but now that transition is done so I don't really mind. The only thing is the taste, the aftertaste of the tablets, if that is all I have to worry about it's grand.* (Frances)

The healthcare professional in this case seems to exhibit more of a real engagement 'with' the patient than the previous example. This narrative also acknowledges the positive outcomes associated with discarding personal preferences in favour of professional recommendations. It also shows patient respect for 'professional' knowledge with regard to treatment decisions.

The narratives above reflect the tensions that exist for healthcare professionals as they negotiate respect for autonomy and patient preferences with their professional responsibility. These tensions reflect the reality of autonomy in a healthcare situation where professional obligations, as outlined in nursing and medical codes of practice, and evidence-based protocols demand that professionals think beyond patient preferences in the delivery of care. This indicates a relational understanding of autonomy as introduced in the initial ethical analysis at the closing stages of the literature review (see section 2.2.3). There are echoes of Holm's (1997) 'protective responsibility' here. 'Protective responsibility' does not accept autonomy as absolute

but recognises that something else may be required to maximise patient well-being in times of ill health. Holm (1997, p.127) explains the term as follows:

> When you meet the patient you meet another human being who is vulnerable, who often trusts you, and whose life you can influence in a significant way. This creates a special responsibility towards the other human being, which can be difficult to understand for outsiders, but which
>

Protective responsibility may provide a suitable model to bridge the abyss that exists between the more stringent positions of autonomy and paternalism. However, the degree of influence and mutual respect within the relationship is significant. These issues will be revisited in the discussion chapter.

The healthcare system itself can fail to support autonomy and be covertly paternalistic in how self-testing is managed. This is apparent in Alex's situation noted earlier, where he sought to be more autonomous in terms of seeking out information and organising the self-testing process. However, for him, the 'system' does not allow it. A particular source of frustration for Alex was the lack of repeat prescriptions, which impeded his ability to continue self-testing:

> *It just makes more sense to me that the equipment that you need should be available to you. It would make sense if I could walk into my chemist and just pick it up and likewise, they have my long-term illness card in my chemist, I should be able to walk in and just pick up the strips in my view, without a prescription...* (Alex)

The rhetoric of autonomy exists, but paternalism continues to permeate the healthcare system. Despite Alex's long-term diagnosis, he requires the ongoing written approval of medical personnel to acquire self-testing equipment. Other evidence of this 'covert' paternalism, as alluded to previously, is evident among healthcare professionals as they report the 'allocation' of patients to specific education programmes or specific self-testing devices. In the context of the monitor:

> *I wouldn't always offer patient choice. I would usually tend to pick something that I would feel would suit a patient. That's not the right way but most patients when they are diagnosed would ask "What do you think?" and they are happy for me to choose for them. ... I would always*

feel that if the patient is finding it difficult to assimilate their diagnosis and they are quite tearful and upset, you might offer them the simplest thing for the moment, until such time as they digest it and that might take a year, it might take six months, it might take 6 weeks, and you might upgrade then…likewise in the older population I am personally inclined to pick the simplest [monitor]. (HCP3)

In this sense, the healthcare professional could be viewed as being overly paternalistic or it may reflect a care-based interaction, based on notions of beneficence as opposed to autonomy, as alluded to in the context of 'protective responsibility' above. The perspective whereby healthcare professionals decide what 'options' are to be made available to patients further asserts that the healthcare professional is the 'person in charge'. For reasons, which may be morally justifiable in some contexts, the healthcare professional takes the lead in the patient/healthcare professional relationship. This resonates with Mol's (2008) perspective on the problematic nature of citizenship in a patient context, as noted in accordance with the theme, *Autonomy as contingent in chronic illness*. It is reasonable to suggest that the patient may be more accurately construed as a 'subject' as opposed to a 'citizen' in this context.

Another dimension to the sub-theme *Autonomy versus covert paternalism* relates to the capabilities of the self-testing device itself. While the device can assist in promoting autonomy, by enabling patients to self-manage their blood glucose levels, the type of information generated can also act as a form of surveillance. There is some sense of this surveillance in the patient experiences recounted in *Freedom within constraints*. Through the process of self-monitoring and reporting, healthcare professionals can intrude on the home life of the diabetic patient and assess the extent to which they are compliant with treatment measures. This is even more pronounced with advanced computerised technology. While Alex would like to have blood glucose readings computerised in order to enable a more seamless transfer of information from the monitor to the healthcare team, Betty is reluctant to welcome such advances:

I know my GP is a bit into, sort of you know, "Oh we'll get you a monitor that I can upload it onto the computer", and I'm thinking "Oh my God, you know this is scary, she'll be able to check me way too much!" [Laughs] (Betty)

Even when using a manually filled log book Frances refers to the surveillance that the self-testing promotes: "… *it's like having to report to someone all the time".* HCP1 acknowledges the sense of surveillance that can be associated with self-testing, albeit not for all patients:

> *Some people come in and they love to show you their book, their results. They feel good when they show you their results and you think; 'This is the two of us doing it not just the person with the diabetes'. For other people I don't know does it put a barrier there that 'this guy is only checking up on me' which I suppose in a certain way we are.* (HCP1)

HCP1's extended narrative suggests that the degree of surveillance is real and is compounded by an interest in more long-term HbA1c results. Healthcare professionals interviewed refer to the scepticism with which they view "pristine" logbooks with a series of *"strange results"* (HCP1), *"all filled in the same biro"* (HCP6). Despite acknowledging the value of intermittent self-testing results, there is a general agreement among healthcare professionals in this study that HbA1c results will give a more accurate recording of results over time. These results are: *"objective, laboratory based, reflecting more sugars than are represented in a diary no matter how often the patient does it" (HCP6).* This lends further support to the notion of particular 'truths' being more acceptable to professionals, as discussed earlier in association with Foucault's analysis of the politics of truth and power.

Another dimension to the covert paternalism explored in this sub-theme, is that a self-testing device has the potential to limit the participant's ability to be autonomous depending on how it is employed. While the scientific community participants refer to the role of self-testing devices in creating empowerment, their narratives suggest that this empowerment should have certain limits. In contrast, for the most part, the healthcare professionals associate the most effective self-testing processes with combined self-management practices. This 'caution' from the scientific community participants is evidenced below, when SCP2 was asked to develop her ideas around interpretation of results:

> *Yeah, just so the patient does not feel they need to interpret or that they do not interpret at the back of their mind and either get worried or complacent*

about various different things. That could be a thing with self-diagnosis in the future. Just let the doctors be doctors and let the patient still be a patient while still empowering the patient with information. (SCP2)

This suggests that patients go through the 'semblance' of empowerment, but that test interpretation and subsequent treatment decisions remain within the remit of the doctor. It also suggests a similar concern for individual welfare, versus enhanced autonomy, among the scientific community. There is further suggestion of instilling a 'feeling' of empowerment as opposed to a reality:

> *The patient as we say is empowered, they are actually doing something, they are not just lying in a bed having IVs put into them and then the doctor coming and bringing you off for the mystical tests 'we have to do tests'. A patient who does something themselves gets a number, whether they understand the number or not, they feel they are contributing ...* (SCP4)

SCP3 refers to the autonomy issue in the context of information: "*comes down to ownership of information. It comes down to whether people think you should have ownership of information or not*". There is debate among the participants regarding the extent to which patients should have sole ownership of information gleaned through self-testing. Acknowledging the disadvantages associated with self-testing in the absence of professional support SCP5 suggests the need for some sort of "tagging" system that would allow tracking of individuals who may self-test and realise that they have increased markers for cancer. This tracking system would facilitate follow up in patients who may ignore results, "*go into depression and decide not to do anything about it*" (SCP5) but require treatment or psychological support.

A sense of covert paternalism may become more common in future technological developments. A lesser role for patients in interpreting results seems to underpin the ethos of a 'Connected Health' approach to diagnosis and follow-up care, in accordance with the views of one participant. She refers to a specific 'vision'

> *... to put healthcare more into the hands of the patient rather than the healthcare provider – no, to include the patient more in the partnership with the healthcare provider. We call this connected health, in other words a lot of the testing and monitoring that would normally be done by a patient, going to their healthcare provider.* [The testing] *will actually be done by the person at home and then those results transmitted to the*

healthcare provider. That will facilitate more frequent monitoring of a person's condition and the assumption is that that would be better for that person's health in the long term. Because not only will you get the more frequent monitoring which of itself is probably going to be better for the patient, but you get a better patient buy-in or you get a better patient adherence to management of that condition overall. (SCP1)

I would argue however, based on the experiences reported by some individuals in this study, that the 'buy-in' from the patient in this scenario could be quite limited if they are not involved in interpretation of results and associated decision-making. I suggest that in not asking different types of patients directly about these issues, the wider medical device industry may underestimate the role that patients can take with regard to the use of technology in their care. It is significant that the participants in this study are primarily involved in the development of point of care devices for use under clinician supervision as explained in section 1.3.4. This 'focus' may legitimately limit their appreciation of a possible greater role for patients in interpretation and management of results.

In conclusion, I propose that the experiences of patients in this study, and the associated perspectives offered by other healthcare professionals suggest that while the rhetoric of patient autonomy and empowerment exists, there is a degree of covert paternalism in the interactions of patients with their healthcare professionals and the wider healthcare system. In addition, some degree of paradox is present, as the technology that is deemed to empower patients may actually involve greater surveillance. Furthermore, while a move towards connected health systems, which limit the patient's role in interpretation of results, may be an excellent way forward for some patients, it may potentially disempower others who are capable of greater self-management as evidenced by the experiences of some of the participants in this study. It is important to note that I do not apportion negative connotations to this covert paternalism but merely acknowledge that it exists.

5.6 Conclusion: *The interdependent phenomenon of autonomy in self-testing*

This chapter has revealed a series of 'understandings' related to the patients' existential experiences of 'being-with' self-testing technology. These understandings collectively represent *Autonomy as lived: The interdependent phenomenon of autonomy in self-*

Testing. This interdependent phenomenon is underpinned by three thematic components or relationships: *Relationship with device*; *Relationship with illness;* and *Relationship with healthcare provider*. Each of these themes encompasses a number of distinct sub-themes that collectively represent the wider phenomenon. The term 'interdependence' is significant, as autonomy is best realised when there is a particular fusion of the three relationships. Any individual component of the relationship may influence, and be influenced by, the other two and may affect the experience of autonomy.

Interdependence is also significant as it implies that autonomy is not conceptualised in a negative sense, as meaning freedom from constraints, but rather that autonomy is present through self-mastery, and self-determination, which can exist 'within' certain constraints. The extent to which individuals self-impose, and accept certain restraints, influences the degree of autonomy they experience. Autonomy is not something that we can 'create' through technological advances. It requires a particular series of social interactions, and personal circumstances, in addition to technological capabilities. *Autonomy as lived* is context dependent. This interpretation of the lived experience of autonomy within the self-testing process contributes to the current understanding of autonomy in healthcare. It is also significant in terms of the development and use of self-testing technology. Such significance will be discussed in the chapter that follows.

CHAPTER 6: DISCUSSION/ETHICAL ANALYSIS

... the philosophical exercise is to identify the weakness of the conceptual apparatus that supports current practice; to argue for reformulations that allow reform; to present a moral compass to find our way in a social system of extraordinary complexity.

(Tauber 2005, p.24)

6.1 Introduction

The empirical component of this study interprets the patient experience of autonomy in self-testing as *Autonomy as lived: The interdependent phenomenon of autonomy in self-testing*. The basis of this phenomenon is that participants experience autonomy within a series of interdependent relationships: *Relationship with device*; *Relationship with healthcare provider*; and *Relationship with illness*. This contextualised understanding of autonomy is situated in the real world of participants with diabetes engaged with self-testing technology. The purpose of this chapter is to engage in philosophical/ethical analysis and explore the normative implications of this understanding of autonomy for bioethics and healthcare practice. I return here to the autonomy conundrum (the extent to which autonomy should triumph over other ethical principles) as a moral problem, outlined at the outset of the study, and explore the contribution that this empirical work has to offer in accordance with the empirical-ethical mode of collaboration outlined by Rehmann-Sutter et al. (2012).

Empirical work in bioethics has been criticised for failing to address the normative implications of empirical findings (Salloch et al. 2012). The application of McMillan and Hope's (2008) model of empirical bioethics in this study averts such criticism. This discussion closes the cycle at the point where an ethical analysis of new data generated can illuminate normative enquiry. In this study, the normative contribution is to extend the existing understanding of autonomy in bioethics. As the discussion unfolds, I will draw on the concept of *Autonomy as lived* to outline an alternative construction of autonomy for bioethics. I do not claim to draw generalisable conclusions about autonomy that are directly transferable from this population to multiple settings. As is the purpose of interpretive phenomenological research, these

understandings are temporally located, in accordance with Heideggerian philosophy, and have the potential to evolve through further research (Todres 2004).

However, while recognising the limitations of qualitative work, and the epistemological problems associated with empirical ethics, I suggest that the empirical findings can inform normative ethics for two principal reasons. Firstly, this claim is congruent with the understanding of empirical bioethics underpinning the study. In chapter three, I reject the absoluteness of the 'is-ought' problem and argued for a meta-ethical position of neo-naturalism as outlined by Stewart (2009). Put more succinctly, outlining normative implications does not suggest a rejection of the 'is-ought' distinction, but rather suggests that what 'is' has some contribution to make to what 'ought' to be (McMillan and Hope 2008, Salloch et al. 2012) (see section 3.3).

Secondly, the application of reasoned argument distinguishes the transfer of knowledge in this study from immediate assumptions of generalisability. Rehmann-Sutter et al.'s (2012) phenomenologically informed hermeneutic model of empirical-normative collaboration, relies on reasoned argument to utilise empirical data to make normative conclusions. This is compatible with the identified need to link empirical facts to normative conclusions by means of evaluative premises. Holm (1997 p.209) argues that if we interpret generalisability, not in a quantitative sense, but rather as meaning "transfer knowledge to other settings" then the findings of empirical studies can be 'generalised'. Holm, similar to Rehmann-Sutter et al., acknowledges the importance of argumentation in order to generalise from one setting to another. This argument should "show that the situation we generalise from is similar in the relevant respects to the situation we wish to generalise to" (Holm 1997, p.209).

The 'merit' of argumentation is central to Rehmann-Sutter et al.'s method. Empirical work is utilised to "kick-start" reflection. The task for the researcher lies in reconstructing the empirical facts within the case to be argued and presenting this case in a manner that makes sense to the reader. The merit of the normative conclusion rests on the quality of the researcher's argument. The qualitative data "contributes to the conditions that make it possible to evaluate these arguments and the conclusions drawn from them, but as ethical researchers making normative claims, we cannot hide

behind our interviewees or what they have said" (Rehmann-Sutter et al. 2012, p.440). The argument is owned by the researcher.

The chapter has four core sections. In the initial section, I summarise the situated understandings of *Autonomy as lived*, which the empirical study brings. The second section proceeds to explore the significance of this empirical contribution in light of existing perceptions of autonomy in bioethics and concludes with a summary of autonomy as conceptualised in this study. In the third section, I suggest a 'working' account of autonomy for healthcare practice that will enable healthcare professionals to operationalise an understanding of *Autonomy as lived*. Here I return to the original ethical analysis undertaken at the outset of the study prior to empirical investigation. I utilise the empirical facts of this research to construct an argument, which has normative relevance beyond this study. The 'revised' argument presented in this chapter does not disregard previous considerations, but rather suggests that the original analysis merits consideration, as other perspectives are also valid in light of the empirical data and subsequent discussion. In conclusion, I argue for an alternative operational account of autonomy for bioethics, negotiated autonomy, which draws on the study findings and acknowledges the strengths and limitations of previous bioethical perspectives.

The chapter concludes with a refinement of the understanding of autonomy originally presented. In this sense McMillan and Hope's (2008) cyclical model of empirical ethics is fully realised. The basic tenets of interpretive phenomenology are also fulfilled as pre-understandings are altered based on the new understandings that emerge from the empirical study. Data from the empirical study is utilised throughout to support discussion and argument. While the study primarily has normative implications with regard to extending the understanding of autonomy in a clinical context, there are also more practical considerations to explore. The study findings have particular resonance in the context of diabetes care due to the sample population. In order to avoid repetition, and maintain the central focus of discussion, the findings in a diabetes context are not explored separately, but interlinked with the wider autonomy discussion in respect of illness experience, interaction with healthcare

providers and technology use. The study also raises a number of issues of significance with regard to human-technical relations, which are similarly interwoven.

6.2 Summarising *Autonomy as lived*

The overarching contribution of the empirical study is that of *Autonomy as lived* – a contextual understanding of autonomy in self-testing that cannot be sufficiently defined by appeals to positive or negative perceptions of liberty alone. In their everyday 'being-with' self-testing technology in the social world, the participants related varied experiences of autonomy within a series of interdependent relationships. While this perspective has previous resonance in the chronic illness literature (Agich 1995, Mars et al. 2007, Mars et al. 2008, Delmar et al. 2006), care of the older adult (Agich 2003) and the field of mental illness (Schlimme 2012), I have not found previous studies which specifically conceptualise autonomy in this way in the context of self-testing technology. Mars et al. (2007) included individuals with diabetes in their study of autonomy in chronic illness. However, the use of a technological device was not explicit within the study. Karlsson et al. (2008) undertook a phenomenological analysis of the transition towards autonomy among teenagers with type 1 diabetes. The study focused on acquiring autonomy in self-management as a developmental process, and did not explore the implications of the self-testing specifically (Karlsson et al. 2008). However, the study does lend support to the interdependent phenomenon of autonomy outlined here. The overriding theme of "hovering between individual actions and support of others" was utilised to describe the transition to autonomy among participants (Karlsson et al. 2008, p.566).

The normative contribution of this study lies in its illumination of autonomy in a specific clinical context. The understanding of autonomy in self-testing, as outlined within the various themes and sub-themes, collectively presents an account of autonomy in the real world of healthcare practice. The points of understanding can be summarised as follows: (1) Autonomy is context dependent and related to the individual's experience of illness. Autonomy is not something that could be prescribed by healthcare professionals or created solely by technological advances. The sense of autonomy experienced by participants was contingent on personal issues related to:

their overall stage in their illness trajectory; their experiences of chronicity; and their willingness to take an active role in the management of their own health. This understanding of autonomy reflects the contextual, interdependent nature of autonomy that is central to a Heideggerian understanding of our connectivity to the world around us. (2) Autonomy, for many participants in this study, exists as *Freedom within constraints* whereby the device supports autonomy in some respects, but within a wider system of control. While the participants express a sense of freedom or control, there is an accompanying acknowledgement of the demands imposed by the self-testing device and the wider associated experiences of illness and chronicity.

(3) Autonomy exists within a series of interdependent relationships. Autonomy does not necessarily require isolated decision-making. This study highlights that engagement, or influence from others, often rejected in a libertarian sense, is not only permissible, but necessary to enable autonomous behaviour. In this study, the significance of external 'influence' is evident in the presence or absence, of: a supportive healthcare professional; access to health services; meaningful educational assistance; and accommodating, user-friendly technology. The extent to which healthcare professionals provide 'real' support for autonomy, relative to professional obligations towards patient welfare, encompasses an important dimension of this 'influence'. (4) The technological capabilities of a device influence the degree of autonomy that patients experience. The device enables participants to know their own body and initiate self-assessment and possible self-management techniques, albeit acknowledging some complaints regarding the device. The device also has the paradoxical potential to simultaneously support autonomy and induce surveillance. The device is also instrumental in causing unwelcome burdens for some participants that are inextricably linked with their overall illness and life experiences.

In summation, *Autonomy as lived* presents autonomy as an interdependent, contextualised process. This 'process' relies on an ongoing sense of mutual responsibility and understanding between patients and healthcare professionals and is not confined to discrete moments of choice. However, this interdependence goes beyond the patient/healthcare professional relationship. One's personal relationships with her illness and the self-testing device are also significant. In this continuum, some

individuals exhibit greater control over their lives than others, yet also, a particular individual can be more autonomous at different points in time relative to a range of contextual factors.

6.3 Conceptualising *Autonomy as lived*

6.3.1 Autonomy, self and illness: Freedom and constraints co-existing

In this study, the participants who experience autonomy relate a positive synergy between all three interdependent relationships. The participants' interactions with the self-testing technology are important for their overall experiences of autonomy. *Relationship with illness*, associated with a sense of acceptance, self-efficacy and a willingness to take control of their illness is also significant. In addition, one's ability to be autonomous depends on her particular stage in a personal illness trajectory. The relationship with one's associated health care providers, particularly with regard to education, is also an important factor in the overall experience of autonomy. The extent to which participants are offered tangible support in being autonomous, and educated sufficiently are integral to the participant's experience of autonomy. The experiences of autonomy recounted by those interviewed include: the flexibility to dine out with friends; the freedom to travel abroad more confidently; the ability to operate a business; and the opportunity to remain in full-time employment. The ability of the self-testing device to facilitate greater control and enable self-management for patients is also evident in data from other stakeholders. The role of the self-testing device in increasing empowerment, control and a sense of freedom for participants in this study resonates with the findings of other studies.

Barnard's et al. (2010) survey of 289 individuals with type 2 diabetes found that 80% of participants reported a high satisfaction with self-monitoring of blood glucose (SMBG) and reported feeling more 'in control' of their diabetes when engaged in self-monitoring. The positive association between self-testing in diabetes care and patient control and empowerment is also evident elsewhere in the literature. The qualitative component of the DiGEM study observed 'empowerment' as another core theme emanating from patient data (Farmer et al. 2009b). Specific aspects of empowerment listed by the researchers included: convenience of self-testing; link with initiation of

physician communication; and role in informing healthcare decisions. These elements of empowerment are evident among the participants in this study. Empowerment is assisted by appropriate education. This will be explored later in this chapter as the significance of interaction with healthcare professionals is examined.

However, even for those participants who appear to exercise greater control, there is an acknowledgement that this 'control' or 'freedom' existed within certain constraints imposed by the demands of the device, and associated self-monitoring programme, or, the wider experience of illness and chronicity. Mol's (2000) account of autonomy in her empirical/philosophical analysis of blood glucose measurement is similar to that presented in this study. Mol (2000, p.18) notes that "the autonomy of a self-regulating diabetes patient is of a complex kind". The use of a self-monitoring device facilitates certain liberties, "but not freedom" (p.17). This reflects the sense of *Freedom within constraints* experienced by participants in this study. The freedom which participants gain is achieved only by mastering and utilising a series of time-consuming, sometimes inconvenient self-management techniques, previously only understood by healthcare professionals. Mol's (2000, p.18) account very succinctly articulates this somewhat dichotomous position where one gains a number of liberties "but another rule takes over":

> For someone with diabetes who is engaged in self-regulation it is no longer necessary to follow 'doctor's orders' which means that a lot of autonomy 'vis-á-vis' professionals is gained. But handling this autonomy is not a matter of living out the whimsicalities of some wild untamed self. Instead, the self must come to behave like a professional.

As Mol (2000, p.21) notes an individual may have gained autonomy but such autonomy is accompanied by a series of "new obligations".

While recent empirical evidence with regard to the impact of self-monitoring on glycaemic control and patient satisfaction does not make specific reference to the concept of *Freedom within constraints* revealed within this study, analysis of the overall findings of the DiGEM trial (Farmer et al. 2009b) lends some support to the co-existence of dependence/independence presented here. While the qualitative element of the DiGEM study reported the experience of empowerment among

individuals, analysis of questionnaires about health related beliefs did not find an increase in perceived control over diabetes. It could be, as portrayed by participants in this study, that while self-monitoring yields some sense of control for participants, as evidenced in accounts of empowerment during interview, this could not negate the overall sense of restraint associated with a diagnosis of chronic illness. Somewhat similarly, O'Kane et al. (2008) surmise that the higher depression scores among individuals in their trial of self-monitoring versus non-monitoring may be associated with the strict discipline of a self-monitoring regime, as opposed to feelings of absolute powerlessness.

This *Freedom within constraints* is also echoed in empirical work that explores the use of medical technology, beyond blood-glucose monitoring devices, in patients' homes. Lehoux (2004, p.7) explored the home-use of four different technologies (IV therapy, parenteral nutrition, oxygen therapy and peritoneal dialysis) using a symbolic interactionist approach and concluded that technology "simultaneously improves and constrains patients' lives". Fex et al. (2009) utilised descriptive phenomenology to explore the lived experiences of individuals using technology at home. Even though the technology was of a more advanced nature than that of the blood glucose meter, (including ventilation, home dialysis and oxygen therapy), there are similarities in the patients' experiences of autonomy. The researchers utilise the terms "feeling tied up" and "feeling free" to explain a particular facet of the participants' experiences of technology in the home. The sense of 'feeling tied up' related, among other things, to the way in which the use of the technology directed the participants' social activities and demanded rigid schedules. This reflects the experiences of participants in this study. "Feeling free" also shares similarities with the aspects of *Freedom within constraints* identified in this study. Fex et al. (2009, p.2815), explain this 'freedom' as follows, noting that there are existential dimensions at play:

> Freedom was experienced in the ability to depart from set routines and to be able to adjust the time, duration and frequency of treatment to fit in with social activities or work …Feeling free in spatial terms involved the freedom of having the possibility of being at home and indeed outdoors, without being restricted to hospital care. Feeling free in relation to others involved the will and increased capacity to manage things for oneself, to be in control of day-to-day activities and to be less dependent on others.

There is wider understanding in the literature that freedom, or independence, is not always possible when living with a chronic illness, or the limitations associated with long-term care in old age, thereby requiring a re-conceptualisation of autonomy in practice (Agich 1995, Delmar et al. 2006, Mars et al. 2007, Mars et al. 2008, Schlimee 2012). This understanding is central to a phenomenological account of living 'with' illness and the extent to which one's experience of illness impacts on one's expression of autonomy (Agich 1995). Agich (2003, p.123) uses the term 'actual autonomy', as preferential to other conceptualisations and theories, to describe "what autonomy actually means in the every-day world of long-term care" where a "wide chasm exists between ideal competence and actual incompetence".[67] Agich notes that dependence is integral to human development. "Human life and hence, human development are essentially phenomena that involve interdependence" (2003, p.103).

For Agich (2003), the dependence associated with human development is more pronounced in ill health where there is an associated "dissolution of the unity of body and self" (p.104). This perspective resonates with the interpretation of the lived body within this study, and has implications for autonomy in accordance with the sub-theme, *Autonomy as contingent in chronic illness*. The earlier, yet enduring, work of Pellegrino and Thomasma (1988) supports an understanding of autonomy as compromised in ill health where beneficence requires greater consideration. Thomasma (1984) refers to his work with Pellegrino concerning the dichotomy that exists between promoting patient autonomy, on the one hand, and the realities of the doctor/patient relationship, on the other. Most relevant here is Thomasma's (1984, p.2) reference to the "wounded state of humanity" associated with disease and the limits that this places on personal autonomy:

Mols's (2008) concern with 'patients as citizens' is also relevant in this context. Mol believes we are only capable of citizenship with the healthy part of our bodies. For Mol, citizenship signifies control, freedom and civilisation (meaning that our bodily functions and passions are kept under control). However, as she observes, these traits are not always possible for an individual with illness. This perspective resonates with

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[67]Agich's work will be explored in greater detail as final conceptualisations of autonomy are offered later in discussion.

the experience of frustration among some participants related to variations in health status and unfavourable self-testing results. This is noted elsewhere in the self-testing literature. French et al. (2008) reporting on the more qualitative aspects of the DiGEM study, suggest that diabetics who are eager to pursue health-related behaviours can be demotivated by self-testing when the results do not accord with what the patients perceive to be their recent glucose-reducing behaviours. Similarly, Barnard et al. (2010) note that one of the patients in their study referred to self-testing as "dispiriting and demotivating" when results failed to improve over time despite adherence to medication.

This study's findings also share a number of similarities with the work of Mars et al. (2007) who undertook a grounded theory study to examine how people with Chronic Obstructive Pulmonary Disease (COPD) or type 2 diabetes experience autonomy. The study concluded that chronic illness limits one's experience of autonomy in two ways. Firstly, it prompts a reappraisal of life's activities in light of ill-health and secondly, it limits one's opportunities. The former aspect was more prominent among the participants with diabetes, which the authors associate with the "tangibility of long-term consequences" (Mars et al. 2007, p. 490). The future-directedness of the actions of an individual seeking to avoid the long-term consequences of diabetes was also a feature of this study and served as an additional example of *Freedom within constraints*.

The altered sense of autonomy experienced over time by participants acts as further testament to the 'reappraisal of life's activities' which Mars et al. (2007) refer to in the context of chronic illness. Self-testing becomes more frustrating for Alex as his pancreatic function diminished. Frances continuously re-appraises her adherence to prescribed therapy, and self-testing protocols, relative to her own personal relationship with her illness. The temporal experience of illness is particularly relevant in this regard as various life events impact on her perception of illness and her coping responses. More recent research also supports the extent to which temporal concerns are important in one's overall chronic illness experience. Karademas et al. (2009, p.406) make the following observation:

> … the experience of chronic illness does not take place in a vacuum, but is bursting into the patient's life context. In the same vein, it is also possible that perceptions a person holds about illness and the specific ways he/she chooses to deal with it are associated with the stress experienced in other domains of life, such as work or family.

However, despite the acknowledgement of the constraints which diabetes, chronicity and self-testing ensue, there is evidence of greater autonomy, 'contingently-being-in-control', among some participants. Significant in their stories, as revealed in the sub-theme, *Taking control*, is their willingness to actively take control of their illness and a corresponding belief that this was possible. One's locus of control refers to the extent to which he/she believes life events to be within personal control (an internal locus of control), or dependant on fate or chance (an external locus of control) (Lange and Tiggemann 1981). The importance of personal control in the context of chronic illness is evident elsewhere in the literature. A greater internal locus of control, in the specific context of individuals with diabetes, has been positively correlated with adherence to treatment regimes and positive clinical outcomes (Morowatisharifabad et al. 2010).

Toombs (2002) refers to 'being in control' specifically in the context of her phenomenological account of living with chronic illness. She points to the sense of indestructibility that is central to being human and how the experience of illness challenges this perspective. To realise "that one's body cannot be 'fixed' is to experience the most extraordinary sense of loss of control, of powerlessness, of helplessness" (p.127). Toombs (p.130) links this sense of powerlessness to alienation from one's body, highlighting the importance of "becoming attuned to one's body" as a means of addressing this sense of alienation: "the act of taking the body back gives one a sense of control". This is apparent in the stories of the participants noted in *Freedom within constraints* who speak so positively about the self-testing experience, and their ability to take control of their diabetes through knowledge of their bodies - knowledge of their blood glucose levels. For these patients, knowing their body is a positive experience, which allows them greater freedom in the context of their daily lives. This reflects the importance of the corporeal dimension of illness for the participants in this study. Toombs's account of her own existential struggle with illness provides us with a means of understanding why self-testing, when accompanied with

a preference for being in control, is a positive experience for this group of patients and promotes autonomy.

> Recognising that one always has the capacity and opportunity to make meaningful choices (even though such choices may be severely circumscribed) is essential for the task of preserving self-integrity (healing). (Toombs 2002, p.131)

This sentiment very much echoes the views of Mars et al. (2008) who propose that autonomy can be increased by maximising opportunities through which individuals can control their lives. The patient's dependence on self-testing, as articulated in *Freedom within constraints*, may not be seen as constraining if it is self-imposed. Rather, self-testing can provide an opportunity for the patient to make "meaningful choices", as Toombs suggests. In this sense autonomy, along with self-integrity, can be promoted and preserved. In order to experience a sense of autonomy in self-testing, within the associated constraints of chronic illness, participants actively 'taking control' of their ill health is a significant factor. The experience of autonomy in self-testing for these participants is an existential one with corporeal, relational, spatial and temporal dimensions. Despite having the desire and the requisite equipment to facilitate autonomy and self-management, autonomy may not necessarily occur.

6.3.2 Autonomy and engagement with healthcare professionals

Central to the participants' experiences of autonomy is their relationship with individual healthcare professionals and with the wider healthcare system, as outlined within the theme, *Relationship with healthcare provider*. This particular aspect of *The interdependent phenomenon of autonomy in self-testing* highlights the significance of patient education and information in patient empowerment and maximising autonomy. However, also apparent in some patient narratives was that they valued the interaction with healthcare professionals beyond mere education, and noted the lack of access to the healthcare community within the current health care system. This study revealed patient stories that did not seem to be told in the general consultation process, despite their importance in the overall patient context. In this sense, a more mutual sharing of knowledge may be required to maximise patient autonomy. This discussion is mostly

based on the sub-themes, *Empowered by education* and *No room at the inn*; however, some elements of other thematic understandings are also interwoven.

Within a number of patient narratives, the role of a healthcare professional in transferring information regarding the self-testing process, and associated diabetes management, is integral to a positive experience of autonomy in self-testing. The role of individualised education to enable patients to understand and react to blood glucose levels is commented on by all six healthcare professionals in the study. There is a general understanding among healthcare professionals interviewed that the difference between self-monitoring and self-managing centres on the degree of education provided and the corresponding patient understanding. The importance of education in terms of patient empowerment in diabetes management, and its impact on the overall efficacy of SMBG, is a prominent theme in recent systematic reviews and current clinical guidelines (Clar et al. 2010, IDF 2009, Parkin et al. 2012, ADA 2013).

Participants in this study express a concern that the healthcare team have little interest in self-monitoring data and rely on HbA1c results to monitor progress. Clar et al.'s (2010) systematic review of qualitative evidence pertaining to self-monitoring supports this analysis. Peel at al. (2007) observed similar concerns among participants in their study, noting that patients sometimes ceased self-testing due to the perceived uninterest of healthcare professionals. However, when interviewed about the value of self-monitoring results, healthcare professionals in this study note the clinical relevance of specifically timed and more regular readings of blood glucose in specific patient contexts. It appears that healthcare professionals may value patient readings and act on results, but fail to communicate this to patients. Care protocols and guidelines may actually be effective, but fail in the absence of effective communication. Dialogue with patients in this regard is listed as a recommendation in Peel et al.'s (2007) study. While the researchers acknowledge the non-inclusion of healthcare professionals in their study as a limitation, the perspective of healthcare professionals obtained in this study supports this recommendation.

Empowerment is a term used by healthcare professionals when applying the philosophical concept of autonomy to a contextualised patient care scenario. Abbot et

al. (2007) specifically make this specific link in the context of diabetes care. Holström and Röing (2010) suggest that empowerment is a recent phenomenon in healthcare, associated with patient-centeredness and autonomy. The term empowerment has its basis in political freedom as an alternative to oppression, and is most commonly associated with the critical social theory of Paulo Freire[68] (Anderson and Funnell 2010). The notion of autonomy as empowerment is consistent with a growing discourse in healthcare, whereby patient autonomy is given precedence over other ethical concepts, and often equated with independence and freedom to choose (Campbell 2011). The claim is that empowering individuals assists them to act more independently in a healthcare context, as it increases opportunities for greater autonomy and involvement in decision-making (Holström and Röing 2010). HCP4 specifically refers to empowerment in this context, noting that self-testing "*empowers them* [patients] *to actually make choices and take action*".

Also implicit within this study is the role of education and knowledge in enabling patients to exert more power in their interactions with healthcare professionals. Foucault's work is appropriate here to explore the relevance of education within an autonomy framework. Foucault's enduring philosophical contribution lies in his post-structural concern with power. [69] Knowledge, for Foucault is seen as a route to power – power is not a fixed entity. The curtailment of knowledge can limit the autonomy of individuals, as they are ill-equipped with the "techniques and procedures accorded value in the acquisition of truth" (Foucault 1980, p.131). In a diabetic context, these techniques and procedures involve practical knowledge about self-testing, yet also a more theoretical understanding of glucose physiology. Attaining this knowledge assists individuals to exert greater autonomy in their daily lives, yet also assists them to engage in discussion with healthcare professionals in a more confident and productive way. This type of interaction is seen in both Alex's and Frances's accounts of dialogue within the consultation process.

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[68] The significance of Freire's work will be developed as this discussion continues

[69] "Originally labelled a structuralist, the French philosopher and historian Michel Foucault came to be seen as the most important representative of the post-structuralist movement. He agreed that language and society were shaped by rule-governed systems, but he disagreed with the structuralists on two counts. Firstly, he did not think that there were definite underlying structures that could explain the human condition and secondly he thought that it was impossible to step outside of discourse and survey the situation objectively". (See http://www.philosopher.org.uk/poststr.htm).

Bradbury-Jones et al. (2008) explore Foucault's understanding of power in a clinical context noting two perspectives as of particular relevance: disciplinary power and knowledge-power relationships. The latter is of significance in this discussion. The authors show how Foucault's philosophy of power, as distinct from a Freirean concept of empowerment, can assist in the empowerment of nurses and patients. Bradbury-Jones et al. (2008) explain that in accordance with a Foucauldian lens certain discourses are accorded status as 'truth' and assume a position of power, while other sources of knowledge may be less respected and disqualified. In this respect, Bradbury-Jones et al. (2008) distinguish between the power of nursing knowledge versus medical knowledge, and the power imbalance between patient knowledge and that of the healthcare team. The authors encourage nurses to be alert to disqualified knowledge in the context of themselves and patients, and consider how both they and patients could be disenfranchised within less respected discourses. Applying Bradbury et al.'s analysis, I suggest that as patients become more familiar with medical and nursing discourses the power imbalance may begin to shift as their opportunities for empowerment are increased as within this study.

However, looking at the issue through a post-structural lens, I suggest that being 'required' to adopt the language of another could be perceived differently as demeaning and disempowering. This analysis does not contradict Bradbury et al.'s position but rather acts as an extension of it. The authors encourage nurses to reflect on knowledge-power relationships and suggest that an understanding of these relationships can promote empowerment. Learning the language of another is not necessarily problematic if there is a mutual recognition of the value of an alternative discourse. Knowledge transfer needs to involve a two-way process. In this sense, while patients are more suitably equipped to engage in discussion with their healthcare professionals, the dialogue will only become of more enduring value if there is a corresponding willingness among healthcare professionals to understand the patient story. Freire's (1970/2012) approach to empowerment can be used, in association with Foucault's post-structural understanding of power, to engage with patients in a way that empowers them and maximises their autonomy.

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In *Pedagogy of the Oppressed,* Freire (1970/2012) signifies the importance of education as a means to empowerment. While Freire's work emerged through an understanding of the role of education in empowerment in a political sense, his work has an enduring appeal in a broader pedagogical context. His theoretical perspective is relevant here in terms of understanding the role of education within the experience of autonomy in self-testing, yet also the importance of real engagement with the other. Freire's concept of dialogical practice is significant here. Freire's work offers an interesting contribution as it refers to the 'manner' in which an empowering education process could evolve. Freire's work has been previously applied by others to underpin a suitable model of empowerment in diabetes education, whereby the focus is on maximising user's autonomy and not compliance with prescribed treatment (Anderson and Funnell 2010). For Freire, the essence of education is not to bring those marginalised into the fold but rather to alter the fold so that it appreciates their contribution:

> The truth is, however, that the oppressed are not "marginal," are not people living "outside" society. They have always been "inside" – inside the structure which made them "beings for others." The solution is not to integrate them into the structure of oppression, but to transform the structure so that they can become "beings for themselves." (Freire 1970/2012, p.74)

The experiences of individuals in this study, and the enthusiastic manner in which some patients share these experiences, suggest that while education is of critical importance in supporting autonomy, additional supportive engagement is also required. There is a need to listen to the patient's story. This aspect of the phenomenon is explored within the theme: *No room at the inn.* What is most salient here is that these stories might never have been told in the absence of the research study. This signals the need for interaction with patients that offers meaningful engagement with them and their story - Freire's dialogical practice (1970/2012) offers a means to progress this type of engagement.

However, there are difficulties associated with educational provision and wider patient engagement. While all healthcare professionals interviewed note the importance of educational initiatives, time and financial constraints are also evident. The sub-theme

'*No room at the inn*' explores the extent to which the lack of availability of healthcare professionals is acknowledged by both patients and the healthcare team. The time pressures faced by healthcare professionals in this study, and their acknowledgement of insufficient opportunity to engage with patients on a more psychosocial level, mirrors the broader contemporary concerns of nurses. A study, undertaken in the UK, as part of the European Seventh Framework research programme in nurse forecasting, RN4CAST,[70] points to 'care left undone' by nurses due to a lack of time (Ball et al. 2013). Activities most frequently left undone by nurses were comforting or interacting with patients (66%) and educating patients (52%). These findings were replicated in the more recently published Irish results (Scott et al. 2014). A recent study exploring patients' abilities to assimilate DAFNE principles into their everyday lives highlights the importance of engagement with healthcare professionals in addition to other factors (Murphy et al. 2011). Five factors were seen as important in facilitating this adjustment: embedded knowledge, continued responsive support, enduring motivation, a relationship shift and being empowered. This study lends further support for the interconnecting series of factors necessary for successful self-care management as explored previously in the discussion.

HCP4 acknowledges specifically the lack of psychological support available for individuals with diabetes. However, the lack of engagement with the more affective aspects of the patient's history cannot be attributed solely to a lack of time. There is some indication in the data that it is not always perceived as necessary. Patients' expectations may be viewed as unrealistic. In a 'tongue and cheek' reference to the perceived hierarchy of 'scientific' data, Brody suggests that the physician who does not pay heed to the patient story as a significant source of data, "might as well go into the laboratory and try to study slides through a dirty microscopic lens" (2002, p.134). Brody asserts the significance of the patient's narrative that involves a shift in how we perceive medicine. For Brody, medicine is less about "biomedical abnormalities" and more about "what the patient is thinking" (2002, p.138).

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[70] For an account of this European study see Sermeus W., Aiken L.H.; Van Den Heede K. et al. & RN4CAST consortium (2010) Nurse forecasting in Europe (RN4CAST): Rational, design and methodology. BMC Nursing, 10, 6. Available online at: http://www.biomedcentral.com/content/pdf/1472-6955-10-6.pdf (Accessed November 7th 2013).

Supporting this analysis in a specific diabetes context, Abbot et al. (2007) suggest that an unnecessary focus on the technicalities of self-monitoring precludes a more detailed engagement with patients regarding other aspects of their care. The authors propose that self-monitoring may serve as a "proxy" for patient engagement (Abbot et al. 2007, p.10). The patient story is however essential to the overall success of self-monitoring and one's ability to exercise autonomy. This is central to *The interdependent phenomenon of autonomy in self-testing* presented in this study and the associated existential understanding of chronic illness. The realities of everyday life impact on the patient's ability to act autonomously, as patients are obliged to "internalise medical acquiescence in relation to the erratic character of life" (Mol 2000, p.19). An understanding of *Autonomy as lived,* as outlined in this study, emphasises the contingent nature of patient autonomy relative to their personal experience of illness. Trento et al. (2008) support the importance of psychosocial care in the management of diabetes and the impact of emotional issues on capacity for self-care:

> To help persons with diabetes manage their condition, health professionals need to widen their understanding of human behaviour. Caring for diabetes is radically different from the treatment of acute illnesses, and therefore requires a different conceptual framework to inform the operator's behavioural, educational and clinical approaches.... Emotional responses appear to be closely connected with attitudes towards the disease reflecting the patients' psychological adjustments and how much responsibility they are prepared to assume for self-management. (Trento et al. 2008, p.86)

In accordance with the phenomenological analysis in this study, it could be argued that the existential experience of acute illness may not be entirely different to that experienced by diabetic patients, as issues with regard to the 'lived body' in illness are similar in some respects, regardless of the illness course.

To conclude, key factors in the patient experience of *Autonomy as lived* are related to their interaction with healthcare professionals. This includes the role of healthcare professionals in patient empowerment through the process of education. Education provides patients with the knowledge and practical skills necessary to engage in more autonomous behaviour, and plays a role in shifting the balance of power between patients and healthcare professionals, as it provides patients with access to a respected discourse. Also significant in interaction with healthcare professionals is the lack of

engagement in more psychosocial dialogue. Due to a lack of time, or a lack of perceived importance, this prevents the healthcare professional from capturing the existential nature of the patient's illness, and impedes the mutual interaction that is central to patient empowerment. These factors are important considerations in terms of operationalising *Autonomy as lived* in practice, and will be addressed as discussion proceeds.

6.3.3 Respecting autonomy in different ways

The sub-theme of *Autonomy versus covert paternalism* particularly highlights the contextual reality of respecting patient autonomy in the healthcare setting, and the tensions that can be associated with this from a healthcare professional perspective. While healthcare professionals may profess a rhetoric of patient empowerment and autonomy, in the lived world of practice this can be an onerous task, which may conflict with other morally justifiable values related to considerations of patient well-being, preventing harm and professional responsibility. Such considerations influence the manner in which patient autonomy is respected in healthcare and the nature of patient choice. The wider sense of power inherent in the healthcare system is also evident in Alex's frustrations regarding the failure of the system to facilitate easier access to necessary supplies. This impacts on his autonomous behaviour. As noted in the findings chapter the question of paternalism is raised as an observation and not as a criticism. This section teases out some of the more paternalistic concerns that may motivate an alternative perspective on patient autonomy

The empirical study highlights a number of instances where patient autonomy becomes problematic for healthcare professionals. There appear to be two competing concerns or values at play here: a concern for patient autonomy and an acknowledgement of one's professional role to act in the patient's best interest. Is it morally permissible to 'coax' patients into doing what healthcare professionals believe to be in their best interests? There is evidence of this approach among the healthcare professionals interviewed in this study. However, the manner in which healthcare professionals engage with patients to influence a change in behaviour exhibits subtle differences. Some healthcare professional's narratives suggest a greater understanding and respect for the patients' story than others, and a more nuanced approach in addressing issues

of concern. I suggest at this point that these subtle differences are significant and will return to them as an alternative construction of autonomy is developed.

For now, I draw on the earlier analysis of autonomy presented at the outset of the study. In specific reference to patient autonomy and the clinical relationship Olsen (2003, p. 705) refers to "the ethical use of influence" within a patient/clinician context. Olsen proposes that influence is not only 'intrinsic' but 'desirable' within the clinical relationship. Olsen's discussion centres on the process of coercion in mental health practice whereby the use of coercion is justified in a rights-based approach. In accordance with this approach, the patient is seen as an autonomous self-governing agent who has the right to act free from external influence. In this context, coercion is justified only if the patient lacks capacity to make a judgement or may cause harm to himself, or others. Olsen offers an alternative relational approach whereby influence is seen as a constant feature of the clinical relationship and treatment decisions are continuous and subjective. The relational approach demands that every action of influence, despite its magnitude, is assessed for its ethical suitability. Therefore, respect for patients is paramount throughout and the power relationships are continuously acknowledged. In accordance with this understanding of 'ethical influence', healthcare professionals seek to protect patient welfare in their interactions with patients.

Dooley and McCarthy (2012) support an interdependent approach in healthcare decision-making. The authors suggest that persuasion is legitimate in the patient/healthcare professional relationship, but that coercion and manipulation are not. They recommend a dialogical approach based on shared communication and professional engagement. This resonates with the relational accounts of autonomy within the literature review whereby concern for the other takes precedence over a blind reverence to autonomy. 'Protective responsibility' (Holm 1997), 'protective empowering' (Chiovitti 2008) and a 'logic of care' (Mol 2008) all suggest that more is required. Participants in Chiovitti's study (2008, p.210) "described a consistent interplay between protecting and empowering patients". Healthcare professionals in this study display a similar interplay in the context of diabetes care. Downie (1998) contends that a degree of paternalism is inherent within a professional relationship,

whereby the principles of beneficence and non-maleficence may on occasion take precedence over respect for individual autonomy. This perspective in the literature – the need for healthcare professionals to move beyond an unwavering reverence of patient autonomy - supports *The interdependent phenomenon of autonomy in self-testing* in this study. Autonomy is revealed as an interdependent, contextual process whereby healthcare professionals recognise their professional responsibilities towards patient welfare, and may on occasion minimise patient autonomy in their practice, or facilitate autonomy through supportive interactions.

The restriction, or promotion, of patient autonomy arises in the study in situations of choice. While HCP1 refers to the importance of patients making choices relative to their own perspective, and supports this position in much of his narrative, there is some evidence to the contrary within his perspective, and that of other healthcare professionals. His interactions with the patient who initially resisted insulin administration provides an example of this. Similarly, references to 'coaxing' the patient and 'keeping them coming back' by other participants suggests a process which eventually results in patients 'choosing' the options healthcare professionals believe to be in their best interests. There is also evidence of limiting the degree of choice afforded to patients with regard to the selection of a specific blood glucose monitor. This decision is made depending on the healthcare professionals understanding of the abilities of individual patients. As a registered nurse, I can resonate with this. If an individual may be further confused by the 'burden' of greater choice, I believe it morally defensible to limit their anxieties and share a monitor with them which does not impede their participation in self-testing but limits the technological capabilities it offers. The study also highlighted the subjectivity associated with the decision to extend a patient's level of education and possibly invite him/her to attend for structured education programmes. While this may be permissible, and sensible, in some patient perspectives, it is also possible that healthcare professionals are underestimating the abilities of patients in these examples. It may be that such practices are not examples of individualistic care, but rather constrain autonomy among a group whose degree of control is already compromised.

The 'nature' of patient choice in healthcare has been recognised elsewhere in the literature. There is an understanding that choices occur over time, and are influenced by healthcare professionals in different ways (Kukla 2005, Agledahl et al. 2011, Upton et al. 2011). Mol's (2008) 'logic of care' is presented as an alternative discourse to 'a logic of choice'. Mol's central argument is that more choice does not lead to better care and actually may negatively affect care. Upton et al. (2011) interviewed nurses about their interactions with patients regarding the selection of an inhaler for asthma management. Similar to the healthcare professionals in this study, the actual choice which patients were presented with was already mediated by the nurses in light of their assessment of patient need. Olsen (2003) sees influence as a constant feature of the patient/healthcare professional relationship, while Tauber (2005) refers to the inescapable dependence implicit in medical practice.

Kukla (2005) supports this analysis in the context of obstetric care. Kukla contends that an understanding of autonomy, as related to considerations of self-determination and informed consent in moments of discrete choice, is not a realistic interpretation of how autonomy is exercised in the healthcare environment. Kukla (2005, p.36) seeks to "decouple self-determination from autonomy, and to suggest an alternative working notion of autonomy that is not restricted to expression in punctate [once-off] decisions". Her account of the ongoing interaction between healthcare professionals and patients resonates with the process of communication and negotiation of care practices within this study:

> Notice that pregnant women are responsible for a great deal of ongoing self-management. Far from being the merely passive objects of medical care that they are deplored as being in some feminist discussions, pregnant women are expected to be active, self-disciplining participants in their own prenatal health care. At the same time, this extra-clinical, ongoing self-care is not independent of the professional, institutionalized health care delivery system, for these practices are both recommended and monitored by health professionals, and pregnant women are held accountable to these professionals for their self-management in routine and regular ways. Indeed, we regard checking in with and being properly monitored by medical professionals as essential to responsible health practice during pregnancy. This means that much of the care that falls under the purview of health care professionals and institutions actually goes on outside the clinic, and the responsibility for its execution is largely placed on patients themselves. (Kukla 2005, p.36)

Self-care was similarly directed and monitored by healthcare professionals in this study. As Kukla's analysis suggests (p.37), "a neat continuum between self-determination and paternalistic displacement of agency is an inadequate tool for measuring many healthcare activities". Kukla's account very much reflects the interdependence that is central to the phenomenon of *Autonomy as lived* and the associated co-existence of freedom and constraints. The dietary constraints and the 'bind' of self-testing which participants engaged in this study resonates with the self-care activities employed by pregnant women. As Kukla (2005, p. 37) explains, these "healthcare practices pervasively involve a mix of self-management and accountability to medical authority". Kukla's observations provide an alternative understanding of influence in healthcare professional/patient interactions. Kukla proceeds to explore the responsibility of patients in their relationship with healthcare providers in terms of a particular understanding of autonomy: 'conscientious autonomy'. This will be addressed later in the discussion.

As a final point, an interesting dimension to this discussion is that Frances valued the role of her healthcare professional in not conceding to her request to recommence insulin. Frances preferred the flexibility in her dietary intake that insulin facilitated and sought to recommence insulin. However, despite her physician's refusal to prescribe insulin at that point, as time progressed Frances noted being pleased with the outcome of the consultation. She had adjusted to the oral medication regime and particularly noted the expertise of the healthcare professional whose knowledge facilitated this outcome. Had Frances's physician been an advocate of autonomy, above other morally justifiable principles of beneficence and non-maleficence, this outcome might not have ensued.

This echoes Brody's (2002) perspective that in the healthcare arena patients may prefer their physicians to be powerful and willingly accept more subservient roles. Patients, in Brody's analysis do not seek out powerless physicians. On the contrary, patients "seek out the most powerful physicians and want very much for the physician to use that power on their behalf" (Brody 2002, p. 135). Empirical evidence offers some support for this perspective. Salloch et al. (2013) note that patients in their study,

diagnosed with pancreatic cancer, valued the professional opinion of their attending physicians, and placed a significant degree of trust in them, with regard to treatment decisions, particularly in the earlier stages of diagnosis. Similarly, Madsen et al. (2007) interviewed patients with ovarian or breast cancer about their experiences and perceptions of being asked to participate in a randomised controlled trial. The researchers refer to "loneliness of autonomy" as a unanimous experience among all patients related to their lack of knowledge and other resources required to make an informed choice. This 'loneliness' is evident in the following extract:

> I couldn't decide - I wanted the doctor to decide which treatment was the best for me . . .I just remember that I chose my own treatment, and I didn't feel good about that at all . . .I was really surprised that they put me in that situation with such a serious disease, and want me to make choices about my own disease. It had an incredible effect on me, I felt bad about it, and I couldn't get the doctor to just give me advice … (Ida [breast cancer, trial decliner, ovarian radiation] (Madsen et al. 2007, p.54)

In conclusion, in the real world in which patient autonomy exists, or does not exist, healthcare professionals value patient autonomy, but they also value patient well-being and the significance of their professional responsibilities. The nature of patient choice is sometimes restricted to promote patient well-being and prevent harm, while interactions with patients are motivated towards compliance with best-practice for similar reasons. As in the case of the patient examples outlined here, real autonomy involves a negotiation between patient and healthcare provider in recognising when expectations and desires may require reassessment. Patient autonomy is not best represented as a feature in unique moments of discrete choice. In long-term care a 'process' of ongoing interaction more accurately reflects the reality. HCP1 continued to see his patient who was on a self-imposed diet of seeds despite his professional misgivings, while Frances continued to engage with her healthcare provider and follow the plan of care prescribed despite her personal desire for alternative treatment. The nature of patient choice is sometimes curtailed in the real world of practice. An understanding of *Autonomy as lived* recognises the positive moral motivation behind such restriction, yet also acknowledges the potential for an inappropriate use of power if such limitations are not employed in tandem with patient engagement and assessment.

6.3.4 Technology, autonomy and the social world

Technology is a non-neutral entity. Its use occurs within the social world and there is a reciprocal relationship between technology and the social world. One's place in the world shapes one's use of technology; one's use of technology can in turn shape one's place in the world. This was evident among participants in this study whose engagement with the self-testing device was shaped by, and influenced, their personal circumstances. Deirdre's eagerness to manage her own health added meaning to the use of the device for her, while Con's use of the self-testing device reinforced his negative feelings about the chronicity of his diabetes. This human-technical interface underpins the lack of neutrality in the application of technological devices. In short, because technology is used by real people in dynamic situations, technology has the potential to do things we intend it to do, not do things we intend it to do, and do things we never intended it to do.

While acknowledging associated difficulties, Gubala et al (2011) associate self-testing technologies, in the context of chronic monitoring, with assisting individuals to manage their own health (Gubala et al. 2011). While this was true for some of the participants in this study, it was not necessarily the case for all participants. This section explores more specifically the human-technical relations, which the study findings portray, and their implications for autonomy. While the nature of human-technical relations in the study centred on the use of a blood glucose monitoring device by individuals with diabetes, the discussion will have some resonance for the wider community involved in the development of future diagnostic and chronic illness monitoring devices.

The nature of human-technical relations underlines the philosophy of technology discourse, which essentially sees technology as a non-neutral entity (see section 3.4 for a more detailed analysis of this discourse). This study adds to the work already undertaken by philosophers of technology, who have embraced empirical methods to illuminate theoretical discussion (Mol 2000, Willems 2000, van der Burg 2009, Boenink 2012, van der Burg and Swierstra 2013). Mol (2000 p.10) used the term "empirical ethics" to describe her use of real world situations to engage in philosophical work regarding the moral value of diagnostic devices. In an earlier

empirical exploration of the use of blood glucose monitors among individuals with diabetes Mol (2000, p.9) contends that "diagnostic devices actively intervene in the situations in which they are put to use". This is also true for this study. Echoing many of the observations made here Mol (2000, p.12) notes:

> And thus blood glucose measurement is not only a matter of producing numbers. It has many more aspects. Economy is one of them. As are the stresses and strains that come with it. The pain of pricking in fingers. And the practicalities of measuring.

The appropriate question to ask, as Mol (2000, p.20) suggests, is not "What does this technology do?" but rather, "What may this technology do under which specific circumstances?" Here I attempt to pose some answers to this question in the specific context of the self-testing device and patient autonomy.

As a starting point technology has the potential to promote autonomy as intended but only in certain circumstances. As previously explored, the self-testing device promoted autonomy for some participants, albeit a freedom with certain constraints. For those individuals there was a positive synergy between the individuals' relationships with the device, their illness and health care providers. A central feature of this autonomy was the initial awareness of their bodies, which the self-testing device facilitated. The ability of self-testing to enable participants to be more aware of their bodies, their diabetes, and their blood glucose readings, was positively recounted by some participants in this study and noted within the theme: *Knowing the body*. This aspect of self-testing is also acknowledged elsewhere in the literature. The qualitative component of the DiGEM study (Farmer et al. 2009b) interviewed 40 patients about their experiences of self-testing. 'Awareness' emerged as one of the three thematic findings of the qualitative analysis. Participants noted the role of monitoring in assisting them to understand the relationship between blood glucose levels and felt symptoms and the physiology of blood glucose control with regard to lifestyle behaviours.

Peel et al. (2007) specially refer to participants' increased awareness of their bodily signs as they are engaged in self-testing over time. For some participants their

subjective knowledge of their blood glucose levels led to a reduction or cessation of self-testing. Participants within Peel at al.'s (2007) study noted the reassurance of self-monitoring and listed this as one of the reasons to continue the process. The DiGEM study also noted the sense of reassurance that awareness of their blood glucose levels created for patients, and the role of self-monitoring as a motivating factor in adopting more healthy behaviours (Farmer et al. 2009b). In this study, Ann refers specifically to the role of self-monitoring in creating awareness and its significance in incentivising her to live a healthier lifestyle. Her perspective very much resonates with one of the participants in the DiGEM study who notes:

> I think you can certainly tell whether you've eaten the wrong things. Or whether you've overdone it and then you obviously need to go and correct that by doing exercise or being extremely good you know. (D33, 45-year-old-woman, DiGEM study, Farmer et al. 2009b)

The role of self-monitoring in assisting patients to evaluate the effect of behaviour changes was also highlighted in Barnard et al.'s (2010) survey of patients with type 2 diabetes. However, the study also highlighted that few individuals utilised results to alter medication. The authors note that this is not uncommon, as oral medication is generally not altered by patients. For many of the participants in this study the awareness of their blood glucose levels was positively evaluated. The more negative experiences associated with awareness will be addressed as the discussion proceeds, but for some of the patients who referred to knowing their bodies in more favourable terms, their experiences of autonomy were more pronounced.

However, technology will not always do what we intend it to do if there is a problem in one of the interdependent relationships. There are many different facets to these relationships, as explored within the findings chapter, which impact on the extent to which a self-testing device promotes self-management and autonomy. This matrix of interdependence, as presented in Figure 3 in the previous chapter, is theoretically, and sometimes graphically, reflected in other studies that address patients' engagement with technology in a self-management context.

Lehoux (2004) points to a number of technical and human dimensions that collectively shape user-friendliness in technology. These include technical dimensions, such as the functionality of the device and its physical properties, and human dimensions such as the user's knowledge, skills, sociality, self-image and self-efficacy. Lehoux associates self-efficacy with patient autonomy. The human dimensions within this study have already been explored in detail in this chapter and share many similarities with those identified by Lehoux. The technical aspects of the device were also significant for participants in this study. However, for the most part participants seemed to accept any less-than-ideal technical issues as part of the 'bind' of the self-testing process. Practical details regarding the device such as its size, its number of component parts, its potential to induce pain and its visibility may not just impact on the degree of comfort, which users experience, but may also, influence their decision to use it at all.

In this sense, the practical aspects of the device are significant in its ability to facilitate more autonomous roles. While advances in technology are acknowledged, many participants refer to the cumbersome nature of the device, particularly with regard to the number of component parts. Participants also relate their desire for more instantaneous, discreet and less invasive monitors. The importance of such practicalities to patients is noted in other research. Mol (2000, p.20) suggests, "fighting with a burdensome machine may spoil the day. So it is quite likely that tiny practicalities are responsible for the success or failure of an apparatus". Similar to the participants in this study, previous research has shown that while participants associate pain with self-testing it does not cause them to cease monitoring (Farmer et al. 2009b). Both healthcare professionals and the scientific community participants acknowledge the pain factor and the need for developments in this regard. The wider diagnostic community are currently exploring the possibilities of non-invasive monitoring, and appreciate its importance among diabetic populations (Gubala et al. 2011).

An interesting dimension is that technology may do things we never intended it to do. Distress, anxiety and guilt, as outlined in accordance with the theme *Unwelcome burdens,* are examples of this. The experience of anxiety among individuals who self-test has been reported elsewhere in the literature (Barnard et al. 2010). Similarly, feelings of guilt and self-chastisement are noted in other studies (Peel et al. 2007,

Farmer et al. 2009b, Clar et al. 2010, Barnard et al. 2010). As explored within the analysis stage, Willems (2000), in a broader self-management context, highlights the association between self-management strategies and personal blame for poor medical outcomes. As patients are more involved in their medical care, there can be a tendency to apportion blame to one's self, when strategies employed do not result in more favourable results, despite the possible non-behaviour related causes. In a shifting of roles, patients share the responsibility for health management along with the healthcare team and correspondingly share accountability when the disease is not 'effectively' controlled. Peel et al. (2007) make the point that the sense of failure experienced by individuals with diabetes may be inappropriate. While health related behaviours might be of benefit in terms of overall blood glucose control, as evidenced by HbA1c, their impact may not be seen in more immediate self-testing results.

The continual awareness of one's blood glucose levels also has the impact of increasing one's perceptions of chronicity. This is a significant factor in mediating the participants' experiences of autonomy and reflects findings in other studies. Harris and Cracknell (2005) note that patients expressed relief at not having to continuously self-test, and equated this relief with the tendency for self-monitoring to reinforce perceptions of ill-health. Similarly, Thompson et al. (2013) highlights that home-based blood pressure monitoring acts as an unwelcome reminder of ill health among participants. Echoing the sentiments expressed by Con in this study, one of the female participants in the DiGEM study describes self-testing in the following manner:

> …a sort of reminder of the fact that you know that I I've got something wrong with me…I don't like to be reminded particularly. (D15, 67-year-old-woman, group 2, Farmer et al. 2009b)

This reflects the spatial dimensions of the self-testing experience as explored in interpretation in the previous chapter. Through engagement with the self-testing device, the presence of diabetes and the ill body are no longer 'invisible' states. High blood sugar readings make the reality of a diabetes diagnosis and ill health more apparent. The 'ill' body, previously hidden and 'ready-to-hand', is now revealed in its 'unready-to-hand' mode and becomes 'present-to-hand' through use of the self-testing device (Heidegger 1927/1962).

An interesting dimension of the device with regard to its human-technical relations is that it has the ability to simultaneously promote and constrain one's freedom. Previous studies have found that freedom and restraint co-exist in terms of home technology use, which reflects a complex understanding of the association between technology and autonomy (Mol 2000, Lehoux 2004, Fex et al. 2009, Thompson et al. 2013). Hofmann (2003) coined the term 'technological paternalism' to expand traditional notions of paternalism. "Technological paternalism" extends paternalism "beyond intentional reduction of individual autonomy to also include altered autonomy due to epistemiological and societal frameworks" (such as technology) (Hofmann 2003, p.351). Essentially, technology alters the landscape in which patients and healthcare professionals interact. I suggest that the potential surveillance role of technology, as identified in this study, provides an example of the altered epistemic and social structures to which Hoffman refers. Willems (2000) refers specifically to the surveillance induced by a peak flow breath-monitoring device. Willems compares the self-monitoring device to a "Trojan horse" (p.29) which intrudes into patients' home lives, and limits their privacy with regard to compliance with prescribed self-management strategies.

The scientific community focus group participants vary with regard to the extent to which they believe patients should be autonomous in their care and the role of technology in this regard. There is a tension between the patient having greater ownership of results and their ability to manage results effectively. This may be attributed to their role in developing point-of-care devices for use under clinician supervision, as opposed to self-testing devices. One participant supported the movement towards a connected health agenda, whereby patients would be required only to take a result and not actually interpret it. I suggest that this development, if indiscriminately employed, could potentially disempower patients. While some patients would value a smaller role in interpretation, a connected health agenda could potentially remove the sense of 'being-in-control' that the monitor allows for others. The value that participants place on self-testing, as noted in their narratives, is not merely that it allows them to physically test at home, but rather that it permits them to

live more autonomously with their diabetes, through taking an active management role in their illness.

It is also significant that despite the various human-technical interactions revealed in this study, including negative experiences, there was no evidence of a formal review of the self-testing process. Healthcare professionals acknowledge that self-testing may need to be discontinued for some individuals with type 2 diabetes who experience difficulty. Any issues are addressed once they arose in consultation, but this was not in response to a structured evaluation of self-testing. HCP3 noted that desirable follow-up with patients, who had recently commenced self-testing, did not take always place due to time constraints. There was limited reference to specific guidelines or particular research studies with regard to self-testing among HCPs when asked, despite relating knowledge of current evidence during interview. The varied experiences of patients in this study support recent guidelines that stress the importance of individuality with regard to the use of self-monitoring (International Diabetes Federation 2009, American Diabetes Association 2013). NICE (2011) guidelines also suggest that self-testing be evaluated annually to determine how results are managed, the likely benefit of continued self-testing and the impact of self-testing on the patient's quality of life.

It is apparent from the discussion here, that while the use of the self-testing device promoted autonomy for some participants and assisted them to live more independent lives, this did not occur in all cases. The varied experiences of participants engaged with self-testing technology in this study, point towards the ontological implications of technology that may often go unnoticed, and are seldom anticipated. For Heidegger, (1955/1966, p.50), the 'greatest danger' of technology is that it would shape our being in ways which we would not notice as "the power concealed in modern technology determines the relation of man to that which exists". More modern philosophers of technology refer to these 'unintended consequences' as the 'soft' impacts of technology. Such impacts occur over time and are not considered at the trial stages of development. Soft-impacts of technology involve more cultural issues related to "changes in our way of perceiving, acting, valuing, hoping and relating" in comparison to more 'hard' impacts related to technological hazards and economic benefits (van der Burg and Swierstra 2013, p.4). Mol (2006) articulates the unintended outcomes of

technological interventions specifically in the context of blood glucose monitoring. Echoing Willems' (2000) perspective, Mol (2006, p.48) refers to the "unexpected effects" of technologies which "generate forms of pain and pleasure which nobody predicted". Evidence of such unintended 'pain' is evident among the participant experiences recounted in this study.

What is significant here is that those involved in the early stage of device development, the scientific community participants interviewed in this study, did not engage with patients in a manner that may potentially highlight some of these consequences, even at the earlier proof of concept stage. It is not that the scientific community participants were insensitive to the potential difficulties which may arise for patients, but rather that their frame of reference was more focused on quantitative efficacy based outcomes: the hard impacts of technology. The role of the laboratory scientists in this study was not unusual. Their prime role in ensuring clinical accuracy and reproducibility of results explains their quantitative focus.

The scientific community participants are working in the laboratory setting on research programmes agreed through the Institute's clinical, academic and scientific partnership. Primary intelligence gleaned from patients, but in most cases indirectly from clinical research leads, and secondary desk-top research, is utilised to validate new programmes, highlight limitations in current technologies and apply for funding. However, the extent to which initial validation is sufficient, in the absence of further more qualitative investigation is debatable. While the researchers interviewed in this study are primarily involved with 'getting the science right', and ensuring the device's suitability for clinician use (see section 1.3.4), there are implications of this science, that may impact on a patient's day to day experience of the device, in ways which may not be imagined without more focused exploration. For example, in the context of the connected health discussion above, while some patients may value a less autonomous role, others may be disempowered if they lose the ability to interpret results. In the absence of engagement with the patient perspective beyond clinical efficacy, there may be a mismatch between innovation and specific patient need. As an additional example, should the urea breath monitor be utilised as a personal monitoring device in the future, this may have implications for patients whose ammonia levels are not significant

enough for emergency dialysis, but may cause concern over a weekend situation when, depending on geographical location, the dialysis unit may be closed. Conversely, for a growing number of patients who undertake haemodialysis in the home environment, the ability to self-test dialysis efficacy following treatment, may provide reassurance and self-management opportunities for patients similar to the participants in this study. These 'soft' impacts of technology cannot be imagined without greater patient engagement or reflection.

The scientific community participants seemed to welcome further engagement with the patient experience. Participants positively evaluated their experiences in the focus group. The focus group interaction was viewed as an opportunity to reflect on the end-user applications to a greater extent as opposed to primarily considering how things work. SCP2 also made the interesting point that collaboration could occur in both directions, whereby scientists could engage with end-user stakeholders, but yet also these stakeholders could engage with scientists to more fully understand the technological know-how underpinning certain aspects of device construction.

In summation, technology in this study, as an integral component of *The interdependent phenomenon of autonomy in self-testing*, both constrained and promoted the autonomy of its users. The impact on autonomy, as reflected in other studies, depended on the individual patient's relationship with the device relative to other factors. It is also apparent that the technology resulted in both intended and unintended consequences for users. A series of interacting factors were necessary for the technology to work as desired and positively impact on patient autonomy. This reflects the analysis of autonomy as an interdependent phenomenon, as presented in this study, and develops a greater understanding of autonomy in a clinical context. The discussion also has relevance for healthcare professionals in the specific context of diabetes management, yet also in a broader self-management framework when home-based technology is an integral part of care. The discussion is also pertinent for those working in the scientific community as it suggests the need for greater reflection and engagement with the soft impacts of technology.

6.3.5 Final thoughts: Conceptualising Autonomy as lived

In general, the study findings support an interdependent understanding of autonomy. Autonomy is context dependent and cannot be created solely by use of a technical device, as it is more relationally constituted. Autonomy exists within constraints, including those internally imposed by the existential experience of illness and is dependent on real patient engagement and a recognition of mutual responsibility between patient and healthcare professional. This sense of autonomy correlates with more relational perceptions of autonomy, in comparison to an autonomy associated with negative freedom, often subscribed to in current health care policy and practice. Such perspectives often rely on a misguided understanding of Kantian philosophy associated with independence, isolated decision-making and freedom of choice. The reality of autonomy for participants in this study, who take some control in the presence of various constraints, is quite different to the self-determining individual who, in accordance with Beauchamp and Childress (2013, p.101), "acts freely in accordance with a self-chosen plan". This study adds to the philosophical analysis already in the bioethics literature which suggests that autonomy needs to be understood in a different way (Meyers 1989, Holm 1997, Downie 1998, Seedhouse 1998, O'Neill 2002, Scott et al. 2003a, Christman 2004, Tauber 2005, Whitney and McCullough 2007, Moreno 2007, Harnett and Greaney 2008, Kearns et al 2010, Chiovitti 2011, Agledahl et al. 2011, Greaney et al. 2012).

As previously noted the concept of 'actual autonomy' as advocated by Agich (1995, 2003) provides a means of understanding the expressions of autonomy revealed by participants in this study. However, at this point I propose that this relevance goes beyond support for the individual theme of *Autonomy within constraints* to incorporate the wider phenomenon. Agich coined the term 'actual autonomy' as "central to any philosophical theory that adequately accounts for autonomy as a concrete feature of persons developing, interacting and living in the world of everyday life" (2010, p.110). The conceptualisation of 'actual autonomy' came about through Agich's empirical and philosophical work exploring expressions of autonomy in long-term care and care of the older adult (1995, 2003). He subsequently applied this treatise on autonomy and long-term care to other settings including chronic illness (1995). 'Actual autonomy' holds much resonance for the findings in this study as it reflects an autonomy that is

in some ways constrained, is context dependent and relies on a degree of interdependence:

> Actual autonomy is the term I came to use to characterize the non-ideal expressions of autonomy in everyday life. So regarded, the concept of actual autonomy has to account for the fact that, as individuals, we develop relationally and that our actions, beliefs and thoughts are invariably shaped by biological, psychological as well as social factors. (Agich 2010 p. 109)

Agich was concerned that the manner in which autonomy was conceptualised in the ethics literature did not take account of patient narratives and was overly concerned with the polarised positions of positive and negative liberty.[71] Agich proposes that a more realistic account of autonomy, 'actual autonomy' does not reject the value of liberty, but embraces the notion of relationality that is central to more positive accounts. A phenomenological understanding of existence is central to Agich's perspective. He utilises the concepts of temporality and affectivity to explain the context-dependent nature of autonomy in chronic illness. For Agich (1995, p.137), "actual autonomy is not best understood in terms of decisional nodes but in the daily ebb and flow of action and experience".

Agich's account of 'actual autonomy' supports the understanding of *Autonomy as lived* or autonomy as an interdependent phenomenon, as revealed in this study. What therefore does the concept of *Autonomy as lived* offer to the autonomy conundrum identified at the outset of this study? How can healthcare professionals operationalise an understanding of *Autonomy as lived* in the everyday world of practice? What does the existing bioethics literature have to offer in this regard and what else is required? I now turn to these questions.

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[71]In a later commentary of his work, Agich (2010) acknowledges that as his research took place in the mid-eighties, the subsequent development of feminist ethics has resulted in a more relational perspective on autonomy in the ethics literature. I would also add that the subsequent growth of empirical bioethics (see section 3.2) makes his work more revolutionary in that time.

6.4 Revisiting the autonomy conundrum

Autonomy as lived is different to autonomy as frequently conceptualised in a healthcare context. The interdependent expression of autonomy within this study, as a contextual process based on mutual responsibility, does not accord with many of the negatively orientated accounts of autonomy referred to in the bioethics literature. However, from the analysis to this point, I suggest that alternative accounts of autonomy (which recognise and morally defend the need for interdependence and healthcare professional influence) may also fall short of a pragmatic account of patient autonomy in healthcare, despite their obvious appeal in some respects.[72] In order to present an alternative 'working' account of patient autonomy, which recognises the empirical findings and acknowledges the strengths and limitations of other prevailing accounts, I return here to the initial ethical analysis of autonomy presented in chapter two (see section 2.2.3). The empirical work, and subsequent discussion, necessitates refinement and development of this initial analysis, as McMillan and Hope's (2008) model of empirical ethics proposes it should. The original argument can be outlined as follows:

Initial argument:

> **Premise 1:** Current healthcare ethics and recent social policy documents uphold patient autonomy as a paramount ethical principle.

> **Premise 2:** This model of autonomy goes beyond merely encouraging participation as autonomy is increasingly portrayed as individual freedom to choose.

> **Premise 3:** Such a model is not a suitable benchmark for healthcare policy, or professionals, because (a) it represents a one-dimensional, sometimes misguided, perception of autonomy associated with the absence of constraints and (b) it denies important considerations of relationality, care and responsibility, which may better serve patients.

> **Conclusion:** Therefore, healthcare practice and policy, which uphold the primacy of autonomy and equate it with increased patient choice and freedom in decision-making, should be reviewed, or at least accepted with caution.

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[72] From this point I refer to such accounts of autonomy as 'moderate' accounts, reflecting a less emphatic appeal to autonomy in light of other concerns.

I propose at this point that the initial argument retains its validity, in light of the supporting premises (this study further supports the moral imperative of healthcare professionals to look beyond negative perceptions of autonomy towards patient welfare), but that other considerations, gleaned through empirical investigation, now render this original analysis incomplete. An understanding of autonomy as occurring in tandem with constraints, and the contextual nature of autonomy in light of the existential reality of the patient experience, also merit consideration. Other perspectives, notably the importance of meaningful patient engagement and patient responsibility for their own healthcare are also of significance. This understanding of *Autonomy as lived*, in association with the analysis of the bioethics literature to this point merits a reappraisal of the initial argument. The revised argument represents an extension, as opposed to a rejection, of the earlier argument.

The initial two premises remain factually correct, as more recent additions to healthcare policy and ethical guidance suggest the ongoing prominence of autonomy as an ethical principle, and continue, for the most part, to associate this autonomy with independence and freedom in decision-making (Health Service Executive 2013, Nursing and Midwifery Board of Ireland 2013). The third and fourth premises also retain their significance. As analysis to this point suggests, negative accounts of autonomy are not representative of *Autonomy as lived* and care, relationality and responsibility remain important considerations in healthcare practice. The need to exercise caution with regard to elaborated accounts of patient autonomy, based on freedom to choose, remain well founded on the basis of this study. However, further consideration is required to outline how *Autonomy as lived* can best be respected or operationalised in the healthcare context. The original argument concluded with preliminary considerations regarding a more suitable account of autonomy for clinical practice. I now seek to extend these preliminary considerations in light of the empirical work and further discussion. I therefore present the following argument as an extension to the original:

Revised argument

> **Premise 1:** A significant body of philosophical and empirical work recognises the limitations of negative accounts of patient autonomy, which focus on independence and freedom in decision-making. This body of

literature represents a more moderated account of autonomy, which points to the distinct role of healthcare professionals, and may require their influence based on considerations of care, relationality and responsibility.

Premise 2: Such accounts are insufficient, in isolation, to operationalise the understanding of *Autonomy as lived* presented in this study as (a) some may promote a return to paternalism, in an authoritarian sense, which I suggest is not in the best interests of patients or healthcare practice, and (b) other accounts, while representing a worthwhile contribution to the understanding of autonomy in the real world of practice, do not sufficiently encompass the contextual, patient-orientated, phenomenon of *Autonomy as lived* identified within this study

Premise 3: *Autonomy as lived* presents autonomy as an interdependent, contextual process, which relies on real engagement with patients, an understanding of the existential constraints on autonomy associated with ill-health, and a sense of mutual responsibility among patients and healthcare professionals to maximise patient welfare.

Premise 4: Interdependence, engagement, understanding and a sense of mutual responsibility, suggest that autonomy involves a collaborative, negotiated process.

Conclusion: An understanding of autonomy as a 'negotiated' concept more accurately reflects the reality of *Autonomy as lived* and represents a more pragmatic account of autonomy for application in healthcare practice.

6.4.1 Should we resurrect paternalism?

As the initial argument suggests, the bioethics literature has afforded particular attention to recognising the limitations of more negatively orientated accounts of autonomy, which focus on patient independence and freedom to choose in healthcare. I refer to such interpretations of patient autonomy as 'moderated' accounts. While deliberating on an account of autonomy that would best provide a 'workable' interpretation of *Autonomy as lived,* a return to paternalism was considered, as many 'moderated', or muted accounts of autonomy use language that is more suggestive of paternalism than autonomy. Terms such as 'beneficence-in-trust' (Pellegrino and Thomasma 1988), 'professional beneficence' (Gaylin and Jennings 1996), 'protective responsibility' (Holm 1997), 'principled autonomy' (O'Neill 2002), 'conscientious autonomy' (Kukla 2005); 'an ethics of responsibility' (Tauber 2005) and 'protective

empowering' (Chiovitti 2008), are all indicative of a paternalistic appeal[73] to beneficence and non-maleficence, based on the professional responsibilities of healthcare professionals. Autonomy is not of paramount importance. Protection, responsibility and care are common themes among these various discourses.

In addition to the concepts of care, protection and professional responsibility noted in the accounts of patient engagement above, *Autonomy as lived* suggests that other concepts are also significant, interdependence, engagement, understanding and mutual responsibility. In an effort to encompass these constructs the terms 'engaged paternalism', 'collaborative paternalism', 'permissive paternalism' or 'respectful paternalism' were considered as possible operational concepts. Why not reconfigure paternalism if the language of autonomy is inadequate to support the contextual reality of the patient/healthcare professional relationship? A retreat to paternalism may suggest a leap too far, depending on how the concept is defined and understood, but is none the less worthy of consideration. Should we resurrect paternalism? I intend to show here that this would be unwise. While many of its central tenets are worthy of consideration, a determined return to paternalism may signal an endorsement of an authoritarian healthcare system, which could potentially be as unacceptable as an over reliance on exaggerated libertarian accounts of autonomy.

A more comprehensive review of paternalism is warranted at this point. Beauchamp and Childress (2013, p.215) note the association between paternalism in healthcare and its lexical root as a form of parental administration, whereby "the analogy is that a professional has superior training, knowledge, and insight and is thus in an authoritative position to determine the patient's best interests". The appeal of paternalism in healthcare has diminished over time. However, Szerletics (2011, p. 2) notes that while paternalism has developed more negative connotations in accordance with the enlightenment project, and the more recent emergence of modern liberalism, this was not always the case.[74]

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[73] I am not suggesting here that these accounts endorse a return to paternalism, rather that, directly or indirectly, behaviours which could be viewed as paternalistic are supported.

[74] Szerletics's comprehensive account of paternalism was undertaken under the auspices of the Essex Autonomy Project previously alluded to in this study. While I summarise some of his

> Although the present attitude to paternalism is determined by these modernistic assumptions [the triumph of individualism and distrust of authority], paternalistic behaviour has not always been associated with pejorative connotations. Aristotle, for example suggested that the *polis* does not only have the right to act paternalistically toward its citizens, but often has a duty to do so. (Szerletics 2011, p.3)

Szerletics (2011, p.4) proposes that paternalism involves two core elements: "(1) the interference with the subject's autonomy and, (2) the benevolent aim of preventing self-harm or promoting benefit". It appears that, depending on the prevailing historical context, the former or the latter element may receive greater prominence at one point in time, i.e. an appeal to autonomy or benevolence. There is some evidence of a cautious resurgence of paternalism in the mid-eighties, as autonomy gained momentum in healthcare ethics (O'Neill 1984, Gillon 1985). However, the concept has now, for the most part, receded into the background to the point where paternalism is typically viewed as the antonym of autonomy, and classified as an "out of favour" (Gaylin and Jennings 1996, p.54), or "historically perverse concept" (Drolet and White 2012 p.583).

While paternalism can be classified in various ways (Szerletics 2011), in the wider bioethics literature the distinction between soft and hard paternalism has received greatest prominence (Dooley and McCarthy 2012, Beauchamp and Childress 2013). The capacity, and associated voluntariness of the individual whose will is overwritten is central to distinguishing between soft (weak) and hard (strong) paternalism (Szerletics 2011). While Beauchamp and Childress (2013) note the conditions necessary to justify hard paternalism,[75] there is a prevailing view that 'soft' paternalism is morally justified but 'hard' paternalism, which involves overriding the actions of a competent individual, is not. Dooley and McCarthy (2012, p.12) specifically refer to weak (soft) paternalism as "justified paternalism" which "overrides a non-autonomous person's decisions or controls their actions in order to protect them from harm or promote their good". While acknowledging that the

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observations here, a more thorough account of paternalism, and its various classifications, is beyond the scope of this work. Szerletics provides an excellent resource for further reading.

[75] See discussion p. 221/221 'Justified hard paternalism'

distinction between 'soft' and 'hard' paternalism represents a significant element of the bioethics debate, I propose that such a distinction is unhelpful in the context of the current discussion, as 'weak paternalism' may be construed as 'not' involving paternalistic behaviour as it does not involve denial of autonomy.

The core issue under discussion here is whether paternalism should be officially reinstated as a means to encompass an operational account of *Autonomy as lived*. This operationalised concept requires a means of reconciling respect for patient autonomy with the professional demands of beneficence and non-maleficence in the real world of practice. This creates tensions that are central to the autonomy conundrum identified in this study. Soft (weak) paternalism, involves no such tensions as it "does not involve a deep conflict between the principles of respect for autonomy and beneficence" (Beauchamp and Childress 2013, p.217). Therefore, for the remainder of the discussion I assume paternalism to consist of two principal elements, as Szerletics (2011) suggests; an interference with autonomy and the benevolent goal of promoting benefit or preventing harm. While not diminishing the significance of patient autonomy, I do not differentiate between 'soft' and 'hard' paternalism beyond this point.

Despite a general understanding that paternalism has fallen from grace, ongoing empirical work, including the current study, suggests that paternalistic considerations are very much at play in healthcare practice (Holm 1997, Chiovitti 2008, Lynöe et al. 2010). The reality of the healthcare environment suggests that the polarisation of autonomy and paternalism is unhelpful and impractical (Kukla 2005). The more moderated accounts of autonomy, outlined at the outset of this discussion, represent a deliberate attempt to bridge this gap and present 'a middle ground', which more accurately reflects the reality of the professional/client relationship in the healthcare environment. It is difficult however, to decide the extent to which the pendulum should swing in favour of either a more paternalistic, or autonomy-based understanding. The terminology utilised in the various accounts do not incorporate the word 'paternalism'

despite the obvious inclusion of paternalistic elements.[76] It is as if the sentiments of paternalism are employed without a return to paternalism, per se, or use of the actual word.

A recent study by Lynöe at al. (2010) makes this point explicitly. The researchers developed a tool to measure 'disguised paternalism' using the 'disguised paternalism index'. The index measured 'disguised paternalism' relative to the extent to which physicians prioritised non-maleficence over considerations of autonomy. The study concluded that only 3-4% of participants openly supported a paternalistic argument with regard to physician-assisted suicide, despite the presence of 'disguised paternalism'. While a more elaborate account of the study is beyond discussion here, it is sufficient to note that the study supports the significance of non-maleficence as a core issue for current physicians in clinical practice, despite the prominence of an autonomy rhetoric. The authors surmise that paternalism is disguised, since to support it more openly would go against current social norms. I believe there is particular merit in this assumption based on my observations in this study. The theme *Autonomy versus covert paternalism*, supports the appeal of paternalistic considerations among some healthcare professionals interviewed despite the wider parlance of autonomy. It is as if paternalistic considerations have gone 'underground' in some respects. Professional bodies endorse an autonomy focused healthcare culture despite the more paternalistic concerns of some healthcare professionals.

The legal context represents a significant marker of prevailing social mores. Irish law, reflecting the broader westernised context, has exhibited increasing support for patient autonomy in the context of healthcare practice. The Mental Health Act (Government of Ireland 2001) and the more recent Assisted Decision-Making (capacity) Bill (Department of Justice and Equality 2013) demonstrates an incremental support for patient self-determination in mental illness and other contexts where vulnerability may be established. However, there is evidence of some incongruence between legislative intent and interpretation in case law. A review of the *Interim Report of the Steering*

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[76] It is important to note that among empirical studies, the terminology used has evolved through analysis of data from the healthcare professional participants. In this sense, it is the participants who have exhibited a reluctance to name paternalism more overtly.

Group on the Review of the Mental Health Act 2001 (DoH 2012b) supports this analysis.

> The Mental Health Act 2001 introduced a human rights ethos into our mental health law. It was anticipated that the introduction in the Act of the statutory *"best interests"* principle would lead to a new emphasis on the rights of the patient, but the reality is that the principle has been interpreted by the Courts in a paternalistic manner. This paternalistic interpretation of the 2001 Act is undermining the significant advances in mental health law which the Act was intended to enshrine, and has given rise to concerns that the human rights aspects of the legislation have been diluted and diminished.[77]

It seems that the courts have endorsed the paternalistic intent of healthcare professionals in practice to some extent. This supports the analysis within this study that a rhetoric of autonomy prevails, in the legislation in this context, despite a more paternalistic reality. However, in the broader legislative framework, a patient's right to self-determination and autonomy is required of healthcare professionals by law, in accordance with a human rights discourse. Yet, for the individual healthcare professional, this may not necessarily alter an inherent motivation towards care and protection. As Tauber (2005, p.140) suggests, "the moral calculus of care doesn't change, only its legal implementation".

It appears therefore, from the analysis to this point, that paternalistic considerations are present in current healthcare practice, philosophical debate, and legal discourse, despite a reluctance to endorse paternalism in an overt way (albeit acknowledging the courts' paternalistic interpretations of mental health legislation noted above). However, this is not to suggest that respect for autonomy is obliterated, merely that it is afforded less supremacy in contextual settings. There is, it seems, a distinction between respecting one's right to autonomy and respecting autonomous choices. This is congruent with a distinction made by Seedhouse (1998) between respecting and creating autonomy. Creating autonomy may involve not granting an individual all their choices. In keeping with the distinction between positive and negative liberty outlined earlier in this chapter, denial of one's choices may maximise one's autonomy overall.

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[77] For a more detailed review of judgement in relevant case see the report p.10

In a somewhat similar analysis, Freyenhagen and O'Shea (2013) recognise the limitations of procedural accounts of autonomy in law, which, once certain criteria are satisfied, suggest non-interference with one's choices, regardless of the implications of those choices for the individual's welfare. (This reflects Donnelly's (2010) analysis of capacity as a "flawed gatekeeper"). However, the authors are also concerned that restraining one's autonomy because they make 'unsuitable' choices, as in substantive accounts, may "be unduly paternalistic, even authoritarian, and open the door to abuses of power" (p.65). The offer "indirect substantivism" as a possible alternative, a mid-way point of sorts, which seeks to "rehabilitate substantivism" (p.65). I propose that this 'indirect substantivism' is yet another means of addressing the 'autonomy conundrum', and another example of a more 'moderated' account of autonomy. It seeks to recognise autonomy, yet also promote welfare. However, while 'indirect substantivism' may be too abstract a concept for application in the clinical context, there are certain features of this account which are worthy of consideration. I will return to this later in the discussion.

Some 'moderated' accounts of autonomy make more overt reference to paternalism, and are worthy of consideration at this point. Van De Veer's (1986) 'Autonomy respecting paternalism' and, more recently, Drolet and White's (2012) 'selective paternalism' are such examples. While Van De Veer's (1986) 'autonomy respecting paternalism' holds initial appeal, on closer analysis it is apparent that he defers to consent based paternalism which does not justify paternalistic action on the basis of a duty to promote welfare or prevent harm. The individual's 'self-direction', and not considerations of beneficence and non-maleficence, is Van De Veer's primary goal. I propose therefore that Van De Veer's (1986) account is unhelpful as an operational concept as it does not support situations where healthcare professionals are faced with the need to choose between patient autonomy and patient welfare, particularly in the context of competent patients.

Another construct, "selective paternalism" is presented as a means to "describe the practice of situational decision-making by physicians" (Drolet and White 2012, p.583). This appears, at the outset, to provide a more appropriate means of operationalising

Autonomy as lived in a clinical context. The authors incorporate beneficence and non-maleficence as grounds for paternalistic action and focus on the process of decision-making in a clinical context. Paternalism is defined as "choosing a course of action in the patient's best interest but without the patient's consent" (Drolet and White 2012, p.583). However, here I turn briefly to part (b) of the second premise, and suggest that this means of addressing the autonomy problem in practice is not sufficiently patient-orientated to support the interdependence that is central to an understanding of *Autonomy as lived*. Drolet and White (2012) present their proposal with the aid of a diagrammatic framework to explain how selective paternalism could work in practice. The graphic outlines a number of factors that the healthcare professional contributes to the decision-making process: personal values, medical knowledge, standard of care and evidence-based medicine. However, by comparison the patient perspective is associated only with one element: personal values. The patient's knowledge base is not acknowledged.

As suggested in part (a) of the second premise of the argument outlined above, 'moderated' accounts of autonomy may sway so far towards a paternalistic perspective that they represent a return to an authoritarian health service. Even proponents of more 'moderated' accounts of autonomy acknowledge that in the absence of sufficient respect for autonomy the distinction between a more nuanced understanding of autonomy and paternalism may be lost (Holm 1997). This is the main reason why I resist a return to paternalism to provide a workable understanding of *Autonomy as lived*. I present one particular case as an example of this.

In *The Perversion of Autonomy* Gaylin and Jennings (1996, p.55) lament the passing of a more paternalistic approach to healthcare in the following account:

> In dealings between professionals and clients a conscious concern for autonomy has lead clients to lead a more active and controlling role. Nowhere is this more evident than in the practice of medicine, where an ethical and legal emphasis on the patient's right to 'informed consent' has supplanted the days of the benevolent physician … It is easy to see ways in which this represents a gain; individuals are better protected from the exploitation inherent in the unequal power of the professional-client relationship. It is less easy, but no less important, to see what has been lost. Professional beneficence and dedication to the well-being of the client has

suffered considerably from the recent autonomy orientated adversarial atmosphere.

This lament is appealing in many respects as it refers to the core of the autonomy conundrum in healthcare practice – how to negotiate two imperatives: respect for client autonomy with a professional duty to care for others. The authors suggest the need for a 'common sense morality', as "common sense tells us to reach out to those in need, to step up and take charge of a situation when we can clearly see disaster impending or needless hurt coming" (p.3). The authors' thesis is that a prevailing "culture of autonomy" promotes a "decadence" (p.5) and sense of abandonment, which is not in the best interests of society or the individual.

The authors make a distinction between the 'morality of interdependence' (and associated mutual responsibility) and a libertarian conception of autonomy. This distinction supports the understanding of *Autonomy as lived* presented in this study. However, despite its many appealing factors, a more thorough analysis of *The Perversion of Autonomy* suggests that, despite rhetoric to the contrary, the authors are concerned with social control to a greater extent than is consistent with a fundamental respect for autonomy. The following extract supports this analysis:

> There is something immoral about spending millions, even hundreds of millions, of dollars on programs to "educate" people to change their behaviour, when we know that what is necessary is either intimidation or coercion. (Gaylin and Jennings 1996, p.22)

Therefore, despite their proposal that the criticism of paternalism is well founded, I suggest that in reality, Gaylin and Jennings support a return to a more paternalistic model of healthcare, in an authoritarian, as opposed to benevolent, sense.[78]

At this point in the argument, I conclude that certain moderated accounts of autonomy have many appealing traits that could usefully be employed to support a workable definition of *Autonomy as lived* in practice. However, despite their incorporation of

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[78] It is important to acknowledge that in the public health sphere, to which the authors generally refer, there is more acceptance of a utilitarian approach to ethics. Nonetheless, I do support their overall appraisal of the autonomy/paternalism conundrum.

values such as care, protection and harm prevention, which could potentially justify a resurrection of paternalism, I reject a more overt return to paternalism as a means of operationalising autonomy concerns in practice. Even more 'moderated' accounts of autonomy, which appear at the outset to support autonomy and value interdependence and mutual responsibility, could potentially promote a return to an authoritarian, coercive paternalism as outlined in the example above. I therefore conclude that paternalism should not be resurrected as a means to underpin patient/healthcare professional interaction.

As previously discussed, paternalism has its roots in governmental, parental and later physician-based authority. Any concerted return to paternalism has the potential to extol authority and control over other considerations. I propose that what is required is a modest understanding of autonomy as opposed to a tempered conception of paternalism; an understanding of autonomy, which recognises the caring elements of paternalism, without a return to paternalism per se. A more considered account of autonomy is warranted which applies some paternalistic ideals of care, protection and responsibility in a broader autonomy-based framework. The various 'moderated' accounts of autonomy explored in some depth to this point offer possible considerations, but not comprehensive solutions. I now return to part (b) of the second premise in the argument outlined above, which suggests that any of the moderated accounts of autonomy explored are not sufficient in isolation, as they do not satisfactorily encompass the contextual, interdependent, patient-orientated phenomenon of *Autonomy as lived* identified within this study

6.4.2 Not just about healthcare professionals: The importance of engagement with and by patients

Autonomy as lived represents an interdependent understanding of autonomy that is reliant on engagement with patients to appreciate the existential reality of their daily lives when living with ill-health. However, it also demands that patients engage with healthcare professionals and accept responsibility for their own health and well-being. It is for this reason particularly that I find some attempts to deal with the autonomy conundrum problematic, as they lack sufficient orientation toward the patient perspective. This is the basis of part (b) of the second premise outlined above.

Chiovitti's 'protective empowering' (2008) and Holm's 'protective responsibility' (1997) have been explored earlier in this chapter as useful constructs in understanding the nature of autonomy in practice. While Chiovitti's work is based in a psychiatric setting, it retains relevance here as it explores the core of the autonomy conundrum: balancing concern for patient welfare with respect for autonomy. However, I propose that more is required in order to adequately respect *Autonomy as lived* in everyday practice. The core limitation with these perspectives is that while they acknowledge patient vulnerability, and healthcare professional responsibility, they do not sufficiently acknowledge patient capability and responsibility. This is an observation as opposed to a criticism; the lack of a patient focus is understandable when one considers the origins of these perspectives, neither of which emanated from a deliberate analysis of patient autonomy in practice. 'Protective responsibility' emerged as a core category in Holm's (1997) grounded theory study of the moral reasoning of healthcare professionals based on their self-reported accounts. Similarly, Chiovitti's (2008) theory of 'protective empowering' was constructed following interviews with registered nurses to identify the meaning of caring for patients in a psychiatric setting. As both constructs were devised in light of insights from healthcare professional participants, it is reasonable that they would be more orientated towards this perspective. Holm (1997) describes 'protective responsibility' as a virtue held by healthcare professionals based on deontological considerations of a professional duty to care. I believe this virtue is an important dimension to respecting *Autonomy as lived* but an understanding of the patient perspective is also an equally important dimension.

As portrayed in the study findings, *Autonomy as lived* recognises the importance of the patient actively taking control of the management of her illness. Those individuals who verbalised a preference for being more actively involved, as noted within the theme *Taking control*, indicated greater experiences of empowerment and autonomy related to self-testing. This aspect of the phenomenon was interpreted in accordance with the locus of control construct (Rotter 1966 cited in Lange and Tiggemann 1981). This suggests that those individuals who believe life events to be within their control cope more effectively with a chronic illness. The association between the active role of the participant and the sustainable use of technology in healthcare is noted by Barker

(2011). Barker points to the active participation of the patient as a core component of a successful and viable healthcare system. In accordance with analysis to this point, it is reasonable to accept that in addressing the autonomy conundrum in practice an understanding of patient vulnerability is essential. However, I propose that this understanding is incomplete without a corresponding appreciation of the inherent capabilities of patients to manage their own health, and their corresponding responsibilities in this regard.

Kukla (2005) uses the term 'conscientious autonomy' to describe the process of patients becoming actively involved in their own healthcare in a responsible way. As previously explored within his chapter, Kukla (2005) is also concerned with how healthcare professionals reconcile patient autonomy with professional responsibility. For Kukla (2005, p.38), Beauchamp and Childress's (2001) suggestion of non-interference as a marker of autonomy, is "impractical and problematic in many domains of health care practice". Conscientious autonomy "involves a particular type of responsibility": it implies "being responsible in our actions to standards to which we are committed" (p.38). This is significant, as it demands not merely that patients are involved in their care but that they adhere to certain standards of behaviour. Conscientious autonomy may involve patients adhering to healthcare regimes they view as undesirable in pursuit of good health. Kukla (2005, p.38) uses the expectant mother as an example.

> … the *conscientious* expectant mother will usually watch her diet, take childbirth classes, document fetal kicks, show up to doctor's appointments, and so on. Usually, she does these things neither because they represent her own self-chosen plan, nor because she is coerced into doing so, but because she is committed to the rightness of these practices and takes responsibility for diligently carrying them out.

This example reflects the experience of participants in this study who refer to the 'bind' of self-testing, yet continue to engage with the practice in pursuit of health goals. In accordance with the theme *Freedom within constraints,* the autonomous patient takes control of her illness while also exercising self-control with regard to dietary restrictions and self-testing practices. Kukla's conscientious autonomy is a "limited autonomy", underpinned by "responsible, committed action" which may on occasion

"involve the displacement of decisions and deference to experts" (p.39). It involves an ongoing process that moves beyond protecting patients' self-determination. It requires healthcare professionals to respect patient capabilities and assist them in understanding and managing their health. However, despite its obvious merits, on occasion Kukla's conscientious autonomy strays into more paternalistic ground. At one point Kukla refers to the weakness of character that may preclude patients from conscientiousness. While Kukla may correctly incorporate patient capabilities, I suggest that vulnerabilities are not always understood. However, the concept of conscientious autonomy is worthy of consideration as it suggests that patients do not merely have certain rights but also that they have certain responsibilities. What is important is that in care decisions patient capabilities are balanced with any vulnerabilities.

This echoes a particular theme in the literature that receives less prominence than other discourses, presumably, because it is politically incorrect. Redlich (2001, p.5) notes that in an increasingly medicalised society "we believe we can commit any health crime we wish, and that somehow, as by magic, medicine will wipe it out". A sense of personal responsibility is lost. A review of the 2002 European Charter of Human Rights suggests that patient rights may be articulated to the detriment of a more pronounced understanding of patient responsibilities (O'Mathúna et al. 2005). Barker (2011) offers a similar analysis to Redlich, ten years later, in the wake of further technological advances in healthcare. In this extract, Barker refers to personal health prevention and echoes much of Kukla's and Redlich's sentiments:

> We should treat our bodies as least as well as we do a new car or any other expensive piece of machinery – with daily care, regular preventative maintenance and careful attention to any signs of trouble. Huge spending on health magazines, health clubs and 'nutraceuticals' shows that we desperately want to be healthy and vigorous. But somehow, when it comes to painful action or self-denial to prevent disease occurring, we close our eyes and hope for the best. (Barker 2011, p.100)

Listing the strategies essential for effective patient engagement in healthcare Barker notes 'skill and will' as core components. In Barker's analysis it is not sufficient to merely tell individuals to take responsibility for their health; "they need goals, and the information, tools, expertise, resources and incentives to pursue them" (Barker 2011,

p.69). This explains why a blood glucose monitor accompanied by a wider self-management ethos, will not necessarily enhance autonomy, or improve blood glucose levels.

This suggests the need for engagement with patients to decipher their needs and assist them in this regard. However, engagement is required not merely 'by' patients but 'with' patients. The existential experience of illness outlined earlier in this chapter, which influenced the participants' experiences of autonomy, suggests the need to engage with patients to ascertain their personal life story and support them individually in this regard. The significance of the patient narrative has been previously explored from a physician (Brody 2002) and patient perspective (Toombs 2002). In order to determine the extent to which patients are vulnerable or more capable at a certain point in their illness trajectory it is necessary to hear their story. This can assist in determining their place in the autonomy continuum.

6.5 An operational account of autonomy for practice: 'Negotiated autonomy' as a possible solution

6.5.1 Why Negotiated autonomy? What does it mean?

I now offer a possible solution to the autonomy conundrum in practice: negotiated autonomy. In order to justify this claim it is necessary to summarise discussion to this point. What has been leaned about autonomy in the process of reconstructing the empirical findings within reasoned argument? How can we operationalise this understanding in a manner that has normative value for practice?

This chapter initially summarised the basic tenets of autonomy as revealed within *Autonomy as lived: The interdependent phenomenon of autonomy in self-testing*. This understanding presents autonomy in self-testing as an interdependent, contextualised phenomenon which occurs within constraints and exists on a continuum mediated by the individual existential experience of illness and other life events. An individual's relationship with the self-testing device, her own illness and associated healthcare providers were all significant factors in the experience of autonomy. Discussion has identified that the findings of this study resonate with the experiences of other

individuals with diabetes engaged in the self-testing process. In order to explore the relevance of this account of autonomy in the wider bioethics context the central aspects of the phenomenon were then explored in light of the existing bioethics literature. A number of core concepts were identified in the course of this discussion. These included: the significance of care, relationality and responsibility in professional caring; the limitations of negative perceptions of autonomy; the associated arbitrary nature of choice in the healthcare environment and the role of influence in patient/healthcare professional interaction; the difficulties associated with autonomy in times of ill-health and the value patients place on professional expertise. Other significant issues included: the importance of an existential understanding of illness which mediates the experience of autonomy; the significance of engagement with patients from an educational perspective, but also to understand their personal story; the shifting competencies of patients from vulnerability to greater capability; the importance of patient responsibility and the value of patient knowledge; and finally the significance of the things in the world, e.g. technology in shaping our experience of autonomy.

In light of this conceptualisation of autonomy, the initial ethical argument was re-visited in order to incorporate these new insights. The basic thrust of the revised argument was that while the literature had much to offer in terms of operationalising this account of autonomy (in terms of moderated accounts of autonomy) something more was required. A return to paternalism was considered and rejected. While many of the tenets associated with this construct had value for operationalising *Autonomy as lived*, the potential for a return to an authoritarian system of 'Dr. knows best' was deemed problematic. In addition, more moderated accounts of autonomy were not always sufficiently orientated towards the patient perspective or congruent with the contextual account of autonomy presented in this study. In order to encompass the various interdependent tenets of autonomy as conceptualised in this study, and address the limitations in the current perceptions of autonomy, an alternative account of autonomy is presented here as a pragmatic understanding of autonomy for healthcare practice. This account is 'negotiated autonomy'. The term 'negotiation' emerged through the iterative processes of reading, writing, reflecting and conversing that are

integral to hermeneutic phenomenology, a sometimes tedious task of 'letting thinking come' (Smythe et al. 2008).

Negotiated autonomy appreciates the need for some paternalistic ideals but within an overall autonomy framework. It avoids the use of the word 'paternalism' to prevent a potential return to an overarching rhetoric of 'doctor (or nurse) knows best'. Negotiation signifies an appeal to dialogue and engagement; paternalism does not. Negotiated autonomy supports autonomy as an interdependent process where patients and healthcare professionals hold mutual responsibilities, and are afforded mutual respect. Negotiated autonomy recognises the vulnerability of patients, yet also their capabilities. It appreciates that the existential reality of *Autonomy as lived* in practice demands an ongoing engagement with the patient to hear their story and agree a place in the autonomy-paternalism continuum. Negotiated autonomy also has the capacity to incorporate 'self-negotiation', whereby, as in this study, patients relinquish certain freedoms to attain others. Negotiated autonomy respects autonomy, but recognises other values of beneficence, non-maleficence and justice. It is not based on authority but on respect for individuals, their welfare and their potential. It is essentially patient-orientated, while encompassing respect for the healthcare professional's role. Negotiated autonomy sees autonomy as significant within the wider process of healthcare and not merely a factor in discrete moments of choice and decision-making. Negotiated autonomy was therefore selected in preference to 'engaged autonomy', 'collaborative autonomy', and 'responsible autonomy', other possible terms that include indirect reference to 'paternalism'.

While the term 'negotiated autonomy' has not been utilised specifically in a healthcare context there is evidence of an appeal to negotiated autonomy in political discourse. Tang and Tang (2001) outline how two tribal villages in Taiwan have regained autonomy in the wake of external intrusion. The authors comment that success is attributable to a negotiation process whereby villagers willingly developed mutually beneficial relationships with external stakeholders. Dolan (2013, p.69) refers to autonomy as a "negotiated concept" in a political sense. Using informed consent as an operational account of autonomy, Dolan outlines how the evolving guidance for informed consent acts as testament to autonomy as a negotiated or "malleable term"

which is altered by the prevailing "apparatuses of the state" (pp.69-70). In this sense, Dolan highlights the definition of autonomy as negotiated as opposed to individual processes of interaction.

Redman's (2005) outlines 'negotiated compliance' to refer to the patient's adherence to a plan of treatment negotiated with their healthcare professional. Albeit, not using the term-negotiated autonomy per se, there are echoes of its sentiments in Davies and Elwyn's account of 'optional autonomy', which seeks to decipher the degree of autonomy in decision-making that patients desire in light of broader constraints on their freedom of choice. Dudzinski and Shannon (2006) utilise the term 'negotiated reliance' to describe their considered approach to a competent adult's refusal of nursing care. The situation involved a dying patient, considerably obese, who refused wound care and regular turning due to the pain involved, despite the healthcare team's pharmacological efforts. This created distress for nurses as it led to the patient lying in her own excrement and further compromised her skin integrity. In this regard, the authors raised particular concerns about the patient's right to refuse nursing care; despite established legal precedent, that medical care could be refused. Following a thorough analysis of the pertinent issues (beyond the scope of this discussion) the authors engaged in a process of negotiation with the patient which they refer to as 'negotiated reliance'. This involved the nurses relinquishing their desire for more frequent changing of position, while the patient agreed to be turned once daily despite her expressed wish to the contrary. Dudzinski and Shannon (2006, p.618) describe the process of negotiated reliance as follows:

> A negotiated reliance approach conscientiously strives for a more even handed negotiation between respect for autonomy, respect for vulnerability and respect for others. It recognizes the reliance of the patient on her care providers and the necessity of the person to be cared for in defining the role of the care provider. It combines empowerment and dependence by requiring negotiation from the competent patient while attempting to minimize harm. It presupposes a relationship of care and intimacy that acknowledges the increased power that health care providers enjoy in that relationship. It allows for more therapeutic and reciprocal responses than other approaches. A negotiated reliance approach may permit invasion of privacy and force, but, rather than to advance a paternalistic agenda, to advance a shared and negotiated agenda.

Many aspects of this approach are appealing in light of discussion in this study. However, I take issue with the concept of 'force' and have some reservations about the manner in which the power of healthcare professionals is outlined. The concept of 'real negotiation' by practitioners however, is particularly appealing. Negotiated reliance seeks to achieve a compromise that infringes on the patient's autonomy to the least degree possible, but also demands that healthcare professionals make "an equivalent sacrifices" (p.618).

Negotiated autonomy adopts many of the principles elucidated by Dudzinski and Shannon (2006) but not all. Negotiated autonomy involves a similar yet different approach. Negotiated autonomy is underpinned by a contextual account of autonomy, *Autonomy as lived.* It recognises autonomy as relational (Meyers 1989) and occurring in the real world, where actual autonomy may be different from ideal autonomy (Agich 2005). It appreciates more substantive accounts of autonomy and recognises that while patient decisions may be rational; this is not sufficient grounds to accept them without question (Freyenhagen and O'Shea 2013). It supports a 'logic of care' as opposed to a blind adherence to a 'logic of choice' (Mol 2008). Negotiated autonomy does not condone force in competent adults and is underpinned by mutual respect and understanding. The discussion to this point contains a number of concepts that collectively support an understanding of negotiated autonomy. While many of the moderated accounts of autonomy explored in discussion are insufficient in isolation to provide a means to operationalise autonomy as lived, collectively they represent a theoretical scaffolding to support a process of negotiated autonomy. Negotiated autonomy demands the same commitments and behaviours from patients and healthcare professionals.

6.5.2 Understanding and respecting negotiated autonomy

A graphic representation of negotiated autonomy is presented in Figure 4 below. Negotiated autonomy comprises five core, interwoven concepts, which reflect the various conceptualisations of autonomy, deemed central to an understanding of *Autonomy as lived*. These concepts draw on the empirical findings in this study and the normative discussion that follows. The various elements are, openness to negotiation, respect for autonomy, respect for the other story, acceptance of personal

responsibility, and a commitment to dialogical practice. All five are required in order for negotiated autonomy to be fully realised.

Figure 4: Negotiated Autonomy
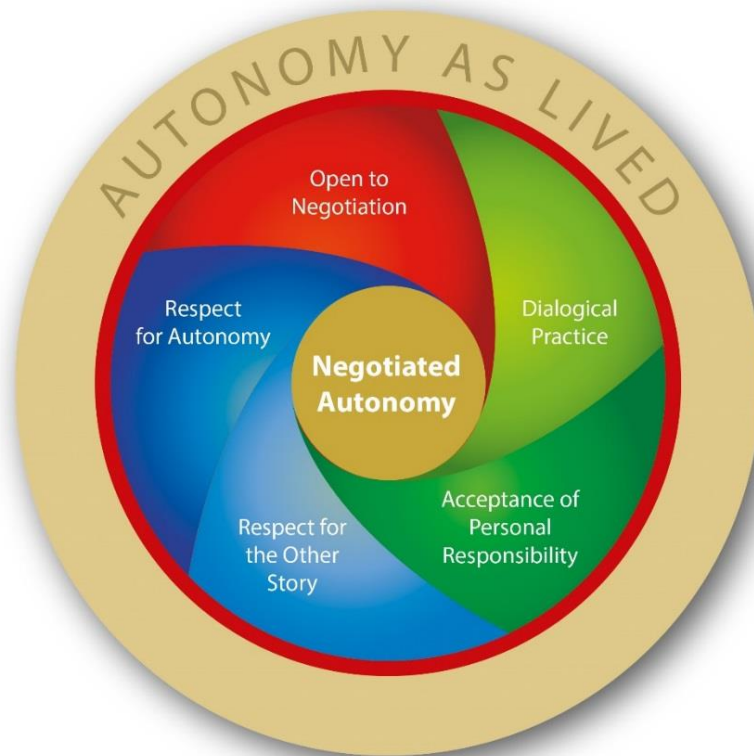
Open to negotiation

An essential component of negotiated autonomy is that healthcare professionals are open to the concept. In the absence of an understanding of the value of negotiation and a willingness to engage with the practice, negotiated autonomy will not be realised. A degree of humility is significant in this regard. Badaracco (2002) presents modesty as an essential component of the moral leader. Modesty is presented as a 'quiet virtue', which involves the agent recognising that they do not have all the answers and remaining open to new ways of thinking and acting. A willingness to negotiate with patients to find a common ground between what the best-evidence suggests, and what patients may request is an essential component of negotiated autonomy. There was evidence of this type of interaction in the interplay between patients and healthcare professionals in this study.

It is also important for patients to appreciate the need for negotiation when their expressed wishes do not accord with medical advice, or available services, in some respects. In accordance with the concept of 'negotiated reliance' (Dudzinski and Shannon 2006) outlined above, patients may need to relinquish some of their immediate preferences in meaningful dialogue with healthcare professionals. Frances was open to negotiating with her consultant regarding treatment options despite her explicit preference for one modality. Negotiation may also be involved initially as patients determine the extent to which they seek to be autonomous within the decision-making process.

Respect for autonomy

At the outset, respect for autonomy in accordance with a true Kantian approach is a significant pre-requisite. In this sense, autonomy is not an isolated individual concept, as often interpreted, but involves an appreciation of other moral agents. One of the most recent philosophers to comment on misinterpretations of Kantian autonomy is Onora O'Neill. In *Autonomy and Trust in Bioethics,* O'Neill (2002, p.74) takes issue with a number of distinguished philosophers who isolate Kant as a major proponent of individual autonomy. O'Neill argues that Kant's unique understanding of autonomy is "quite different from the ethically inadequate conceptions of individual autonomy so commonly ascribed to him", and that a careful reading of Kant's work provides no evidence for a Kantian autonomy rooted in individualism. The term 'autonomous individuals' is not found within Kant's writings. Rather, as O'Neill explains, he refers to the 'autonomy of principles' associated with a duty towards others and respect for their rights. Based on her analysis, O'Neill presents the notion of 'principled autonomy' which is most strongly associated with the principle of obligation. In this sense, the basis for negotiated autonomy is a respect for autonomy which also recognises obligation.

This understanding of autonomy does not support an isolated autonomy which demands respect for individual choices and the absence of any influence. However, it does demand the ethical use of influence as presented by Olsen (2003). For Olsen, as previously explored, influence is an ongoing feature of patient/healthcare professional

interaction. It involves a relational approach whereby every action of influence, despite its magnitude, is assessed for its ethical suitability. Chiovitti (2011) presents a series of reflective questions, which could be usefully employed in this context to ensure that negotiated autonomy does not become paternalism disguised in other language. The questions encourage the healthcare professional to deliberate on the motivation for their actions prior to adopting a more 'protective' interaction with patients.

It is essential that patients appreciate the significance of autonomy. Healthcare professionals, various patient charters, bills of rights and advocacy groups can assist patients in understanding their right to dignity, and real engagement with decisions affecting their health. However, it is also essential that patients appreciate that respect for their autonomy may not necessarily be diminished, should their healthcare professional, or significant other, take a greater lead at certain points in their illness trajectory. Chronic illness, as evidenced in this study, can be mapped by varying periods of independence and dependence. Exercising one's autonomy may suggest that they voluntarily assume less autonomous roles at different points in time.

Respect for the other story

Respect for the other story is a significant element of negotiated autonomy. It involves healthcare professionals respecting the individual story of patients; the personal narrative that each patient brings to a healthcare situation. The patient's personal story, relative to their own illness trajectory will influence their place on the autonomy continuum. Respect for the patient's story is grounded in the work of Brody (2002) and Toombs (2002) explored earlier in discussion. However, the need for respecting the 'other' is mutual. It also encompasses patients appreciating the professional responsibilities of healthcare personnel, which may conflict with the patient's exercise of free choices.

Acceptance of personal responsibility

Negotiated autonomy involves acceptance of personal responsibility by both patients and healthcare professionals. Kukla's (2005) conscientious autonomy as outlined earlier in discussion could be suitably employed here to underpin the patient responsibilities towards their own health, while O'Neill's (2002) principled autonomy,

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with a focus on obligation could underpin the responsibilities of healthcare professionals. Holm's (2007) protective responsibility and Chiovotti's protecting empowering (2008) could also be incorporated as a means to encompass the healthcare professional's responsibility to avoid harm and promote patient well-being within an overall autonomy respecting framework. The process of negotiation will involve patients accepting responsibility for acknowledging when they may need more assistance in decision-making. Also, acceptance of personal responsibility involves the healthcare professional recognising when they are not best placed to assist in the negotiating process.

Commitment to dialogical practice

Finally, both parties must engage in dialogical practice. This can facilitate moving beyond a contractual account of the caring relationship (Tauber 2005). This dialogical practice promotes interdependence in decision-making and draws on the work of Brody (2002) and Freire (1970/2012) to promote a genuine sharing of language, knowledge and beliefs. How can we best engage with patients in a manner that respects their personal narrative, encourages their autonomy relative to that narrative and provides supportive education?

Here I return to Freire's work. His dialogical practice suggests an approach to education and engagement that could address the apparent disconnect between patient and healthcare professionals often present in healthcare. For Freire (1970/2012, p.75) the pedagogy of dialogical practice involves a real sharing between teacher and student which appreciates the ontological position of being "with" the world, not merely "in" the world. Freire refers to the role of the "humanist revolutionary educator" as follows:

> From the outset her efforts must coincide with those of the students to engage in critical thinking and the quest for mutual humanization.... To achieve this they must be partners with the students in their relations with them. (Freire 1970/2012, p.75)

Earlier discussion noted the need for mutual learning in the patient/healthcare professional encounter; a learning underpinned by an acknowledgement of the patient story. While healthcare professionals may know many things, they may not necessarily

know 'more' than patients. Chiovitti's (2008) theory of 'protective empowering' incorporates 'Viewing the patient as knowledgeable' as a sub-category of the central category of 'Respecting the patient'. In this sense, "nurses blended their knowledge with patient's knowledge to help patients consider information available so that patients could decide how they wanted to be in their situation" (Chiovitti 2008, p.211). To assume, as a healthcare professional, that one knows more than patients, is arrogant in some respects, yet also possibly sensible in an alternative situation. With regard to some treatment decisions, the formal education and broad experience of healthcare professionals may mean they do know more about the options available, particularly with regard to technical aspects of care (Gillon 1985). However, they may not know more about the benefit of these options for particular patients if they fail to fully engage with them. The patient is an 'expert' in relation to their own life path.

Tauber (2005) is explicit with regard to the need to connect with the patient in the context of the autonomy conundrum. In *Patient Autonomy and the Ethics of Responsibility* Tauber calls for a "humane medicine" (p.43) which acknowledges the limits of reductionist approaches, and appreciates the need for a more psycho-social understanding of the patient situation. Tauber urges healthcare professionals to reassert the covenant model with patients, which transforms autonomy and beneficence into a pattern of mutual support as opposed to adversarial concepts. This type of model, as opposed to more conventional contractual models would assert responsibility "in alignment with the claims of autonomy" (p.19), and avoid more consumer-orientated considerations. In this sense, professional responsibility for patient welfare and respect for autonomy can co-exist. Dooley and McCarthy (2012) present a similar account of approaching autonomy and decision-making as an interdependent process. Recognising the importance of the patient narrative, similar to the analysis presented here, Dooley and McCarthy draw on Brody's account of dialogical practice as a means of promoting patient autonomy. Brody (2002, p.136) outlines a number of elements that can contribute to dialogical practice through a "joint construction of narrative".

6.7 Conclusion

In conclusion, negotiated autonomy is proposed here as a suitable means to operationalise *Autonomy as lived* in healthcare practice. In respecting autonomy as a contextual interdependent process, it exemplifies a pragmatic account of autonomy for clinical practice, which encapsulates the strength of current understandings in bioethics and addresses their imitations. Negotiated autonomy represents a normative proposal for healthcare practice based on the empirical findings of this study, though not drawn 'directly' from them.

CHAPTER 7: SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Technology is at times pivotal in increasing patient's autonomy and enabling them to participate in the social world, but it also imposes heavy restrictions that are intimately woven with the characteristics of the disease itself and with the patient's own life trajectory.

(Lehoux et al. 2004, p.641)

7.1 Introduction

This chapter summarises the research study and explores the contribution of the study findings to the existing literature. The overarching contribution of the study lies in its illumination of autonomy in practice. The research concludes with an understanding of *Autonomy as lived* as an interdependent phenomenon, which can best be operationalised by means of negotiated autonomy. Negotiated autonomy provides a means to address the autonomy conundrum as identified in the introduction. The study also contributes to the current literature in empirical bioethics research, human technical relations and self-management policy and practice in diabetes care. These methodological and pragmatic contributions will be explored as the discussion proceeds. The chapter also explores the limitations of the research study and outlines a series of recommendations for bioethics scholarship, healthcare policy and practice and further research.

In accordance with interpretive phenomenological research, understandings will always be tentative and open to new interpretation as further empirical and philosophical work evolves (Ironside 2005). This phenomenological understanding of *Autonomy as lived* is not presented as a generalised and irrefutable account of autonomy in practice. For Smythe et al. (2008, p.1393) "insight gleaned" [through phenomenological research] is not about the 'generalised' or 'normalised' person who is in fact, no one, but what shows 'me' how better to understand human experiences". In the previous chapter, empirical findings are subjected to reasoned argument to support the normative and associated pragmatic conclusions outlined. This relationship between empirical work and normative analysis enables the transfer of

empirical knowledge to new settings and minimises epistemological concerns regarding the 'disconnect' between 'is' and 'ought' in empirical bioethics (Holm 1997, Rehmann-Sutter et al. 2012). This study extends our understanding of autonomy in a clinical context. What is important is that the understandings of autonomy gleaned through empirical and philosophical exploration in this study have resonance for others, who may incorporate these understandings in their practice.

7.2 Study summary and conclusions

The increasing prominence of autonomy as an ethical principle in bioethics, and healthcare policy and practice can create tensions for practitioners and potential anxieties for patients. I refer to this as the autonomy conundrum. This study examines the principle of autonomy in practice through a philosophical and empirical analysis of autonomy in engagement with self-testing technology. McMillan and Hope's (2008) empirical ethics design is utilised to underpin the methodological processes. The initial ethical analysis raises concerns about the prevailing understanding of autonomy in healthcare whereby autonomy is equated with negative liberty, an absence of constraints, isolated decision-making and 'free choice'. The analysis argues that an alternative understanding of autonomy is required to incorporate the concepts of relationality, care and responsibility that are central to human interaction.

An empirical investigation then explores the meaning of autonomy among individuals engaged with self-testing technology. Interpretative phenomenology is utilised to elicit the experience of autonomy among 12 individuals with diabetes engaged with the self-testing process. Data collection is by means of hermeneutic interviewing. Data from prominent stakeholders - healthcare professionals and scientific community members is also sought to illuminate the patient experience. Data is collectively analysed using an approach advocated by Crist and Tanner (2003).

This interpretive analysis of patient autonomy in engagement with self-testing technology reveals an understanding of *Autonomy as lived: The interdependent phenomenon of autonomy in self-testing*. In accordance with this interdependent phenomenon, the patient experiences autonomy in self-testing as a series of three

interdependent relationships: *Relationship with device; Relationship with illness;* and *Relationship with healthcare provider.* The term 'interdependence' is significant, as autonomy is maximised when there is a particular fusion of the three relationships. Interdependence is also significant as it implies that autonomy is not conceptualised in a negative sense, as freedom from constraints, but rather that autonomy is achieved through self-mastery and self-determination, which can exist 'within' certain constraints. The extent to which individuals self-impose and accept certain restraints influences the degree of autonomy they experience. Autonomy is not something that can be 'created' through technological advances or self-management policies. It requires a particular synergy of all three interdependent relationships. Autonomy for these participants involves 'contingently being-in-control' and exists within a continuum.

This empirical understanding of autonomy is then subjected to further ethical analysis in accordance with Rehmann-Sutter et al.'s (2012) model of empirical-normative collaboration. The initial argument is revised to incorporate the findings of empirical work and new insights gained through further philosophical enquiry. This analysis conceptualises *Autonomy as lived* in light of the existing bioethics literature, and seeks to develop a morally defensible means to operationalise this understanding of autonomy in practice. *Autonomy as lived* conceptualises autonomy as a contextualised, relational process that occurs within constrains, exists as a continuum and involves a degree of influence. In chronic illness, it involves a 'process' of interaction between the patient and healthcare provider and cannot be fully understood in terms of discrete moments of choice. Operationalising *Autonomy as lived* requires that the patient/healthcare provider relationship is underpinned by the ethical use of influence, engagement with the other, a sense of mutual responsibility and an overarching respect for autonomy. In conclusion, an understanding of autonomy as a negotiated concept is presented as a morally defensible means of operationalising *Autonomy as lived*.

7.3 Acknowledging methodological limitations

Phenomenological research, as with other qualitative methods of enquiry, seeks to extend our understanding of human experience. It does not provide a means to

generalise or quantify the world in which we live (Smythe et al. 2008). The qualitative study findings are viewed in this light and are presented as a tentative, temporal, interpretive account of how autonomy is experienced in practice. The qualitative nature of the work is highlighted here as something that needs to be understood as opposed to a limitation per se. However, there are some limitations within the study that merit consideration.

The findings ascertain the perspective of individuals in one western country only, at two hospitals and one research centre, and therefore a degree of cultural bias needs to be considered when interpreting these results. Experiences and subsequent understandings of autonomy in other cultures may be quite different. The sample sizes are small and therefore preclude broad generalisations. However, the study yields rich data regarding the experience of autonomy among those interviewed. In addition, the empirical work is analysed in association with reasoned argument to illuminate the philosophical issues and draw defensible normative conclusions (Rehmann-Sutter et al. 2012). There may be criticisms of the decision to incorporate individuals with type 1 and type 2 diabetes within the study design. However, the study did not set out to provide generalisable conclusions with regard to specific diabetic classifications, but rather to extend the understanding of autonomy among individuals with diabetes engaged with self-testing technology. The study did not include assessment of HbA1c to assess biomedical outcomes. This analysis could have enabled exploration of the extent to which participants' experiences of autonomy correlated with 'clinical efficacy', in addition to self-reported wellness.

There is a possibility that the scientific community participants and healthcare professionals may have responded in interview in ways they deemed socially desirable. This is known as the social desirability response bias (Polit and Beck 2006). However, in light of the variety of responses, and the resonance with previous studies, this is less likely. Clinical research leaders or senior management staff were not in attendance at the scientific community focus group. While acknowledging this as a potential limitation of the study, proponents of focus group methodology suggest that data is more reflective of real concerns/issues if senior and more junior personnel are not interviewed simultaneously (Morgan 1996).

There was not a direct synergy between the patient group interviewed, and the potential recipients of emerging technologies, with which the scientific community participants were engaged. As explored within the thesis, the scientists interviewed were developing point of care devices for near patient use under clinician supervision, as opposed to self-testing devices. However, as individuals the group had various expertise in diagnostic devices and have the potential to shape innovation in self-testing technology. The self-testing/patient autonomy focus was kept centre stage within the focus group with the assistance of pre-prepared questions, additional probes and the use of a scribe to enable the researcher to concentrate on maintaining focused dialogue. In addition, vignettes drawn from patient data were utilised to promote generic reflection on the use of self-tests. It is important to note however, that responses may have been different if participants had specific expertise in self-testing devices.

7.4 Recommendations based on new understandings

This section presents a series of recommendations based on the normative analysis of autonomy. The findings have implications for bioethics scholarship; philosophical understandings of autonomy in healthcare policy and practice; the clinical application of self-monitoring programmes in diabetes management; and the scientific community with regard to the development of future self-testing technologies.

7.4.1 Recommendations for bioethics and healthcare policy and practice: Conceptualising and operationalising Autonomy as lived

The normative contribution of this study lies in the extended understanding of autonomy, which it provides. The research supports the concern in the philosophical literature regarding the prominence of negatively orientated accounts of autonomy. It is important that bioethics discourse continues to recognise and challenge the limitations, and often incorrect assumptions, associated with negative accounts of autonomy. The dominant understanding of autonomy as synonymous with non-interference, informed consent, isolated decision-making and discrete moments of choice requires reassessment. Autonomy for the participants in this study is relationally constituted, interdependent and contingent on one's existential experience

of illness. A re-conceptualisation of autonomy as *Autonomy as lived* provides a more suitable framework to underpin healthcare policy and practice. This construction of autonomy extends the phenomenological understanding of lived autonomy within the existing literature (Agich 2003, 2005, Schlimme 2012).

It is essential that healthcare professionals consider the patient's contribution, the influence of others and temporal aspects of illness and other life events in determining one's autonomy competencies. The autonomy conundrum represents a real problem for healthcare professionals as they seek to reconcile their professional and caring responsibilities with a growing emphasis on an isolated patient autonomy. The autonomy conundrum can be addressed in practice by promoting an understanding of autonomy as a negotiated concept. In accordance with this framework, healthcare professionals possess a degree of influence within the caring relationship based on professional obligations and expertise. Central to negotiated autonomy is an overarching respect for autonomy, respect for the patient's story and a willingness to engage on an ideological and practical level. The graphic representation of negotiated autonomy provides a tangible model to assist practitioners in this regard. Negotiated autonomy requires ongoing dialogue to navigate patients' support and responsibility in addition to that of their caregivers.

Negotiated autonomy also has relevance for patients with regard to how they might more favourably navigate the healthcare system. Patients need to be reminded that while independence and autonomy can be therapeutic, dependence and greater reliance on healthcare professionals is not forbidden and may be required to a greater or lesser extent throughout their illness course. Patients should be encouraged to accept responsibility for their health but expect adequate support in this endeavour. Patients need to understand the limits of medicine, along with its potential, and appreciate the constraints of healthcare professionals in this regard. An appreciation of the professional obligations of healthcare professionals, which may preclude them from certain actions, is also important. Patients should be encouraged to engage with healthcare professionals regarding the extent to which they wish to be autonomous in healthcare decisions. Patients should be reminded that their story is important and deserves to be heard.

The interdependent phenomenon of autonomy in self-testing within this study suggests that policy-makers and healthcare professionals acknowledge the very different experiences, capabilities and wishes of patients when promoting autonomy and self-care. An understanding of the interdependent elements essential for effective self-management will enable an individualised assessment of patients prior to commencement of more autonomous roles and self-care strategies. In the absence of this broader assessment an indiscriminate policy of self-management has the potential to compromise the well-being of certain individuals who are unsuited to the self-care/extended autonomy agenda for a variety of reasons (Newbould et al. 2006). The continuum of autonomy, as experienced by participants in this study, suggests that varied degrees of autonomy are possible and that autonomy competencies can change over time. This suggests the need for continuous assessment of patients to determine fluctuating autonomy competencies and self-care capabilities, based on their illness trajectory and other life events.

An understanding of the paradox of controlled freedom in chronic illness is also important. Healthcare professionals should seek to maximise the 'possible' freedoms available to individuals to minimise the constraining nature of ill-health. It is critical that the role of technology in both assisting and constraining autonomy is understood. Autonomy can never be a pre-determined outcome of technology use. While technology, as evidenced in this study, can be an excellent tool to assist in self-management and maximise autonomy in this regard, it may also induce change in the patient/healthcare provider relationship in non-intended ways and result in unwelcome burdens. Reflection on the costs of technology relative to other healthcare 'goods' is advised. Further developments in Health Technology Assessment (HTA) methodology are required to accurately assess the impact of technology on ethical, economic and psychosocial dimensions of practice.

Finally, it is important that those who educate undergraduate healthcare professionals, clinicians and academics, incorporate the significance of the patient's story and the existential dimensions of illness in their teaching. The reality of chronic illness for patients and their families is not always understood by healthcare professionals – patients are not always asked the questions that may elicit this type of information.

Toombs (2002, p.132) suggests that "understanding these various facets of loss of wholeness can provide important insights into ways to initiate the process of healing" as The patient stories in this study reveal various experiences of illness which may have remained 'unsaid' in the absence of the interview process.

7.4.2 Recommendations for the management of self-monitoring programmes in diabetes care: One size does not fit all

The experiences of participants engaged with self-testing technology in this study revealed understandings, which have significance within a diabetes management context. The findings are not generalisable to a specific diabetic population, but do have relevance in extending the understanding of the qualitative impacts of self-monitoring among this client group. The lack of available evidence to support SMBG in both diabetes classifications highlights the importance of research related to the more psychosocial outcomes. The lived experience of individuals with diabetes in this study can illuminate this issue.

Essentially, the patient interaction with self-testing devices in this study revealed both positive and negative experiences dependent on a series of contextual factors. These experiences share many similarities with those highlighted in previous studies. The findings in this study suggest the need for pre-assessment of individuals to determine their suitability for self-monitoring in light of the interdependent structures required. An assessment of one's locus of control, cognitive understanding of self-monitoring, technical skill and the degree of follow up care required, and practically possible, is important. An assessment of the individual's life story in the context of diabetes management is also required. Protocols should distinguish between self-monitoring and self-managing. In accordance with current practice guidelines, self-monitoring should only be initiated in situations with pre-determined goals of care (IDF 2009, ADA 2013). As the ability to self-monitor and self-manage are temporally contingent, and may induce some feelings of distress, an annual review of self-monitoring as per NICE (2011) is recommended. Engagement with patients in order to understand their existential experience of illness, relative to self-testing and other aspects of diabetes care, is recommended as opposed to a narrow focus on self-testing results per se.

7.4.3 Recommendations for the development of self-testing technology: Understanding technology in play

The interdependent nature of autonomy in engagement with the self-testing device is significant. The study extends the understanding of human-technical relationships in this regard. This understanding has implications for those developing future self-testing technologies, or diagnostic devices that have the potential to be utilised by patients at a future point. Engagement with patients/end-users during device development is recommended. This engagement requires assessment beyond the clinical efficacy of the device to incorporate broader elements of the patient experience. Acknowledgement of the patient experience, at an earlier stage in the development of healthcare technologies, will facilitate technological innovation based on sound ideas regarding the complex reality of living with disease and may minimise the 'soft impacts' of technology (van der Burg and Swierstra 2013). Further engagement in focused reflection, on the psychosocial dimensions of technology, by those engaged in scientific discovery is advised. Extending the role of social scientists and ethicists in research and development 'within' the laboratory setting could facilitate this type of reflection. It is not that the scientists in this study lacked reflective capacities. Similar to van der Burg's (2009, p.11) analysis, the scientists' imagination was focused "narrowly on technological devices and how they can be improved". Feedback from those who participated in the focus group suggests that they value an opportunity to reflect on the more psychosocial aspects of emerging technologies.

The interdependent nature of autonomy in self-testing is an important consideration when marketing self-testing devices and developing promotional and educational material. The success of the device in the participants' daily lives is dependent on a series of interacting relationships and competencies. Collaboration with patients and healthcare professionals at this point will assist in the effective integration of the device in a clinical context. It is also important that the scientific community does not underestimate the impact of the physicality of the device on users. Spatial considerations related to the 'present-to-hand mode' (Heidegger 1927/1962) of self-testing devices impact on the patient's home-life and may crystallise her experience of

ill-health. The importance of the practicalities of the device should not be underrated. As evidenced in the experiences of participants in this study, what may appear to be minor details about the device – size, number of components, visibility – may not just impact on the degree of comfort which the user experiences but may impact on their decision to use it at all.

The study also points towards specific recommendations with regard to developments in blood glucose monitors. Pain associated with invasive self-testing remains a significant issue for patients, thereby reinforcing the significance of innovation in non-invasive devices. Those involved in the development of self-testing devices might also consider advancements in urine monitoring devices as opposed to blood glucose assessment. Recent economic evaluation suggests that SMBG is not economically sustainable (Farmer at al. 2009b, Clar et al. 2010). Assessment of glucose levels using urine testing systems is currently being revisited within a wider policy context in the UK (Dallasso et al. 2012).

7.4.4 Recommendations for future research: Towards new understandings

The inclusion of a possible future research agenda reflects the ongoing cyclical nature of McMillan and Hope's (2008) model of empirical ethics, whereby the ethical analysis presented here can suggest further empirical questions. The identification of future research possibilities is also congruent with the evolving nature of hermeneutic phenomenology (Todres 2004). The current study shows how empirical bioethics can combine empirical and philosophical work to explore ethical problems in the real world of practice. Further studies in this regard, within a wider research team, could serve the dual purpose of illuminating and addressing tangible ethical problems and bridging the gap between philosophers and social scientists. It is important that researchers are specific regarding the precise nature of empirical-normative collaboration within studies to avoid epistemological problems and strengthen scholarship in this area (Rehmann-Sutter et al. 2012, Salloch et al. 2012).

This study supports previous calls for more qualitative research among all classifications of the diabetic community to identify the impact of self-monitoring on

individual patients. The researchers in the DiGEM study (Farmer et al. 2009a) note the importance of further work to identify those 'particular' patients for whom SMBG improves glycaemic control. The research team has outlined a new protocol for a systematic review of trials of SMBG in non-insulin treated type 2 diabetics, which would incorporate individual patient data meta-analyses to investigate specific sub-groups of patients for whom self-monitoring may be beneficial. More in-depth analysis of the experience of living with diabetes will also broaden our understanding of the complex nature of chronic illness and its temporal nature.

Extended research collaboration between scientists, social scientists and philosophers/ethicists is advised to enable the development of technologies that are not only clinically effective, but take cognisance of the wider ethical and psychosocial dimensions of technology use. This study also points towards the importance of developing the HTA agenda and extending the types of methodologies employed. The lack of qualitative and ethical analysis in HTA is acknowledged (Sacchini et al. 2010). Empirical bioethics can assist in this regard.

Understandings gleaned through interpretive phenomenology will always be tentative and open to further clarification (Ironside 2005, Smythe et al 2008). In this light, the concept of negotiated autonomy, merits future research to examine and evaluate its merit in the practice context.

7.5 Summary

This research study illuminates the ethical principle of autonomy in a specific healthcare context and, following reasoned argument, provides a pragmatic means to operationalise autonomy in practice. It relates the lived experience of autonomy among a group of patients engaged with the self-testing process. The study highlights the contextual nature of autonomy in self-testing whereby patients experience autonomy as a series of three interdependent relationships: *Relationship with device*, *Relationship with illness* and *Relationship with healthcare provider*. The study challenges the prevailing understanding of autonomy in healthcare and provides new insights to assist our normative deliberations when faced with ethical problems in practice. These

insights develop current 'moderated' accounts of autonomy. An understanding of *Autonomy as lived: The interdependent phenomenon of autonomy in self-testing* has the potential to resonate with policy makers, healthcare professionals and the scientific community on a more pragmatic level, regarding the actual experience of individuals engaged in self-testing, self-care and the role of technology in this regard. The operationalisation of autonomy as a negotiated concept is offered as a tangible means to address the autonomy conundrum, and facilitate mutual respect for the ethical principles of autonomy and beneficence in the patient/healthcare professional relationship. The graphic representation of the varied elements of negotiated autonomy provides a conceptual tool to assist practitioners in this regard.

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APPENDICIES

Appendix A: Analysis journal extracts

22nd June 2012 – Hastings Centre, New York
Long Day! But getting places with more shared meanings emerging and a more in-depth interpretive focus...Links with philosophy emerging too...
Reading – 'Being and Time' chapter from Harmon text – Literature search re 'the body' and Merleau-Ponty/Gadamer (Papers saved for later reading)
Writing – Frances – Moving to interpretation – Developing connections with philosophical texts and shared meanings with Alex and others...
Engaging – Lunch time presenter re the ethics of pharmaceutical industry. Raised some dubious practices (Seed research, advertising re illness claims pre FDA approval and drug advertising, medicalisation by the pharmaceutical industry). Suggested an ethical framework for the industry/Included 'Autonomy' and suggested it was being upheld by DTC marketing – Not so sure about this! – I think respect for autonomy would be best upheld by 'responsible' DTC marketing … In many cases DTC marketing exploits autonomy as opposed to respecting it...
Reflecting – Understanding more about Dasein within Heidegger's philosophy and links to other concepts – e.g. ready-to-hand
Some in-depth reflection re Frances - autonomy, 'desired' autonomy, autonomy and ill bodies (Links with Willems, Merleau-Ponty, and Thomasma papers), autonomy preferences (being in control) and possible treatment preferences (does Insulin perhaps just suit some patients better and should this be considered? – OR – Is the self-testing regieme 'enframing' (as Heidegger suggests) the diabetic self and invoking a 'wish' for an insulin regieme merely to have testing make more sense?)

1st December 2012 - Analusis continued Ireland
A day of much thinking and reflecting but little writing!
Writing - Began to redraft opening section to explain more clearly, why I chose to use the term 'understandings' in light of the nature of Heideggerian research.
Reading - Re-read Smythe's "The thinking of research" (2005) and sections of Heidegger's 'Memorial Address' re meditative thinking to assist in explaining why understandings is right and how these understandings are arrived at. Attempted to 'unpack' Les Todres comment as M.D. suggested
Reflecting/Thinking - As a typical example of 'letting thinking come' as Smythe suggests - I woke up this morning thinking that Betty's story re having dinner out (which I worked on Thursday), Bart's story re working as a taxi driver and Deirdre's story re going to Australia are typical exemplars of - the 'freedom to live theme' which I have articulated... Will develop this section too...
Also thought some more re Heidegger's 'Technology as revealing' concept as an overarching 'theme' or conceptual framework to present the research understandings… Came up with a new 'circular' scheme to explain data – wonder re existentialist themes but this is it for now…

Update 28th/ 29th January, 2013
Writing, listening, reading, re-reading, thinking, changing
Significant progress made over the last two weeks. Comments of both supervisors were noted and amendments made to December draft of findings chapter. Any outstanding issues for consideration were flagged – e.g. diagrammatic representation. I continued to analyse HCP interviews and link data with themes from patient data. It is possible to

identify salience in all interviews with regard to the patient stories. I am currently completing the final HCP interview, HCP6, and feel that saturation of some sorts has been achieved. The themes have not been altered significantly but acknowledging the HCP perspective within the hermeneutic circle did merit some consideration on the wording of themes e.g. see note from working findings chapter:

Is 'Freedom to live etc.' sub-theme also related to autonomy as expressed by the patient while the 'Autonomy versus covert paternalism' sub-theme is something else related to how autonomous HCP's really are? Must also address somewhere the struggle for the HCP re doing what the patient wants and doing 'right' – perhaps in the 'Autonomy versus paternalism' section and not refer to it as 'covert' but merge this concept of into discussion linking it with surveillance.

The last couple of weeks have been focused on bringing wholeness to the analysis process in order to complete this stage, essentially being satisfied that I have captured the salient aspects of patients' experiences and the related perspectives from other stakeholders. This is an ethical issue for me. I wouldn't be content with the overall analysis, and therefore the study in general, if I felt the analysis process was less than complete. Bringing this sense of completion or 'wholeness' involved revisiting those interviews that I had analysed at an earlier stage where I elicited 'early lines of enquiry' as Crist and Tanner suggest. I looked at those transcripts again taking a more interpretive approach, van Manen's phenomenological reflection, and considered the shared meanings which had emerged in the interpretive analysis of later interviews. In this way I have moved from early lines of enquiry, to interpretive analysis, to shared meanings and back again. This involved looking at, and listening to, the transcripts / interviews again individually, yet also the participants as a whole. Revisiting early lines of enquiry did involve some shifts in thinking e.g. see note re Colette's story:

Update Sunday February 3rd 2013
Progressing, stalling, doubting, focusing, revisiting, thinking, reading, mapping, writing
Synthesis is a challenge – while the nature of the existentialist themes makes them suitable for capturing the patients' experiences in this study, their interwoven nature means that assigning stories to various themes becomes difficulty e.g. temporal and relational understandings are often interwoven. However, to tell the 'story' with clarity I continue to develop the existentialist thematic presentation. I am working on a mind-map where I bring shared meanings and associated HCP / SC (Scientific Community) data together to encompass the skeleton of a theme / sub-theme. (Yet again, while this will work, I have reflected on how much easier a qualitative data package may be if employed at the start!).

The themes '*Promoting autonomy v covert paternalism*' and '*Education processes and autonomy*' have been interwoven within a broader '*Relationship with healthcare provider*' theme in order to ensure their inclusion yet also encompass discussion of broader issues regarding the relationship. The '*Contemporary economic perspectives*' theme has now been discarded and ideas interwoven with '*Relationship with healthcare professional*' and '*Relationship with self-testing devise*'. Retaining the latter theme was an important dimension to remaining true to the study / data as the 'being-with-technology' was central to the overall thrust of the study. Also, patients had a lot to say about the devise itself and these stories can be interpreted in light of many complementary and contradictory insights from HCP'S and members of the scientific community. While the economic issues were certainly a key issue within the participants' stories they existed in so far as they shaped their ideas about their relationships with healthcare providers yet also the role of the devise.

I spent almost two full days with focus group data looking for salience with shared meanings among patients stores and how their vision 'fits' with the patient perspective and that of HCP's. There is some very interesting data which could, as supervisors suggested re HCP's, make an interesting study on its own. However, for the purpose of this study I continued to look for salience with patient data. (See typed analysis notes). A particular finding of interest was the fact that the SC, although they speak of empowerment, may underestimate the ability of patients to be in control. Further interpretation of results by the HCP, through a 'connected health' system may actually demotivate patients and not facilitate the 'real' sense of autonomy that seems to be a feature of some of the participants in this study.

Reflection initiates caution (among participants) more so than possibilities!

Update Tuesday March 19th 2013 – Post hermeneutic conversation…
I continued to work under the new structure and patient stories now 'fit' much better. Theme titles have been altered again - see current outline below. Reverted to '*No room at the inn'* to include other participants who also felt health service had no time for them but didn't seem lost in transit e.g. Betty. Also – renamed titles to incorporate the 'as' structure – device as…

DEVICE 'as'
- A window to the body
- A path to freedom
- A source of discord
- An imperfect technology

ILLNESS
- Taking control
- Autonomy as contingent in chronic illness

HCP
- Empowered by education
- No room at the inn
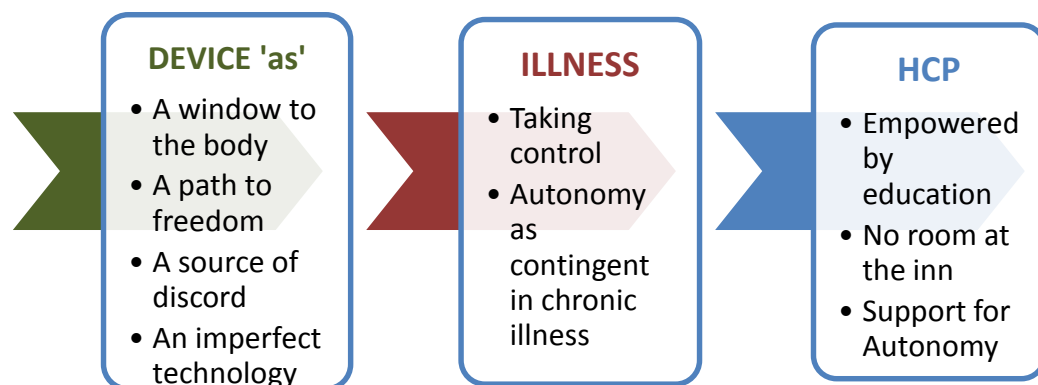- Support for Autonomy

Figure 4.2 Themes within tripartite relationship of autonomy in self-testing

However, the above ideas are already 'shifting'. Work colleague read a draft this week. Lengthy conversation ensued re title of themes and interpretation to date. Some challenges still remain re avoiding repetition, e.g. *A Path to Freedom / Taking control*. Also, an interesting point resurfaced in the course of conversation – the 'surveillance' issue and link with earlier ideas in preliminary lines of enquiry re the device as a 'watchdog' – is it perhaps not only the HCP that may be engaged in surveillance but the device itself? Is the device about freedom for Ann or does it provide a form of surveillance which is limiting / almost suffocating? It does seem to be a reassurance though for her though –Must think about this some more. Perhaps it involves living with imperfection? Earlier interpretation of the device and the autonomy continuum may be more appropriate? In that piece I saw the device as motivating for Ann but not necessarily empowering. Re-reading Ann and Deirdre again - is it about the device as a taskmaster – fitting with previous accounts of self-chastisement! But yet she doesn't want to lose it – speaks positively of it also.

Appendix B: Published autonomy paper

Patient autonomy and choice in healthcare: Self-testing devices as a case in point

Introduction

The growing number of self-testing diagnostic devices available for home use raises a number of ethical, psychological and social questions. Such devices allow individuals to test for a range of medical conditions in the absence of medical supervision. These devices are on sale in pharmacies, super-markets and a growing online industry where over a thousand tests are listed (Parliamentary Office of Science and Technology, 2003). It is now possible to test for HIV (albeit only one system approved) (Federal Drug Administration, (FDA) US, 2009), genetic markers (Levitt, 2001), response to coagulation therapy (Heneghan et al., 2006), glaucoma (Ianchulev et al., 2005) and even dementia (Kier and Molinari 2003) without leaving one's home. The premise underpinning the nature and availability of these devices, which is noted in their marketing strategies, is that they assist individuals to be more autonomous in the assessment and management of their health by assuming a more independent role. Increased patient autonomy is assumed to be a good thing. In this paper we critique this assumption. We do not oppose patient involvement in care, but rather seek to critique a particular understanding of patient autonomy and its practical implications.

We propose that diagnostic self-testing is a specific instance of the application of a developing model of patient autonomy in healthcare policy and practice. Recent legislative change and health policy in Ireland and the UK support this direction (Department of Health and Children, Ireland (DoHC), 2008a) Patients are now granted increased independence in the management of their own health and associated decision-making. Various forms of paternalism are, for the most part, viewed as antiquated and sometimes unethical. Patient autonomy, choice and freedom in decision-making have been embraced as part of a progressive philosophy for healthcare delivery. Wilson (2007, p.354) refers to "the antipaternalistic assumptions"

of modern bioethics which are claimed to support these views. We suggest that policy-makers have adopted these 'assumptions' to underpin current healthcare policy with little substantive debate.

The aim of this paper is to reflect on these 'assumptions' and the extent to which autonomy, in so far as it is often construed as patient choice and freedom in decision-making, represents a progressive principle for healthcare delivery. The central thesis here is that current perceptions of autonomy do not represent a progressive philosophy for healthcare, as they fail to capture the multi-dimensional nature of the concept and undermine other significant issues such as relationality, care and responsibility. The paper draws on the philosophical literature and examples from the self-testing process to support this claim. The self-testing process represents a specific microcosm of greater patient involvement and autonomy in healthcare and therefore provides an ideal practical context for discussion. We conclude by offering an alternative account of autonomy which may better serve patients. We accept that autonomy is constituted, perceived and valued differently in various cultures. This paper draws primarily on the Irish, UK and US perspectives; therefore, we acknowledge that the discussion has relevance primarily in a Western context.[1]

The argument

The argument we propose may be outlined as follows. Current healthcare ethics and recent social policy documents uphold patient autonomy as a paramount ethical principle. This model of autonomy goes beyond merely encouraging participation as autonomy is increasingly portrayed as individual freedom to choose. Such a model is not a suitable benchmark for healthcare policy, or professionals, because (a) it represents a one-dimensional, sometimes misguided, perception of autonomy associated with the absence of constraints and (b) it denies important considerations of relationality, care and responsibility which may better serve patients. Therefore, healthcare practice and policy, which uphold the primacy of autonomy and equate it with increased patient choice and freedom in decision-making should be reviewed, or at least accepted with suitable qualification.

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Autonomy, freedom to choose and contemporary healthcare

Prior to further discussion of autonomy, and its application in healthcare, some initial understanding of the term is required. A definition will not be outlined at this point as one of the central issues under discussion here is what the essential nature of autonomy is.[2] However; some sense of the term must be delineated to allow the argument to proceed. In general usage 'autonomy' refers to a multi-faceted concept encompassing such elements as "self-governance" and "self-rule" (Oxford University Press, 1997) The word is derived from the Greek 'autos' which refers to the self and 'nomos' which refers to laws. In this original sense autonomy referred to a political system shared by a group of citizens. A city in ancient Greece had 'autonomia' when its people were in a position to make their own laws (Dworkin, 1988).

An understanding of autonomy as a feature of individuals is widely attributed to Kantian philosophy where individual agents, as opposed to societies, are viewed as the locus of autonomy (O'Neill, 1992). Within contemporary healthcare the term is often used ambiguously and inconsistently whereby different interpretations suggest different ways of respecting autonomy (Keenan, 1999; Aveyard; 2000; Slowther, 2007). Beauchamp and Childress acknowledge the multifaceted nature of the concept but define autonomy as; "self-rule that is free from both controlling interference by others and from personal limitations, such as inadequate understanding, that prevent meaningful choice" (2001, p.58).

The association of autonomy with lack of interference inherent within this definition is significant. It associates autonomy with freedom or liberty.[3] Foster (2009) denies any ambiguity in healthcare regarding the term autonomy and notes in a rather glib fashion, that everyone is quite clear what autonomy means. It refers to "straightforward libertarianism" (p.3). The libertarian view of autonomy is associated with freedom from constraints and reflects the notion of 'negative' liberty as articulated by Berlin (1969). In accordance with negative liberty one's freedom is in proportion to the degree of non-interference. The libertarian context of autonomy, associated with individual freedom to choose, is growing in popularity in Western healthcare practice

(Scully et al., 2006; Varelius, 2005) and creating a consumer like culture of free choice (Moreno, 2007). There is increasing criticism of this consumer culture within the literature. The basis of the criticism is that patient autonomy now takes precedence over professional judgement within the consultation process with potential negative consequences for patients (Downie, 1998; O'Neill, 2002; Mol, 2008). This position will be developed as the paper proceeds.

Contemporary professional codes of conduct, healthcare ethics texts and policy documents provide some empirical evidence of this shift towards greater patient autonomy. Gillon's (2003) proposal that autonomy should be upheld as the first principle has gained momentum in medical ethics. The Irish Medical Council's (2009) most recent direction to its members, while acknowledging some exceptions, asserts the patient's right to control what happens to her in accordance with her autonomy. One particular medical ethics textbook outlines autonomy as the "primary consideration in patient centered treatment" (Schwartz et al. 2002, p.8). The Irish Department of Health and Children has increasingly noted the need for greater patient involvement at all levels of health service delivery. This includes mental health service provision (DoHC, 2006), safety management (DoHC, 2008b) and chronic illness strategy (DoHC, 2008c). The latter policy states, as one of its core principles, that patients "should actively participate in the management of their condition" within a healthcare system that maximises opportunities for self-care (DoHC, 2008c p.22).

However, current policy goes beyond merely encouraging participation in one's own immediate health. A recent DoHC and Health Service Executive (HSE) document (DoHC and HSE, 2008c) outlines a global strategy for increased user involvement in the health services. The opening chapter suggests that service users should be central figures not only in matters affecting their own care, but also with regard to service design and provision. The language of the document is very consumer orientated. This language, and proposed initiatives such as a patient charter, supports the advent of the patient as an autonomous discerning customer in the healthcare arena and significantly alters the patient/healthcare professional relationship (Mol, 2008). Ryan et al. (2010) associate the current increase in the use of self-testing devices with these policy shifts

in a UK context. The authors suggest that patients may self-test as they perceive this to be a desirable aspect of self-care which is promoted by the government.

This rhetoric of patient autonomy now permeates healthcare practice and policy replacing previous paternalistic models of care and a culture of medical dominance (Rothman, 2001). This shift is attributed to a number of complex social developments. The literature provides a thorough account of these developments which include the advent of neo-liberalism, economic rationalism, consumerism and associated litigation, the commercialisation of medicine and an increasing lack of trust in doctors and healthcare institutions (Rothman, 2001; Willis, 2006; Eldh et al., 2006; Kapp, 2007).[4] Modern American bioethics[5] has also contributed significantly to this change where the principle of autonomy has gained increased prominence as the leading ethical principle underpinning healthcare delivery (Moreno, 2007). Moreno refers to "an autonomy-driven bioethics" (p.417) in the US fuelled by several social events including the blatant disregard for participants in the Tuskegee Syphilis Experiment (1932-1972), the emergence of the Belmont Report in 1973 detailing ethical principles for research and the influential Roe v Wade decision in 1972 which focused on personal rights and liberty.

Autonomy and Self-testing

Moreno (2007) notes that patients' recognition of their right to autonomy in healthcare has greatly influenced the rise of consumerism and supported corporate interests with regard to direct-to-consumer advertising. The author mentions self-testing as a particular example of the interplay between increased patient autonomy and consumerism. Much of the debate regarding the value of self-testing diagnostic devices centers on their role in advancing an individualistic paradigm in healthcare delivery, which replaces a previously more stringently controlled and professional-led healthcare system. This is particularly true in the context of ethical analysis where the ability to self-test and possibly diagnose without, or with reduced, professional support is seen as an example of extended patient autonomy and questioned on this basis (Modra, 2006; O'Lynn, 2007; Kearns et al., 2010). Self-testing diagnostic devices are

marketed as a means to encourage patient participation in healthcare and improve overall health outcomes through the early diagnosis of disease (Simplicity-health, 2009). It is proposed that this early participation is a 'good' thing. Essentially these devices facilitate greater patient autonomy in the context of diagnosis and management of disease.

Studies which investigated the efficacy of diagnostic self-testing kits such as glaucoma computer based tests (Ianchulev, 2005); International Ratio testing (Henegan et al., 2006) and blood glucose monitoring (Towfigh et al., 2008; Alleman et al., 2009) display clinical results which support their value as diagnostic tools. However, despite the positive outcomes noted here, this is not the case for all home testing systems. There is considerable debate as to the value of home blood glucose monitoring, particularly in patients who are not treated with insulin, and research studies reveal different estimates with regard to clinical outcomes (Farmer et al., 2009a). One study in the UK found that clinical outcomes in the context of blood glucose levels were improved when patient self-testing was replaced by a more proactive patient education programme (Harris and Cracknell, 2005). This study also revealed that patients were relieved not to have to self-test on a regular basis, as testing reinforced the illness role and resulted in feelings of failure and negative health related behaviours when results were poor. A considerable portion of self-testing diagnostic tools refer to home screening systems, e.g. prostatic antigen (PSA) tests as a method of screening for prostatic cancer. Despite one web-site declaring that 'early diagnosis significantly improves the outcome of any prostate disorder treatment' (Simplicity-health, 2009) the empirical evidence in the context of prostate screening suggests otherwise. There is no conclusive evidence that routine prostate screening improves health outcomes (Illic et al., 2006), and routine screening is not recommended in the general population but rather reserved for those who exhibit certain risk factors (Burger and Kass, 2009).

The literature with regard to the extended autonomy afforded to patients in the context of self-testing devices, though mainly discursive and non-empirical, raises similar concerns. There is a potential for self-testing devices, including screening initiatives, to promote a culture of the worried well (McMahon, 2009) and contribute to

psychological distress due to the possibility of false positives (Modra, 2006) and the lack of pre-test counselling (Raffle, 2000; Kachroo, 2006; O'Lynn, 2007). Whellams (2008) makes a rather more sinister claim. The author contends that industry's eagerness to gain FDA approval for home HIV testing kits in the US was not proportionate to consumer demand for the product. Whellams's thesis is that corporate motivation for marketing these products is linked to the ease with which future diagnostic self-testing systems may then be commercially marketed. The UK Nuffield Council on Bioethics (2010) recently published an ethical assessment of the increased availability of medical profiling and online medicine. The report concludes that while certain developments may provide some benefits the claims are sometimes overstated and it urges caution, greater regulation and the banning of certain facilities including direct-to-consumer imaging.

Examining current perceptions of autonomy in healthcare

The argument under examination in this paper asserts that the current model of autonomy in healthcare does not provide a suitable benchmark for healthcare policy, or professionals, because (a) it represents a one-dimensional, sometimes misguided, perception of autonomy associated with the absence of constraints and (b) it denies important considerations of relationality, care and responsibility which may better serve the patient. We shall address the former point initially and present two principal arguments in support of our claim. Firstly, a broader philosophical account of autonomy goes beyond notions of 'negative' liberty to encompass an understanding of 'positive' liberty which is not necessarily related to the absence of constraints. Secondly, being autonomous is not solely concerned with acting on one's individual desires or wants in an isolated vacuum but demands an understanding of our societal connections. Our argument addresses a misrepresentation of Kantian ethics which exists in some healthcare literature to the detriment of a richer understanding of autonomy.

Autonomy, constraints and positive freedom

We argue at this point that contemporary notions of autonomy in healthcare, as outlined above, can be questioned because autonomy is not necessarily synonymous with freedom to choose and is not dependant on the absence of constraints for its existence. The libertarian understanding of autonomy in healthcare subscribes to a negative perception of autonomy. This negative perception does not reflect "the positive element of self-determination essential to an adequate account of autonomy" (Young 1986 p.49). Delineating the differences between positive and negative notions of freedom and autonomy are central to this claim. If autonomy can exist in the presence of some constraining factors, then an anti-paternalistic healthcare philosophy which seeks to advance autonomy by promoting individual freedom to choose is fundamentally flawed.

In *Two Concepts of Liberty* Berlin (1969) delineates between positive liberty which is concerned with self-mastery and negative liberty associated with non-interference by others. Berlin's account of positive freedom echoes very much a Kantian perspective when he refers to the 'inner citadel' where people retreat as rational beings to free themselves from desires they know cannot be realised. Berlin tells us that we can free ourselves from obstacles in our path by abandoning the path in a self-determining manner through the use of critical reasoning. We will explain how this is possible in a clinical context later in this paper.

Carter et al. (2007, p.3) explain the distinction between positive and negative notions of liberty as follows:

> "In other words, when such a theorist [proponent of positive liberty] seeks to determine whether people are free, the focus is on what they have done or how they have done it. For a negative-liberty theorist the focus of any such enquiry is very different. In order to ascertain if people are free in some respect, a proponent of negative liberty asks not what they have done but whether they are unprevented from doing something".

This positive, self-determining sense of liberty is also supported by Dworkin's (1988) appraisal of autonomy. Dworkin refers to freedom as liberty and suggests that the terms liberty and autonomy should always be distinguished. He proposes that "autonomy is a richer notion than liberty" and relates to "the idea of being a subject, of being more than a passive spectator of one's desires and feelings" (p.107). Dworkin suggests that autonomy and freedom are not synonymous even though they may at times be linked. He suggests that in forcing a Jehovah's Witness patient to have a blood transfusion against her will one denies her liberty yet also her autonomy. However, in another example Dworkin explains that in deceiving a patient about his treatment, his freedom has not been denied but his autonomy is thwarted by the process of deception.

This reflects a re-occurring theme within philosophical literature that autonomy and freedom are distinctive and that freedom is not a necessary pre-requisite for autonomy. Scott (1998) articulates the difference by explaining that the animals in the field are free, but cannot be said to be autonomous, as they do not possess the attributes necessary for autonomous action, presumably, the ability to act as rational agents. It would seem therefore, as Scott explains that freedom is not a sufficient or even necessary condition for autonomy to exist. Seedhouse (1998, p.184) supports this proposal in stating that autonomy is not "necessarily related to the amount of options available" but is more context related. Seedhouse delineates between respecting and creating autonomy and suggests that one can create autonomy for another by not necessarily granting all their choices.

Dworkin cautions us against a concept of autonomy associated with significant independence. He contends that this understanding "makes autonomy inconsistent with loyalty, objectivity, commitment, benevolence and love" (p.21). This statement is particularly relevant in the healthcare context where healthcare personnel are obliged to consider their professional commitments to care for patients. These commitments, and their inconsistency with the current autonomy rhetoric, will be explored as the paper proceeds.

At this point in the argument we suggest that a notion of autonomy that is equated with freedom to choose, in so far as this refers to negative freedom and the absence of constraints, is questionable. The discussion regarding positive freedom above raises the issue of one's desires which is also significant in debating the merits of contemporary understandings of autonomy.

Autonomy, Kant, desires and relational responsibilities

A philosophical analysis of autonomy to this point reveals that choosing to act on one's immediate desires may not be in accordance with one's autonomy. An autonomous approach to healthcare delivery which seeks to facilitate patient freedom of choice, with little interference, does not sufficiently appreciate that one's initially expressed desires may alter following a reflective process where other factors are considered. Being autonomous is not solely concerned with acting on one's individual desires or wants in an isolated vacuum but demands an understanding of our societal connections.

This view conflicts with the 'negative' understanding of autonomy in healthcare which is often attributed to Kantian ethics. We propose here that Kant's philosophy is often misinterpreted in healthcare literature to the detriment of a richer understanding of autonomy which may better serve patients' best interests. As a case in point, the medical ethics textbook, noted earlier which portrayed autonomy as the paramount ethical principle, contended that respect for autonomy is linked with respect for persons and an associated Kantian philosophy which suggests non-interference with one's "plans, ambitions and choices" (Schwartz et al. 2002, p.8). This is not necessarily how Kantian philosophers perceive his work.

In *Groundwork of the Metaphysic of Morals* Kant (1998) sets out an a priori metaphysic of morality. Essentially the categorical imperative, its supreme principle, outlines what one ought to do unconditionally; "act only in accordance with the maxim through which you can at the same time will that it become a universal law" (G 421). In accordance with this imperative people's duty is to act only in a manner that they

will their actions to become a universal law of nature. Kantian ethics is often portrayed as a judicious approach to morality where a rational being acts solely on the basis of principles which are self-embodied and not causally determined or influenced by outside forces. This understanding of Kantian ethics is often misconstrued as referring to the autonomous agent and his autonomous choices. However, contrary to misinterpretation, Kant's *autonomy of the will* does not refer to autonomous action; rather it refers to the practical reasoning employed in "determining choice to action" (Heubel and Biller-Andorno, 2005, p.7).

Onora O'Neill echoes similar concerns with respect to misrepresentation of Kantian morality. In *Autonomy and Trust in Bioethics* O'Neill (2002, p.74), takes issue with a number of distinguished philosophers who isolate Kant as a major proponent of individual autonomy. "They accuse Kant of identifying autonomy with self-control and independence, with extremes of individualism and with blindness to the ethical importance of the emotions and institutions" (O'Neill 2002, p.74). O'Neill argues that Kant's unique understanding of autonomy is "quite different from the ethically inadequate conceptions of individual autonomy so commonly ascribed to him."

O'Neill proposes that a careful reading of Kant's work provides no evidence for a Kantian autonomy rooted in individualism. The term 'autonomous individuals' does not appear within Kant's writings. Rather, as O'Neill explains, he refers to the 'autonomy of principles' associated with a duty towards others and respect for their rights. O'Neill's thesis is that Kant's reference to 'self-legislation' refers primarily to a 'legislation' that is formulated by oneself in accordance with a number of universal principles (which includes one's duty towards others) as opposed to referring to the 'self' legislating for oneself in isolation from others. The 'self' is reflexive. O'Neill's argument is that those who associate individual autonomy with Kantian ethics focus on the notion of 'self' as opposed to the 'legislation' element of the term. Based on her analysis O'Neill presents the notion of 'principled autonomy' which is most strongly associated with the principle of obligation. The issue of obligation is highly significant in the context of the current argument as it represents one of the alternative perceptions of autonomy which may better benefit patients. We will return to the alternatives later

in the paper but for now we shall continue to outline the misinterpretation of Kantian philosophy as highlighted by others.

Paley (2002) also rejects an isolated interpretation of Kantian autonomy. He refers to the 'myth' that Kant supports a view where individuals make ethical decisions in a detached manner and in isolation from the associated context. He takes issue with an ethics of care which is framed in opposition to Kant and outlines a convincing argument for an ethics of care underpinned by Kantian philosophy. Paley refers to Kant's *Formula of Humanity* whereby one is obliged to treat individuals as ends in themselves and suggests that adherence to the categorical imperative requires one to seek out the 'ends' of another individual so that one can seek to make them one's own. Similarly, Heubel and Biller-Andorno (2005) note that in applying the *Law of Universality*, the first formula of Kant's categorical imperative, one is obliged to consider the accordance of one's maxims with those of others. Therefore an accurate understanding of Kantian morality appreciates that Kant "cannot reasonably be accused of ignoring the fact that autonomy is about our commitments to other people" (Paley 2002, p.135).

Consider an asymptomatic woman who wishes to test herself for the breast cancer gene BRCA1 using a home-testing kit.[6] Prior to sending off the required saliva sample she discusses this with her partner who points out the lack of family history and the fact that a pre-disposition to the disease does not necessarily mean one will develop it. He is concerned that knowledge of the gene will affect his partner's outlook on life, and their life together, and tells her so. The woman, previously so certain of her wish to undertake the test, now alters her choice and decides not to proceed as she deems her inquisitiveness of lesser importance than the value she places on her relationship and current well-being. She makes this decision following a process of critical reflection. She does not feel coerced by her partner but values his input and sees merit in his contribution.

The extent to which she has chosen 'without interference' is arguable yet it is a step further to suggest that her autonomy has been violated 'because' of the interference, as notions of negative liberty would suggest. We propose that in this example her autonomy has been facilitated, as opposed to violated, through a dialogue which encouraged her to critically reflect on her initial desires. This reflects the positive sense of liberty as noted by Berlin (1969, p.46) earlier in this paper. We suggest that in this case the woman has retreated to the "inner citadel" which Berlin refers to using her rational capabilities to reconsider her initial desire to undergo the test. This rational self-dialogue, as Berlin outlines, reflects a Kantian understanding of autonomy whereby one's freedom is not constrained if she willingly imposes restraints on herself. In this case the woman has willingly refrained from taking the test following a reflexive process which considered her partner's position. We suggest therefore at this point, that one's decision making processes need not necessarily occur in isolation as some interpretations of Kant's work suggest.

Marcia Baron (1995), in a somewhat similar fashion, addresses some of the criticisms of Kantian morality, particularly feminists' accounts (Noddings and Gilligan) which condemn the emphasis on duty in his philosophy as being devoid of emotion and connection with others. Baron contends that this misinterpretation is partly due to a mistranslation of the *Groundwork,* particularly a translation by Paton (Kant 1991) which alters the meaning of Kant's philosophy. Paton's translation attributes moral worth to those actions which are done 'for the sake of duty' as opposed to using the correct translation 'from duty'. This is significant because as Baron explains one may act 'from duty' in accordance with Kant's universal law but at the same time seek to recognise and fulfil one's commitments to others. However, if one acts for the 'sake of duty' it suggests that duty embodies both one's motive and the desired result. Baron contends that "one's goal in acting from duty need not be to do one's duty. Duty should be our motivating conception and need not be our end" (1995, p.12).

In accordance with this perspective one may act not solely because one sees it as one's *duty* to do so, but may seek to assist others at the same time. This reflects Korsgaard's commentary on the *Groundwork* (Kant, 2008) suggesting that the needs of others are

significant for moral agents who fulfil these needs because they see helping as their duty. In this context a sense of duty and natural inclination towards others, and their concerns, can coexist.

At this point in the argument we propose that it is reasonable to reject a model of patient autonomy which is based on an individual's freedom to choose in the absence of constraints. This model is not desirable as it is based primarily on 'negative' perceptions of liberty which fail to appreciate the more 'positive', reflexive and self-determining notions of the concept. Furthermore, this version of autonomy is often rooted in a misinterpreted account of Kantian philosophy. Kant does not advocate an individualistic autonomy. His categorical imperative represents an abstract formulation of moral philosophy which does not demand that one exist in isolation from others. In fact, the categorical imperative requires that one consider one's maxims in the wider social context (Heubel and Biller-Andorno, 2005). The analysis to this point suggests that in accepting a model of patient autonomy based on freedom from constraints we are excluding possible alternatives which may be worthwhile. The model of autonomy, based on negative liberty, is rejected here because it denies considerations of relationality, responsibility and care which may better serve the patient population. In what follows we shall address these concepts individually but they are interconnected in ways that cannot, and we suggest 'should not', be obliterated.

Relational autonomy and individual autonomy

The notion of relational autonomy is significant here. One may reject initial desires and wants, not solely for one's own ends, but to meet the responsibilities one has to others by virtue of one's relationships. Relational autonomy represents a broader notion than individual autonomy. One's decisions may be one's own while simultaneously influenced by one's relationships to others. Responsibility to others is an integral component of the decision-making process. Relational autonomy suggests that individual autonomy fails to capture the interdependent nature of our lives where decisions affect not only us but those around us. Relational autonomy is particularly

attributed to feminist philosophy but is also ascribed to by communitarians and proponents of identity politics (Christman, 2004).

Christman (2004, p.143) refers to relational autonomy as:

> "the label that has been given to an alternative conception of what it means to be a free, self-governing agent who is also socially constituted and who possibly defines her basic value commitments in terms of inter-personal relations and mutual dependencies".

This holds great resonance for the healthcare environment. Patients do not make decisions in isolation from their families, dependents and social commitments. However, despite some objections to the concept of relational autonomy, which are concerned with both its inherent logic and normative implications[7,] we suggest that it provides a framework in which autonomy can be understood as a concept which is compatible with the interdependent nature of our lives.

Meyers (1989) account of autonomy as both relational and practical is particularly relevant here. Meyers, similarly to Paley and Baron above, takes issue with an isolated autonomy framed in opposition to socialisation whereby one acts independently of relationships with others. Meyers (p.178) contends that the process of socialisation is critical to an understanding of our true or authentic selves, and that in turn knowledge of one's true self is essential for an autonomous agent as "without reasonably accurate self-portraits, people cannot be self-governing". This 'alternative' model of autonomy, as Meyers describes it, involves the enactment of a number of autonomy competencies: self-discovery, self-definition and self-direction which are, at least in part, socially constructed and render an isolated free-will account of autonomy "dispiritingly fatalistic as well as incomplete" (p.43).

The self-testing phenomenon again provides a platform for this discussion. Kearns et al. (2010) debate the autonomous and relational dimensions of the individual and

propose that while diagnostic self-testing tools can advance individual autonomy through independent testing and decision-making, the results obtained have implications for one's "relational responsibilities" (p.201). Somewhat similar to the example of breast cancer gene testing above, the paper explains this position in the context of a man who finds that he is infertile through use of a home testing kit. Does he have a moral obligation to share these results with his partner and thus fulfil his relational responsibilities? The authors raise further contextual issues with regard to home testing and utilise the work of Charles Taylor to highlight that diagnostic self-testing is not something that occurs in a vacuum but rather holds great significance for those who experience the diagnosis. The paper offers an important dimension to the debate here as it suggests that decisions about diagnostic self-testing cannot be viewed in isolation from the associated contextual issues. We contend at this point that autonomy is a relational concept and not dependant on freedom from constraints in so far as constraints are perceived as input from those who exist in association with us. A model of autonomy which ignores the relational dimensions of a patient's existence does not encompass the reality of the patient's experience.

Professional responsibility and autonomy

The above focus on autonomy as relational is primarily in the context of patients' relational responsibilities towards their significant others. However, there is another dimension to this relationality; the relationship that exists between healthcare professionals and patients, and the responsibilities that exist by virtue of those relationships. In both contexts autonomy is not merely relational but based on obligation or responsibility. The responsibilities and obligations of the healthcare professional are for the most part acknowledged.

As noted above O'Neill (2002) outlines a 'true Kantian' notion of principled autonomy which involves acting on universal principles of obligation as opposed to an isolated, individualistic autonomy. O'Neill's thesis is that the triumph of autonomy has 'contributed' to a mistrust of healthcare professionals as opposed to the other way around. Principled autonomy, in accordance with O'Neill's analysis, rejects coercion

and deception and provides a basis for a trusting relationship. We propose here that in practicing principled autonomy, and considering their obligations towards their patients, healthcare professionals can contribute towards an environment of trust. Principled autonomy offers an alternative to the libertarian account of autonomy, associated with freedom to choose, delineated earlier in this paper.

Consider a patient who contacts his doctor requesting an MRI (an expensive radiological diagnostic test) in response to reoccurring knee pain. His doctor is reluctant to order the test as his clinical judgement suggests it is not required. The patient is currently receiving medication for a recent diagnosis of gout. The doctor is eager that the medication would be trialled for a period of time before entering into further diagnostic and treatment regimes. Furthermore, the physician is aware of the cost of the test and the carcinogenic risks of frequent and unnecessary radiology. The doctor provides this information to the patient. If the doctor refuses to prescribe the investigation it could be argued that the patient's autonomy has been denied. However, it could also be argued that the doctor has acted in accordance with principled autonomy which recognises his autonomy and associated obligations and relational responsibilities towards the patient. The doctor may also be acting in accordance with his responsibilities towards other patients who may require the test in a climate of limited resources.[8]

Through a process of dialogue the patient agrees, albeit with some reservations, to continue the current treatment regime. Perhaps this more interdependent, principled understanding of autonomy, which takes account of the professional's responsibilities, by virtue of their role, and skilfully encourages the patient to engage in critical reflection, might better serve the patient. In this case the doctor has put the principle of non-maleficence before the principle of autonomy. Hofmann and Lysdhal's (2008) paper addressing the use of extensive radiological services supports this course of action. The authors contend that an overreliance on autonomy in radiology can result in exposure to unnecessary radiation. Furthermore, patient autonomy can be misused to reduce the physicians' responsibilities (they may avoid law suits as error is less probable), increase the popularity of the profession (as patients get what they want)

and generate further income for the medical facility (if this is a legitimate consideration). This example supports the central thesis here that a libertarian model of autonomy which fails to take account of professional responsibilities is not one which best serves the patient's interests.

An understanding of relational autonomy places an additional responsibility on healthcare professionals; an obligation to be diligent and skilful in ascertaining the extent to which choices are autonomous. Atkins (2006) applies Meyers' relational autonomy to the healthcare context. In acknowledging the need for critical reflection by the autonomous agent Atkins suggests that such reflective processes involve consideration of one's relationships with others and societal forces. Atkins proposes that healthcare professionals can play a skilled role in assisting these reflective processes to allow the realisation of a richer notion of autonomy which is not limited to free isolated choices. In this context the healthcare professional is obliged to go beyond a patient's initial expression of preferences to illuminate the reasons for these preferences and the societal influences which have underpinned them. This is particularly relevant in circumstances where patients choose to reject therapeutic interventions

Professional care and patient autonomy

Consideration of the concepts of relationality and responsibility suggests that they are important elements of a richer notion of autonomy that seeks to achieve good patient outcomes. These concepts are closely linked with the concept of professional care. Holm (1997) uses the term "protective responsibility" to articulate the sense of obligation experienced by healthcare professionals towards patients in their care. Holm coined the term following an extensive grounded theory investigation of the moral problems experienced by doctors and nurses in practice. It relates to the healthcare professional's awareness of the vulnerability patients by virtue of their ill-health, and their need for assistance with decision-making regarding care interventions.

'Protective responsibility' does not accept autonomy as absolute but recognises that something else may be required to maximise patient well-being in times of ill health. Holm (1997, p. 127) explains the term as follows:

> "When you meet the patient you meet another human being who is vulnerable, who often trusts you, and whose life you can influence in a significant way. This creates a special responsibility towards the other human being, which can be difficult to understand for outsiders, but which nevertheless plays a significant role in the deliberation of health care professionals."

Protective responsibility may provide a suitable model to bridge the abyss that exists between the more stringent positions of autonomy and paternalism. It recognises the interdependent nature of the patient/doctor relationship. This links with Mol's account of the 'logic of care' which she frames in opposition to the 'logic of choice'. Mol (2008, p.43) articulates clearly the tensions that exist when a libertarian model of patient choice permeates healthcare. In *The Logic of Care,* Mol outlines a compelling account of the realities of a consumer-based culture in healthcare. Mol's central thesis is that a 'logic of choice' is not consistent with a 'logic of care' and may lead to 'poor' care. Mol is not concerned with the abilities of individual patients to exercise choice but rather how circumstances of choice emerge and evolve. From her observations and interactions with diabetic patients Mol concludes that more choice does not necessary lead to better care. While the logic of choice is concerned with patients as customers and autonomous, independent individuals, the 'logic of care' suggests a far more messy landscape. In accordance with Mol's analysis (p.62) "the logic of care is attuned to people who are first and foremost related". Mol encourages doctors to cease 'managing' patients and return to 'doctoring'.

Downie (1998) shares a similar perspective in language very closely related to Mol's account. He compares a 'market relationship' to a 'professional relationship' and contends that while serving the bests interests of patients is a feature of the latter, it is not a priority in the former. Downie associates this market relationship and consumer understanding of autonomy with Mill's account of autonomy whereby one is free to act as she wishes, regardless of how irrational those wishes may be, provided her

choices do not cause harm to others. In accordance with Downie's analysis, a healthcare system which refers to patients as customers fuels a culture of 'consumer autonomy'. This may condone a patient persisting with treatment which medical evidence suggests unnecessary or futile. Downie outlines an opposing 'rational autonomy' which he associates with Kantian accounts of autonomy.

This links with O'Neill's (2002) perspective above in so far as Kantian autonomy is more considered, than often portrayed in the healthcare context. One makes decisions not solely on one's initial desires or wishes but in accordance with universal rational laws. Downie is quite direct in his criticism of 'consumer autonomy'. He contends that a degree of paternalism is inherent within a professional relationship whereby the principles of beneficence and non-maleficence may on occasion take precedence over respect for individual autonomy. This certainly supports Holm's account of 'protective responsibility' while also echoing O'Neill's 'principled autonomy' as outlined above.

In specific reference to patient autonomy and the clinical relationship Olsen (2003, p.705) refers to "the ethical use of influence" within a patient/clinician context. Similar to Downie above Olsen proposes that influence is not only 'intrinsic' but 'desirable' within the clinical relationship. Olsen's discussion centres on the process of coercion in mental health practice whereby the use of coercion is justified on the basis of a rights-based approach. In accordance with this approach the patient is seen as an autonomous self-governing agent who has the right to act free from interference. In this context coercion is justified only if the patient lacks capacity to make a judgement or may cause harm to himself, or others. Olsen offers an alternative relational approach whereby influence is seen as a constant feature of the clinical relationship and treatment decisions are continuous and subjective. The relational approach demands that every action of influence, despite its magnitude, is assessed for its ethical suitability. Therefore, respect for patients is paramount throughout and the power relationships are continuously acknowledged. This perspective is coherent with the principles of relationality, responsibility and care outlined in this paper. It provides another example of professional care superseding autonomy in a clinical context.

Gillon's (2003) specific adherence to autonomy as a paramount principle in healthcare practice, which promotes the other bioethical principles, has been rejected by Callahan (2003) in favour of communitarianism and by Dawson and Garrard (2006) on the basis that it rejects the prima facia nature of the principles. The latter argument is significant here as it essentially asserts that the professional duty to care demands that one move beyond mere respect for autonomy in favour of acknowledging other ethical principles when the context requires it. Dawson and Garrard (2006) take issue with Gillon's position that autonomy is 'first among equals' in the context of the four ethical principles outlined by Beauchamp and Childress (2001). They refute Gillon's argument on a number of levels, but particularly with regard to the manner in which his standpoint rejects the Rossian perspective of prima facie, as opposed to, absolute principles. In accordance with an ethic of prima facie duties (Ross 1930) one principle might triumph over the others in accordance with specific situations.

Dawson and Garrard (2006) suggest that justice will take precedence over autonomy in resource allocation issues and that the principles of autonomy and non-maleficence can often be in conflict in a healthcare context. The authors also add that in suggesting that autonomy promotes the other principles Gillon actually exalts their relevance as opposed to rendering them less important. In accordance with Dawson and Garrard's perspective accepting Gillon's position would result in a return to "moral absolutism and its demand that we regard some principles as exceptionless" (p.201). The acceptance of autonomy as the 'first' principle could have negative consequences for patient care as outlined above. There are numerous other accounts in the literature which suggest that an over-zealous adherence to patient autonomy may allow individuals to be disadvantaged by their own choices, create unnecessary confusion and provide a means whereby healthcare professionals abdicate, either intentionally or otherwise, their own professional and caring responsibilities (Holm, 1997; Scott et al. 2003a; Kapp, 2007; Whitney and McCullough, 2007, Harnett and Greaney, 2008).

The empirical literature also provides some evidence for the proposal that patients value the role others take in the decision-making process during their time of vulnerability (Scott et al., 2003b; Levinson et al., 2005; Doherty and Doherty, 2005; Hamann et al.,2007). A large-scale survey design in Toronto investigated patients' preferences for participation in decision-making at three levels: seeking information, discussing options and making the final decision (Levinson et al., 2005). The sample was stratified to ensure representation from the wider population. Results showed that while 96% of patients surveyed preferred to be offered choices and asked their opinions, 52% displayed a preference for leaving the final decision to their doctors. This echoes Berlin's assertion that "individual freedom is not everyone's need" (1969, p.40).

Therefore, it appears that a model of autonomy based on freedom to choose does not always meet the requirements of care as articulated by patients and healthcare professionals. We propose that the interdependent concepts of relationality, responsibility and care are essential components of healthcare. An account of patient autonomy which focuses on the absence of constraints may deny their existence or minimise their importance.

Summary of argument and conclusion

Patient autonomy is widely acclaimed as the new orthodoxy or ethic for healthcare delivery. This is problematic for a number of reasons. Firstly, this perception of autonomy is often equated with free choice which does not reflect the more positive sense of liberty associated with autonomy. In this view self-determination and mastery have greater significance than the absence of constraints.

Furthermore, autonomous choices do not involve acting solely on one's individual desires in a vacuum but encompass a critical, relational, reflexive review of one's initial wants and an appreciation of the impact of choices on others. Misinterpretation and subsequent inappropriate application of Kantian philosophy has sometimes contributed to an account of autonomy in healthcare which is less than complete and

possibly misleading. Finally, a model of autonomy based on freedom to choose, which fails to consider the notions of relationality, responsibility and care does not provide the best means for increasing human potential. We suggest therefore that the combined arguments outlined above provide a platform to question current healthcare policy and rhetoric regarding increased patient autonomy and propose that it should be reviewed or at least accepted with caution.

Conclusion: Towards a new model of patient autonomy

Having raised significant problems with the manner in which autonomy is currently presented in healthcare the discussion would not be complete without providing at least some possible solutions. It is important note that nothing in this paper should be construed as suggesting that patient autonomy is not worthy of consideration. What is suggested rather is that patient involvement in healthcare should be underpinned by a sound philosophical understanding of what it means to be autonomous and an appreciation that autonomy is not necessarily related to the range of options available, of established intrinsic value, or always desired by those it seeks to liberate. The proposals outlined below require another paper to delineate how they may work together but it is important to refer to them here to close the current argument.

O'Neill's (1992) proposal for judging the value of autonomy could be usefully applied to the healthcare setting. In this model autonomy is neither revered nor dismissed but rather viewed in context. She suggests that social independence should not necessarily be desired nor dependence automatically condemned. Rather independence or dependence should be judged on the basis of overall contribution to autonomy and other 'goods'. As O'Neill (1992) suggests we may do well to return to a true Kantian account of autonomy which does not necessarily rebuke interdependence.

Wilson (2007) concurs with much of O'Neill's perspective and suggests that we should value an individual's capacity for autonomy as a fundamental way of respecting autonomy as opposed to necessarily respecting autonomous choices. This echoes Seedhouse's (1998) position that it is essential to differentiate between respecting and

creating autonomy and that the latter may not necessarily involve granting individuals all their choices. Both positions offer alternative perspectives for understanding patient autonomy. O'Neill's (2002) 'principled autonomy' with a focus on obligation, Mol's 'logic of care' (2008) and Holm's 'protective responsibility' (1997) collectively provide an interconnected labyrinth in which to consider autonomy questions in healthcare. The interdependent nature of autonomy within the healthcare setting is central to all these perspectives.

Finally, we propose that Meyers' (1989) account of relational autonomy, as presented above, which is both practical and reflexive presents an overarching framework which could encompass the other proposals outlined, and provide a means whereby patient autonomy can be respected as a socially constructed, non-isolated, concept. It is timely that we question to what extent patient autonomy should permeate healthcare policy, rhetoric and ethics and how we can reconcile respect for autonomy with a professional duty of care. We propose that further philosophical and empirical review, in the context of diagnostic self-testing and other fields, is required to answer these questions.

Notes

1. The impetus for this paper arose from an exploration of the meanings ascribed to autonomy in the philosophical literature. A review of key seminal works revealed an incompatibility with the prevailing understanding of autonomy in healthcare and prompted the particular focus of this paper.

2. The use of the word 'definition' has particular significance in philosophy. Downie encourages the writer to look beyond 'lexical' or 'word-word' dictionary definitions which merely report the common usage of terms. He advocates replacing such *nominal* definitions with more *essential* definitions. The latter, he contends, can be arrived at through classification and analysis. (Downie, R.S. 1994. *Definition. Journal of Medical Ethics* 20: 181-184.)

3. The terms liberty and freedom are used interchangeably here as reflected in the work of Berlin (1969) and Dworkin (1988).

4. It is important to note that this genealogy of autonomy is primarily rooted in western liberal-democratic and liberal-humanistic thought. Therefore, it is important to appreciate the specific cultural context of this discussion. See Pennycook, A (1997) Cultural alternatives and autonomy. In *Autonomy and*

Independence in Language Learning, ed. P. Benson and P. Voller, 35-53. London: Longmans

5. The term bioethics is described by O'Neill (2002) as a meeting ground for those who debate the legal, social and ethical implications of new advances in medicine, science and bio-technology. A detailed account of the 'birth' of bioethics is beyond the scope of this paper but a comprehensive historical account is found in Reich W.T. (1994) The word bioethics; its birth and legacies of those who shaped it. *Journal of Medical Ethics* 4: 319-335.

6. This example was constructed following a review of Kim Atkins' paper which is discussed later in this section.

7. Holroyd maintains that while agents may be relational entities autonomy cannot be. See Holroyd, J. 2009 Relational autonomy and Paternalistic Interventions. *Res Publica,* 15:321-336. Christman, within his account of relational autonomy, raises a concern that a purely relational approach to autonomy may lend itself to an "overarching paternalism" (2004 p.158).

8. A recent "Liberating the NHS" (2010) white paper proposal, announced by the Secretary for State for Health in the UK, suggests a greater role for doctors in managing budgets at a local level through primary care consortia. See *British Doctors to take charge of spending,* www.ama-assn.org/amednews/2010/08/16/gvsb0816.htm (Accessed 4th April 2011)

Acknowledgements

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Appendix C: Process and scope of literature review

A systematic approach to the literature review was undertaken as advocated by Trafford and Lesham (2008). Essentially, the review explores international scholarship in the area of patient autonomy and self-testing. The literature review process began with a subject analysis whereby key terms from the broad research problem were isolated, defined and any synonyms identified. Key search terms included 'patient', 'autonomy', 'self-testing' 'self-determination', 'empowerment', 'self-care', self-management', 'ethics', 'bioethics' 'technology', and 'healthcare'. In order to contextualise the discussion, the latter stages of the review focused specifically on self-testing of blood glucose levels in patients with diabetes mellitus, thus introducing new search words. As noted within the thesis, the analysis and discussion phases of the research required ongoing immersion in the literature to explore the emerging phenomenon.

The scope of the review was determined by isolating key disciplines, periods and geographical areas, where literature of relevance was more prominent. The literature search reflects the various disciplines associated with the subject area, namely, nursing, philosophy, medicine, bioethics, science and technology studies, and emerging areas of scholarship: Ethics on The Laboratory Floor and Health Technology Assessment (HTA). Sociological and psychological works were also reviewed in light of emerging concepts. Certain sections of the literature cluster around key social, ethical, technological and medical developments. The development of autonomy as a concept within American bioethics since the mid-1970s, and an associated international debate which began among the medical and philosophical communities in the 1990s regarding the primacy of autonomy as an ethical principle are of significance. In addition, research regarding the value of self-testing among diabetic patients is prominent in the literature since 2008, following a series of large scale randomised controlled trials (RCTs). The debate regarding self-testing technology among the wider population represents the most recent dimension to the literature. Geographically, the autonomy literature is prominent in a UK and US context but exists across the international community. However, the literature regarding self-

testing among the diabetic community, particularly in the area of HTA, is predominantly UK based, while the most recent literature concerning self-testing is concentrated primarily in a UK and Dutch context.
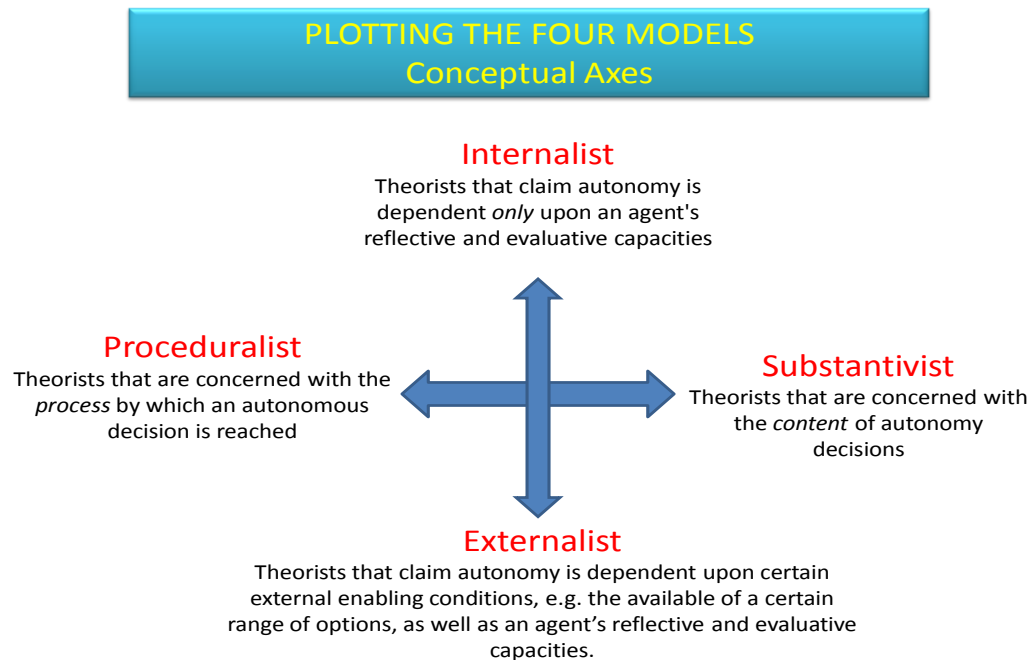
A variety of literary sources were accessed. In light of the empirical ethics study design the scope of the literature review extends beyond empirical studies to include philosophical evidence. Several databases were utilised to search key terms; namely CINAHL, MEDLINE, Philosophers Index, Academic Search Planner, Sage Journals Online, SpringerLink and Biomed Central. Access to more seminal texts and philosophical concepts was assisted by Ebrary books online and the Rutledge Encyclopaedia of Philosophy. The literature encompasses textbooks, journal articles, policy documents and the grey literature, including conference papers, legislation and unpublished theses. Network theory (Ryan et al. 1991 cited in O'Connor 1992)[79] was also utilised as a search strategy. In a network approach, the researcher sources recent articles of relevance from core reputable journals in the field, and works backwards accessing the literature within the articles following the progress of the debate or research. This was particularly helpful in getting a 'feel' for the prominent works.

The body of literature was also developed through attendance at conferences and communication with experts in the field. A series of online alert systems linked to core search items and the 'Table of Contents' of core journals was also helpful. Following initial publication an alert system facilitated by Biomed Central, BioMedLib, assisted in identifying literature of direct relevance to the paper subject matter.[80] Collectively, these various processes of literature searching ensured that reading, writing, reflecting, data gathering and data analysis were cyclical as opposed to linear processes. This cyclical activity is a key feature of hermeneutic phenomenological enquiry (Crist and Tanner 2003, Smythe et al. 2008) which is reflected in the literature review process (Smythe and Spence 2012).

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[79] O'Connor, S.E. 1992. Network theory – a systematic theory for literature review. *Nurse Education Today*, 12, pp.44-50.
[80] Biomed Central provides the service *BioMedLib* to published authors. The service facilitates an alert system to the most recent publications in the paper domain and also highlights citation history.

Appendix D: Personal Autonomy – Conceptual Axes

PLOTTING THE FOUR MODELS
Conceptual Axes

Internalist
Theorists that claim autonomy is
dependent *only* upon an agent's
reflective and evaluative capacities

Proceduralist
Theorists that are concerned with the
process by which an autonomous
decision is reached

Substantivist
Theorists that are concerned with
the *content* of autonomy
decisions

Externalist
Theorists that claim autonomy is dependent upon certain
external enabling conditions, e.g. the available of a certain
range of options, as well as an agent's reflective and evaluative
capacities.

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Appendix E: "Is-ought" paper

Meta-ethical considerations in empirical bioethics research: The significance of Hume's 'is-ought' problem

1.0 Introduction

This paper examines a fundamental meta-ethical problem associated with bioethics research. The 'is-ought' problem concerns the relationship between factual information and normative judgements, i.e. the extent to which the way something 'is' can inform what one 'ought' to do. Hume's (1739/2013) perspective is that there is no logical relationship between 'is' and 'ought' statements. This meta-ethical problem is of direct relevance to empirical bioethics research which combines philosophical and empirical analysis in the pursuit of new knowledge. It is important that the bioethics researcher develop her own metaethical position prior to engaging in empirical work (Salloch et al. 2012). This allows the researcher to pre-establish the relationship between the empirical and the normative throughout the research process. To this end, this paper explores the 'is-ought' problem and the extent to which it represents a valid impediment to empirical bioethics.

The paper's central thesis is that there is an inter-relationship between 'is' and 'ought' statements which supports the use of empirical work in normative judgement. The paper seeks to substantiate two main claims in this regard. (1) An inter-relationship exists between 'is' and 'ought' statements which refutes the absoluteness of the 'is-ought problem', and the associated polarised positions often ascribed to the factual and the normative. An understanding of the inter-play between the factual and the normative in the context of moral choice, and the associated importance of language and meaning within a connected society are utilised to support this claim. (2) In addition, I propose that if the 'is-ought' problem is accepted as absolute an understanding of the reflective, rational activity that represents an important dimension of ethical-decision making is lost. I conclude that polarised positions such as an

absolute 'is-ought' problem are unhelpful and propose a form of neo-naturalism as a preferred meta-ethical perspective (Stewart 2009).

Essentially, the 'is-ought problem' suggests that 'is' premises cannot lead to 'ought' conclusions. The standard Anglo-American interpretation, prior to debate in the 1950s, suggested that there was "no logical relation between 'is' and 'ought' judgements" (Kupperman 2005, p. 343). Searle (1964) expresses the issue in more modern terminology noting that no collection of 'descriptive' statements can entail an 'evaluative' statement without the introduction of an evaluative premise. These issues are of concern for any researcher intending to engage in empirical research to assist in normative analysis.

The basis of the 'is-ought' problem is found in Hume's *A Treatise of Human Nature* (1739/2006). A passage in the final section of Book III – On Morals outlines Hume's position.

> I cannot forbear adding to these reasonings an observation, which may, perhaps, be found of some importance. In every system of morality, which I have hitherto met with, I have always remarked, that the author proceeds for some time in the ordinary way of reasoning, and establishes the being of a God, or makes observations concerning human affairs; when of a sudden I am surprised to find, that instead of the usual copulations of propositions, is, and is not, I meet with no proposition that is not connected with an ought, or an ought not. This change is imperceptible; but is, however, of the last consequence. For as this ought, or ought not, expresses some new relation or affirmation, it is necessary that it should be observed and explained; and at the same time that a reason should be given, for what seems altogether inconceivable, how this new relation can be a deduction from others, which are entirely different from it.

Hume goes on to suggest that "vulgar systems of morality" fail to recognise this 'is-ought' problem. Hume's 'is-ought' problem has been defended and contested over time in an effort to determine its relevance for morality, and in later times, bioethics research. Guevera (2008, p.46) contends that the 'is-ought' issue has a "mature life of

its own, independent of the interpretation of Hume's texts" which secures its place as an enduring philosophical problem.

2.0 Not just the 'is-ought' problem

Prior to considering the arguments regarding the validity of the 'is-ought' problem it is necessary to discuss its relationship with the 'naturalistic fallacy' and the 'fact-value distinction'. The three concepts are related, but they are not one and the same as is sometimes suggested. Harris (2004, p.18) refers to a section of the passage above as Hume's "articulation of the naturalistic fallacy". Similarly Borry et al. (2005) and Sugarman and Sulmasy (2010) make no distinction between the two concepts, while other accounts (Guevera 2008, McMillan and Hope 2008, de Vries and Gordijn 2009) reveal subtle differences between the terms. Curry (2006) delineates the 'fact-value distinction' and the 'is-ought' problem as expressions of the naturalistic fallacy (Curry 2006). However, As de Vries and Gordijn (2009) explain the 'is-ought' problem, the 'naturalistic fallacy' and the 'fact-value distinction' represent distinct ethical problems and are based on different rationales. An appreciation of the nuances in these terms is important in order to adequately explore the 'is-ought' problem.

The term 'naturalistic fallacy' was first coined in Moore's *Principa Ethica* (1903). It refers to "the failure to distinguish clearly that unique and indefinable quality which we mean by good" (1:10). Moore's claim is that moral philosophers commit the 'naturalistic fallacy' when they assign the term 'good' to natural things in the world. In particular he refers to hedonistic utilitarians who equate the 'good' with pleasure (3:36). Hospers (1997, p.253) explains Moore's philosophy in the context of his classic 'open question technique' which he uses to refute naturalism. If we assign 'good' to a certain property in the world, for example honesty, the open question remains: is honesty good? In accordance with Moore's philosophy we go beyond ordinary empirical facts when we refer to the 'good'. For Moore there is a meta-ethical concern with this approach to normative ethics. McMillan and Hope (2008, p.13) succinctly describe the distinction between the 'naturalistic fallacy' and the 'is-ought' problem:

Perhaps the most important difference between these two philosophical problems is that Hume is making a point about validity while Moore is pointing out that there is something normative about moral terms that cannot be captured purely in terms of other facts in the world.

The 'fact-value distinction' also merits consideration here. de Vries and Gordijn (2009, p.198) suggest that the 'fact-value distinction' is not related to a fallacy or problem, but is rather a reference to "meta-ethical views". In accordance with their analysis the 'fact-value' distinction can be reducible to three particular views:

(1) No statement or concept is irreducibly both evaluative and factual.

(2) Evaluative discourse fails to have certain characteristics (such as truth-aptness, objectivity, rationality etc.) essential to paradigmatic realistic discourses like, for example, scientific discourse.

(3) (Scientific) facts do not presuppose values (or, alternatively, science is value-free). (de Vries and Gordijn 2009, p.198)

In this sense, while all three concepts are distinct they also share a core similarity with regard to the claim that moral judgements are normative and cannot be inferred by descriptive, factual representations of the world around us. Herein lies the problem for empirical ethics. Collectively the 'is-ought' problem, 'the fact-value distinction' and the 'naturalistic fallacy' cast doubt over the ability of facts, arrived at through empirical research, to enable one to derive normative conclusions. If ethical judgements cannot be derived from observations of the natural world why engage in this activity? "Whatever we find about what is the case, we are left with questions about what we ought to do" (McMillan and Hope 2008, p.14).

3.0 Examining the merit of the 'is-ought' problem

3.1 Refuting the absoluteness of Hume's distinction

The substantial claim presented here suggests that the 'is-ought' problem is not as absolute as traditionally accepted as there is evidence of a relationship between 'is' and 'ought' statements. The factual and the normative do not occupy polarised or dichotomous positions as the 'is-ought' problem suggests. I present three interrelated

arguments in support of this position. (a) Facts, which are deemed problematic in supporting normative conclusions, are not entirely factual, as they are often imbued with normative meaning. Facts and values are interrelated in a way which refutes the 'is-ought' dichotomy. (b) The relationship between 'is' and 'ought' depends on how we define this 'relationship'. There may be legitimate patterns of inference between factual premises and normative conclusions because of particular aspects of meaning associated with the statements. (c) Finally, an understanding of the relational autonomous agent suggests that one considers the facts of the situation in a societal context in order to determine what one ought to do.

3.1.1 The normative within the factual: Murdoch and others

Harris (2004) affords some merit to Hume's position acknowledging that his perspective challenges us to consider how we can arrive at moral judgements without the accumulation of facts. However, Harris also notes a major difficulty with Hume's 'is-ought' problem. Harris contends that the separation of fact and value, implicit within this distinction, is logically inconsistent as values are "inevitably enshrined in the language with which we describe and present facts" (2004, p.18). This is consistent with the 'thick descriptions' of fact which Kupperman (2005) refers to, Putnam's (2004) 'thick ethical concepts' and, Borry et al.'s (2004) reference to the 'normativity of the factual'. This represents a significant challenge to Hume's assertion that an 'ought' cannot be derived from an 'is', and is the initial argument presented here. Facts are often imbued with normative meaning; therefore, it is contradictory to suggest that factual premises cannot infer moral conclusions.

Iris Murdoch is one of the prominent opponents of Hume's 'is-ought' problem in this context. Murdoch asserts that moral activity is present in all aspects of our cognitive awareness therefore facts cannot be entirely separated from one's sense of value. We interpret facts in relation to our moral compass. Murdoch is "calling attention to, and

criticising, the analytic philosophers' conception of moral rationality" (Diamond 1996, p.82).[81]

Murdoch contends that moral outlook can be expressed in factual terms in the form of specialised moral concepts linked to our cognitive awareness. Diamond gives an example of these moral concepts and the sense of value they portray. For example, there may be a situation where it is clear that one individual took the property of another. However, one party may refer to it as stealing while the other may not. In this sense facts are interpreted in different ways. Diamond (1996, p.103) explains that Murdoch does assign something as 'good' or 'evil' but rather that:

> in ordinary consciousness, in our desires, aversions, images, feelings, attachments and perceptions, values are at work, are being shaped and reshaped in ways which never lose their attachment to the common world but which .are our own.

Murdoch did not accept the prevailing view of analytical philosophers in the 1950s that any attempt to infer an 'ought' from an 'is' was logically unsound as it contained hidden premises, or normative premises cloaked in factual terms. However, Murdoch's position is a rather tempered one. It appears that Murdoch does not entirely refute the 'fact-value distinction' but rather that she suggests another way of looking at how moral judgements are arrived at. In *Vision and Choice* (1956, p.54) Murdoch notes that "fact and value merge in an innocuous way" (1956, p.54). This argument is consistent with the main claim presented here that the 'is-ought' problem is not absolute. Murdoch suggests that philosophers have been misguided in seeking a unified picture of morality and supports a more eclectic understanding of moral choice. In accordance with Murdoch's perspective naturalism is seen "not as a fallacy but as a different system of concepts" (p.56)

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[81] My initial introduction to Murdoch's work was through Diamond's appraisal. Murdoch's own writings were then accessed.

Murdoch's *Vision and Choice in Morality* (1956) begins in support of Hepburn's use of fables as a 'guide' to morality. However, Murdoch extends her arguments to the wider issue of the nature of morality itself, and the extent to which moral judgements are arrived at by recourse to the arts, the factual, imagination, and the transcendental as opposed to merely logical deliberation.

> My point is that if we regard the current view, not as a final truth about the separability of fact and value but as itself representing a type of moral attitude, then we shall not think that there is a *philosophical* error which consists in merging fact and value. (Murdoch 1956, p.54)

Murdoch recognises the hidden evaluative premises that exist in inferring an 'ought' from an 'is' for example, in the context of using statistics to guide moral judgement. Using statistics to inform what one 'ought' to do will only apply if we subscribe to the 'hidden' normative premise that one ought to do what is customary. However, Murdoch does not reject naturalism on this basis, referring rather to the merits of exposing such premises. While the analytic philosopher may contend that exposure of 'hidden' premises supports the logical gap between fact and value, Murdoch's analysis is quite different. In accordance with Murdoch's perspective, the suppressed premise denotes a sense of personal responsibility and relates to the process of individual reflection that is implicit within moral rationality. The inclusion of the suppressed premise, as the associated deliberation, is the reason why one accepts the conclusion on the basis of the facts present. Diamond refers to this as a central theme in Murdoch's work, the notion that "thinking is always an activity of ours as moral beings" (1996, p.82). In this sense Murdoch's rejection of an absolute 'fact-value distinction' is associated with her critique of the analytic philosopher's conception of moral rationality (Diamond 1996).

For Murdoch, cognitive awareness is value-laden. Diamond explains this particular uniqueness to Murdoch's philosophy. While Murdoch's thinking supports a rejection of the traditional 'fact-value distinction' in analytic philosophy she leads us to a different perception of the 'fact-value distinction'. According to Murdoch our moral

rationality allows the awareness/interpretation of something 'in' the factual world. "The morally alive awareness of x may enable us to interpret x into the realm of practical life" (Diamond 1996, p.109). In this sense our own value system allows concepts to be understood In *Metaphysics as a Guide to Morals*, Murdoch (1992, p.26) clearly articulates the interrelationship between fact and value and her opposition to the 'is-ought problem:

> In the majority of cases, a survey of the facts will in itself involve moral discrimination. Innumerable forms of evaluation haunt our simplest decisions. The defence of value is not an attack on 'ordinary facts'. The concept of 'fact' is complex. The moral point is that 'facts' are set up as such by human (that is moral) agents.

This essentially means that we acknowledge and present facts in certain ways because of our ethical perspective. As an example, consider a resuscitation attempt on a male road traffic accident victim. The team in the accident and emergency department are of the opinion that attempts are proving futile. As the lead physician is about to cease resuscitation, one member of the team notes that all other members of the family have died with the exception of a six- month-old baby and this man who is his father. The fact is noted as it is deemed morally relevant in deciding to pursue further resuscitative attempts. This fact is assigned particular moral value. Admittedly, the fact itself is not sufficient to arrive at the normative conclusion that further resuscitation attempts are morally justifiable. There is, as Murdoch has noted, a hidden moral premise. The hidden premise in this instance is that parents of young children should be protected in so far as this is possible. This premise, when exposed, is not a means to support the 'is-ought' problem, but rather an example of the individual reflection that is inherent in moral decision-making in accordance with Murdoch's position outlined above. Other facts related to the possible clinical outcomes post resuscitation will also be considered by the team in deciding to proceed or not.

Murdoch's perspective is supported by Putnam (2004, p.2) who refers to arguments regarding the 'fact-value' issue as "over-inflated dichotomies". In *Fact and Value* Putnam (2004, p.3) articulates that "evaluation and description are interwoven and

interdependent" activities. This reflects the 'innocuous' merging of fact and value which Murdoch refers to. Putnam relates 'the fact-value' dichotomy to the 'analytic-synthetic' dichotomy which has existed since Kantian philosophy as a fundamental dimension of classical empiricism and logical positivism. Putnam uses the word 'dichotomy' specifically to denote a term which has gone beyond the word 'distinction' to place an absolute gulf between fact and value and synthetic and analytic arguments. In accordance with Putnam's analysis we are not surprised if distinctions fail to apply in all situations but the same cannot be said of dichotomies.

Putnam does not accept the absoluteness of Hume's 'is-ought' problem which he claims is directly related to the 'fact-value' dichotomy. He presents two principal arguments in support of this position. Firstly he claims that the 'fact-value' dichotomy rests on a very narrow interpretation of fact. Putnam argues that as science, and man's related understanding of the world, developed the perception of what constitutes fact also evolved. Electrons, protons, and bacteria are all deemed to exist but are not necessarily observable. Secondly, for Putman, facts and values are entangled in what he refers to as "thick ethical concepts" (p. 35). Putnam refers specifically to the use of the word 'crime' by Hume in arguing against the 'fact-value distinction'. Hume's rhetorical question asks: Where is the matter of fact that we call crime? Contrary, to Hume's perspective that 'crime' can never be perceived of as a fact, or a similar assertion by Hare in terms of the word 'cruel', Putnam asserts that fact and value are entangled within both these concepts. While Hare attempts to separate the term 'cruel' into a descriptive and evaluative component, Putnam does not accept this. Rather, he explains, we cannot explain the descriptive meaning of cruel without using the term cruel or a synonym. Putnam explains that to equate cruel with, for example, 'causing deep suffering' would not be sufficient, as a surgeon, prior to the availability of anaesthesia, may have caused deep suffering but this did not necessarily infer he was cruel.

I propose at this point that Murdoch and Putnam present a real objection to the 'is-ought' problem. The facts deemed problematic in supporting normative conclusions are not entirely factual, as they are morally derived or imbued with normative meaning.

This entanglement of fact and value supports the first dimension of the initial claim outlined above. In this context an 'ought' can be derived from an 'is' as normativity is present in fact or, as Murdoch, suggests shapes the realisation of fact in consciousness.

In his rejection of the 'fact-value' dichotomy Putnam refers to the interrelated concepts of language and meaning. Similarly, Murdoch's position cannot be separated from the philosophy of language. This is also an important consideration in this debate.

3.1.2 Language, inference and 'logical relationships'

The philosophy of language acquisition is relevant in this context. This leads us to the second dimension of the initial argument outlined above. The 'is-ought' problem may not be as absolute as claimed because the relationship between the 'is' and 'ought' is dependent on how we understand patterns of relation. There may be legitimate patterns of relation between factual premises and normative conclusions because of particular aspects of meaning associated with the descriptive statements. I utilise Kupperman's work (2005) for much of this analysis.

Kupperman (2005) refers to the manner in which morality and language are intertwined. Kupperman explains that the terms 'good' and 'right' are taught to children by use of examples, which would delineate the sense of 'good' or 'right' the teacher wishes to portray. In this context, "an established morality can be passed on, in the guise of language acquisition" (Kupperman 2005, p.357). Kupperman holds that normative terms have more than one meaning in language. There is the general commendatory way of goodness and the way in which the meaning of goodness has been portrayed to an individual. In this context the contention that an 'is' cannot inform an 'ought' is questionable. One may infer an 'ought' from an 'is' statement if she associates the factual statement with some degree of normativity developed through language acquisition. In this sense, a logical relation between factual premises and a normative conclusion exists because of "elements of meaning that connect premises and conclusions" (Kupperman 2005, p.359).

Wittgenstein's philosophy of language is relevant here. In accordance with Wittgenstein's philosophy we engage in language games when we seek to define concepts. In *Philosophical Investigations* (1958) Wittgenstein uses the word 'game' to exemplify how the concept can only be truly understood by the use of examples which illustrate the ways in which it is used. Peta Bowden (1997) applies Wittgenstein's 'language-games' as the theoretical approach to her philosophical exploration of the ethics of care. Bowden (1997, p. 12) acknowledges that "caring relations vary enormously in their range and application" and accepts Wittgenstein's account of this "practical nature of discursive understanding" as a foundation for her theoretical investigations. Bowden's Caring: Gender-sensitive ethics (1997) presents an account of an ethics of care through the particular contexts in which ethical dimensions of caring exist as opposed to focusing on principles or theories of care. Bowden (1997, p.14) contends that Wittgenstein's outlook provides us with a different way of looking at the world and serves to counteract "reductionist forms of conceptual understanding".

Wittgenstein's philosophy is central to an understanding of a world in which fact and value do not exist in isolation from each other (Harris 2004). Values are, as noted above, imbued with the language we use to present facts. (Murdoch, Putnam and Wittgenstein all support this analysis, albeit in slightly different ways.) Therefore, our particular and practical understanding of concepts may lead us to infer an 'ought' from an 'is', as we see logical inference between factual statements and evaluative conclusions in light of the meaning we assign to those concepts. Cultural and institutional meaning assigned to certain terms equates them with certain values. As an example, consider a conservative guesthouse owner who may utilise the facts of his guests' marital status to make judgements about their moral character when assigning double rooms. The guesthouse owner may have strict religious or moral views about pre-marital sex, which lead him to believe that only married couples should sleep together. In this sense he utilises this moral view point as a hidden premise (as explored by Murdoch) in his deliberations which leads him to decide that the unmarried couple who sleep together are of poor moral character. In addition, he equates the term 'marriage' with certain moral values because of the cultural and institutional meaning

he assigns to the term. In accordance with Kupperman's analysis, he acquired this understanding of 'marriage' through the acquisition of language within the culture in which he grew up; a culture which ascribed certain meaning, status and morality to marriage as a concept and by extension, to relationships that exist outside of this institution.

3.1.3 Relational autonomy and institutional facts

The final dimension to the initial claim rests on an understanding of the autonomous agent as a relational being. In this sense, we assign meaning to facts through our societal connections. Our place in society as a relational autonomous agent means that we decide what ought to be done based on our connections with those around us. I propose here that a relational understanding of autonomy coupled with Searle's (1964) account of 'institutional fact' provides a convincing counterargument to the 'is-ought' problem. A relational understanding of autonomy underlines the significance of the factual and contextual in deciding what one 'ought' to do. This will be further explained as the argument proceeds. Essentially, relational autonomy suggests that the autonomous agent does not operate in an isolated context in deciding what they ought to do in response to the facts that life presents them with.

Christman (2004, p.143) refers to relational autonomy as:

> the label that has been given to an alternative conception of what it means to be a free, self-governing agent, who is also socially constituted and who possibly defines her basic value commitments in terms of inter-personal relations and mutual dependencies

Meyers's (1989) account of autonomy as both relational and practical is significant here. Meyers (p.178) contends that the process of socialisation is essential for the autonomous agent as "without reasonably accurate self-portraits, people cannot be self-governing". This view of autonomy involves the processes, or competencies, of self-discovery, self-definition and self-direction which are, at least in part, socially constructed. Atkins (2006) draws on Meyers's account of autonomy and refers to the

critical processes of reflection which one must engage in, in order to arrive at their authentic selves. These reflective processes involve consideration of one's relationships with others in order to ascertain the extent to which one's autonomous choices are actually one's own or socially imposed. This critical reflection incorporates consideration of what one 'ought' to do in light of the impact on others and the available facts regarding their societal connections.

Searle's (1964) account of 'institutional fact' and 'constitutive rules' supports this claim albeit this was not his intention. To get to this point a wider explanation of his position is required. Searle's (1964, p.44) much-quoted argument in opposition to Hume, outlines a series of factual statements which he contends leads to a normative conclusion thus negating the traditional 'is-ought' problem. The argument goes as follows:

> 1. Jones uttered the statements "I hereby promise to pay you, Smith, five dollars
> 2. Jones promised to pay Smith five dollars
> 3. Jones placed himself under (undertook) an obligation to pay Smith five dollars
> 4. Jones is under an obligation to pay Smith five dollars.
> 5. Jones ought to pay Smith five dollars

I disagree with the general thrust of Searle's argument as there is a significant degree of normativity embedded within the statements which he deems to be wholly factual. There are considerations regarding promises and obligations within the statements which can only be properly understood through some degree of normative analysis or moral awareness. We may not agree that promises place us under any moral obligation at all. Essentially, I suggest that Searle's argument does not provide a sufficient justification for his proposal that normative conclusions can be derived from solely factual statements.

Searle (1964, p.52) does acknowledge that his argument is open to possible objections and offers a distinction between "brute facts" and "institutional facts" by way of confirmation. Searle proposes that there are different types of factual statements. "Smith has brown hair" and "Jones got married" are both statements of fact but refer to different types of fact in Searle's analysis. Searle proposes that 'Smith has brown hair' is a brute fact while 'Jones got married' is an institutional fact in so far as it demands the existence of a certain institution – the institution of marriage (Searle 1964, p.54). Searle goes on to explain institutions as "systems of constitutive rules" (p.55). I agree with his analysis of these different types of facts but suggest that his definition of 'institutional fact' is merely a semantic exercise, as a fact which is institutionally related is imbued with a normative understanding of what that institution entails and the 'constitutive rules' which it embodies.

I propose therefore that Searle's account of 'institutional fact' supports the contention that facts are imbued with normative meaning and are not wholly factual. However, the concept of 'institutional fact' does have significance in light of the argument presented in this paper. I propose that the Searle's concept of 'constitutive rules' holds significance for the third dimension of the initial argument; that a relational view of autonomy requires that one act on the basis of certain facts, albeit, normatively constructed facts, that she is exposed to. As an example, the fact that a nurse's dependants will be disadvantaged if she loses her job may impact on her decision to bring to light abuses within the organisation in which she works. An institutional fact within society suggests that whistleblowers are often treated poorly in the work situation. Being a relational autonomous agent means that the 'constitutive rules' or 'institutional facts' of the society we live in are central facts in deciding what we 'ought' to do. This is consistent with Meyers' (1989) and Aitkin's (2006) view of relational autonomy.[82]

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[82] At the close of the PhD process, it became apparent that this conclusion is congruent with the findings of the research study.

3.1.4 Summarising the initial claim

At this point I suggest that Hume's absolutist position regarding the inability of factual statements to arrive at normative conclusions is questionable for three principal reasons. (a)The factual statements which are deemed problematic in supporting evaluative conclusions are not entirely factual. There is an interrelationship between fact and value with many facts containing some degree of normativity. (b) The degree to which a relationship exists between 'is' and 'ought' depends on our understanding of the nature of this relationship. We may see legitimate patterns of inference between factual statements and normative conclusions because of the sense of meaning we associate with those statements. Finally, (c) an understanding of the relational autonomous agent means that one considers the socially relevant facts of the situation one is in to determine what one ought to do.

3.2 The importance of 'is' and 'ought' in moral decision-making

Here I present the second claim of the argument against the absoluteness of the 'is-ought' distinction. I suggest that accepting the distinction in all cases is to lose sight of the reflective nature of moral decision-making. In the discussion of Murdoch's position above I refer to the fact that while she acknowledges the 'hidden premise' often present in inferring an 'ought' from an 'is', Murdoch sees the suppressed premise as an important feature of the internal reflective processes of moral rationality, as opposed to evidence of a logical gap between fact and value. In accordance with Murdoch's perspective the hidden premise is associated with the sense of personal responsibility inherent within ethical decision making. This reflects a wider theme in Murdoch's philosophy that "thinking is always an activity of ours as moral beings" (1996, p.82). In *Metaphysics as Guide to Morals* (1992 p. 25) Murdoch refers to the "misleading" separation of fact and value which overtime has led to "a diminished, even perfunctory account of morality". This account, fails to incorporate the evaluative nature of human existence.

Murdoch's position regarding the 'hidden' premise as non-problematic, but rather an important facet of moral decision making, is also consistent with the perspective

espoused by others. Diamond (1996) refers to Cavell's account of moral rationality in *The Claims of Reason*. For Cavell a central feature of moral rationality is the individual arriving at a sense of understanding about what she is doing and the responsibilities associated with that action. Putnam's perspective is quite similar. Putnam (2004, p.44) argues that the 'fact-value' dichotomy, implicit within the 'is-ought' dichotomy, represents a "thought-stopper" which removes the process of rationality from ethical-decision making. Putnam suggests that it may be easier to accept the dichotomy between fact and value than accept the responsibility associated with rational thought:

> For one thing, it is much easier to say, "that's a value judgement" meaning, "that's just a matter of subjective preference", than to do what Socrates tried to teach us: to examine who we are and what our deepest convictions are and hold those convictions up to the searching test of reflective examination. (Putnam 2004 p.44)

It appears therefore that in accepting the 'is-ought' problem as absolute we not only ignore the interrelated nature of fact and value outlined above, but promote a form of ethical-decision making devoid of personal reflection and responsibility. I argue that this is problematic in any ethical decision-making process, but particularly within a healthcare context where personal responsibility and accountability are key characteristics required of the moral agent.

4.0 Conclusion: Towards a non-polarised meta-ethical perspective

In conclusion, in accordance with the arguments outlined above, I reject the 'is-ought' problem as absolute. Furthermore, I suggest that it is problematic to subscribe to such a dichotomy as do so is to ignore the processes of reflection, rationality and accountability associated with individual moral choice. I agree with Putnam's perspective that in polarising fact and value harmless distinctions have been "elevated to absolute dichotomies" (p. 2). I propose that moral decision-making is a more eclectic process and therefore propose a correspondingly more eclectic meta-ethical perspective, which allows us to "remain at the level of the difference" as Murdoch

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suggests (1956 p. 57). Stewart (2009) provides a useful means forward here which he refers to as 'neo-naturalism' or 'contemporary naturalism'.

Stewart's neo-naturalism (2009) is supported by his rejection of Moore's 'open-question technique' and other arguments, similar to those outlined above, which refute the absoluteness of the 'is-ought' problem. Stewart's proposes that the open question technique merely suggests that moral terms such as 'good' do not *mean* pleasure but *not* that goodness cannot *be* pleasure or another naturally occurring property. Stewart maintains that in attacking the 'open-question' argument there is an opportunity to revisit naturalism in contemporary meta-ethics. I suggest that 'neo-naturalism' is consistent with Murdoch's 'kind of distinction' between fact and value and Putnam's call for a less dichotomous approach. It supports the perspective of contemporary bioethicists who argue that empirical work can contribute to decisions about want we 'ought' to do (Borry et al. 2004, Holm and Irving 2004, Salloch et al 2012) ethical-decision making.

In summation, Hume's 'is-ought' problem does not preclude empirical bioethics research. An understanding of a neo-naturalist meta-ethical perspective provides the foundation for an empirical bioethics, which recognises the value of the normative and the factual. It is possible through an integrated process of enquiry to utilise facts gained through empirical research to inform decisions about what one ought to do. Recent methodological developments in bioethics research provide a tangible means to utilise the findings of empirical enquiry in this way (Borry et al. 2004, McMillan and Hope 2008, Salloch et. al.2012, Rehmann-Sutter et al.2012).

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Appendix F: Patient interview guide

Final version November 2011

PHENOMENOLOGICAL QUESTION

1. **What is it like to self-test your blood glucose levels?**

   Essentially I am interested in finding out what it is like is for you to self-test your blood glucose levels.
   Could you just start off telling me about self-testing in your life as a diabetic?

Probing questions as the participants begin to relate particular lived experiences?

    a. In what way?
    b. Why?
    c. How?
    d. Can you tell me more about that?
    e. Can you give me an example?
    f. Can you tell me about a specific time that happened?
    g. What did it feel like?

Additional Questions as required:

➢ Can you tell me about a specific time you self-tested your blood glucose levels and what it felt like
➢ *Can you remember the first time you self-tested your blood glucose levels? How were you introduced to it?[83]*
➢ Do you like self-testing? Why?
    o Are there aspects of self-testing that you particularly like?
    o Are there aspects of self-testing that you particularly dislike?
➢ Does self-testing impact on your daily life?
➢ Does self-testing impact on your interaction with your friends and family?
➢ How do you see self-testing fit with your overall diabetes management?
➢ *Is there anything about the self-testing process you would change? What might make it easier for you?*
➢

Following initial interviews – questions to deepen understanding of phenomenon:
➢ What do you do with the results from self-testing – can you tell me something about that?
➢ If the hospital decided to stop self-testing and asked patients to attend more often for hospital-based blood testing, how would you feel about that?

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[83] Questions in italics represent those developed post interaction with the team at Twente University

Appendix G: Healthcare professional interview guide

August 2012

1. Is there a specific protocol or policy with regard to self-testing among the diabetic population? Could you give me some details about this?
    Additional cues as required?
    a. Are particular National/International guidelines followed?
    b. Does the protocol suggest that particular patients are introduced to, or excluded from, self-testing (type 1 v type 2, other clinical criteria)?
    c. Does the protocol outline a specific education programme?
    d. Is there specific criteria regarding how often patients test?
    e. Are there any insulin dose-adjusting programmes for type 1 patients based on self-testing results?
    f. Once a patient commences self-testing is there a review of the process?
    g. Are protocols shared with local GP's?
2. What do you believe to be the benefits of self-testing for diabetic patients?
3. What do you believe to be the disadvantages of self-testing for diabetic patients?
4. Do you think the process could be harmful to some patients in any way in terms of their overall wellbeing – any negative consequences?
5. Do you think self-testing suits some patients more than others and why?
6. Is there a diabetic nurse relationship with all patients who attend the medical out-patient clinics?
    a. Does the self-testing regieme ever differ for those patients who attend the diabetic nurse clinic versus those who attend the medical outpatients alone?
7. Are oral hypoglycaemics always the first treatment of choice for type 2 diabetics once medication is required?
8. Are patients asked to collate the results of self-testing for clinic visits?
    a. What format is this data in?
    b. What do you do with this data?
    c. Do you value HbA1c Results to a greater extent?
9. Does self-testing assist in the more economic management of the diabetic population?
10. Do patients use self-testing as a means to take more control over their illness? How important do you think this is?
11. Do you think self-testing impacts on the patient and nurse/doctor relationship?
12. Does patient involvement in their care ever pose a challenge for you as their healthcare professional?
13. In general do you think further technological developments in self-testing, and subsequent possible increase in patient autonomy is a useful development?

Appendix H: Scientific community participants focus group guide and post evaluation

November 2012

1. **The opening line in BDI'S online video refers to its role in '*Transforming healthcare through innovation in diagnostics*'**
   What does this 'transformation' in healthcare mean to you?
   Probes
   Does this encompass the vision or ethos of BDI or would you add something else?
   Is this something you have talked about as a group previously?

2. **To what extent does BDI involve stakeholders in the development of devices?**
   Who do you see as key stakeholders?
   Probes
   Is the patient an important stakeholder at the development stage? Why?
   What do you think is important to a patient about the specifications of a point-of-care or self-testing device?
   Do you think male/female patients differ in this regard?

3. **BDI Online – Institute Overview, Feb 2010 – States ;**
   Patients will also be empowered to take control over the management of their own health, improving the quality of their lives, reducing hospital stays and saving lives. These devices are targeted at Point of Care applications: these include near-patient testing, self-testing in the home…

   There now appears to be more a focus on point-of-care devices at clinical sites (GP offices/Hospitals) Two things I would like you to consider - Has this vision deliberately changed? Why?

4. **Do the current point-of-care devices under development (or core capabilities within BDI) have the potential to become self-testing devices – either as a diagnostic or chronic monitoring device?**
   Probes/Background Information
   Current devices under development - Meningitis/Breast cancer/DVT/HIV
   Core capabilities - Nano sensors/ antibody applications/integrated platforms/microfluidics
   Do you think the devices currently under development in BDI have the potential to *empower* patients or maximise autonomy?
   Is this something you associate with self-testing devices?

5. **What do you believe to be the advantages/disadvantages of self-testing for patients?**

   Probes
   What about chronic monitoring among patients with a chronic illness?
   Do you think the process could be harmful to some patients in any way in terms of their overall wellbeing – any negative consequences?
   Vignettes – What are your thoughts on having an insight into this patient's story?
   (May not be permissible to use all)

Questions are sequenced to gradually build a patient focus but allow participants to introduce this initially without prompting. Not all probes may be used.

VIGNETTES

Bart

I find it [the self-testing] of great benefit. I asked one of the nurses one day and she really gave me great insight into it and how it worked out and how many units of insulin per your body mass and one thing and another. Like if I want to knock 2-3 points off my reading, well 1 unit of insulin should do that for me. After she explained about it I just feel so much more comfortable. It leaves me eat whatever I like. It's much more convenient. I'd be very disappointed if I had to come in here to have my bloods checked. It would mean disruption of my day.

Ann

It's the one thing that keeps me on the straight and narrow. It's a great incentive. I mean because you know when you test your blood and the reading is not right then you start taking action either maybe not eating as much or cutting out something, or making sure it comes down to a correct reading. It's the one thing that really keeps me really on the road, the testing. I would say that for definite.

Con

Well, when I get up it's the first thing in the drawer that's looking at me, my self-testing kit. I don't really understand. They tell me the lower my blood sugar level is the better. I don't really know I'm only going by what the nurse say. I just can't my head round this thing that I have it. There are certain times I look at the tester kit and I say well, you know if only I hadn't got it, which would be one less thing. Since I had this diabetes it's taken over. Self-testing, appointments with Doctor x, appointments with the nurse. I thought I was finished all that with the cancer and now it's back again... I'm being reminded every day – I have to test

Alex

My feelings about the readings, particularly in the last twelve months would be frustration. I have Type 2. It's very clear it has deteriorated in the last 2 years but particularly in the last year. So when I am looking at it and I take a reading and I see it's a 16 as it was this morning, I know damn well that's not where it should be. It should be better than that. And I have this sense all the time that it's not going to improve so there's a sense of frustration. So the self-testing, all it is an opportunity at this stage to frustrate myself even more because I know damn well they are never going to be where they should be.

EVALUATION FORM - FOCUS GROUP PARTICIPANTS

Thank you for your participation in the focus group yesterday afternoon and contributing so openly to discussion.

As a follow up I would appreciate your honest feedback on two questions which essentially ask you to evaluate the exercise. I am hoping to capture some of the comments made following completion of the focus group. Please note that any feedback may be considered as official data within the study and incorporated within the study findings. Any comments will be annonymised and protected in accordance with other data as explained in the consent form. Please also note that you are free to make no comment at all and thank you for your assistance to date.

Two questions are as follows:

1. How would you summarise your experience of participating in the focus group as a member of a scientific community?
2. Do you think the BDI community would benefit from further discussion on the end-user application of biomedical devices and why?

Appendix I: Analysis worked example - From data to thematic understanding

This appendix shows how raw data concluded as a sub-theme 'Knowing the body' in accordance with Crist and Tanner's (2003) phases of interpretive analysis as adapted within this study. Relevant journal references are summarised and interwoven, as it is impossible to separate analysis in interpretive research from the thinking processes employed (Smythe et al. 2005).

Phase 1: Early Focus and Lines of Enquiry

Transcripts of initial narratives were reviewed. Initial lines of enquiry were identified at this point and explored within the supervision process.

November 2011
'Awareness' was noted in Deirdre's transcript when looking at the role of the device for participants in initial narratives ('keeps me aware'). I also noted corporeal considerations in Bart's transcript ('I can feel it in my body') but did not link knowledge of blood glucose levels with 'knowing the body' at this point.

January/February 2011
Interpretive writing began at this point. I developed these ideas and worked on an early line of enquiry: *Instrumentality of the device*. This early analysis linked with Heidegger's *Question concerning Technology and* the concept of the device 'as'. I explored how the device assisted Deirdre and how it motivated her and facilitated management of her diabetes.

Phase 2: Central Concerns, Exemplars and Paradigm cases: In this phase central concerns, themes or meanings emerging from individual participants were identified and interpretive writing continued.

June/July 2012
I worked on each individual transcript with an interpretive analysis guide developed post Indianapolis phenomenological workshop. I re-listened to all interviews at this point. *Frances's* story revealed a lot about knowing the body (*Frances refers to understanding her body*). 'Seeing meaning' came about with help of reading existential accounts of health and illness. Willems article on peak flow monitoring, and Foucault and Technologies of the Self, was very significant in promoting understanding. Firstly referred to '*Knowing the body'* here when interpreting Frances's story. Earlier written interpretations re the '*Instrumentality of the device'* and the '*Autonomy continuum'* were also considered while engaging in detailed reflection on each transcript. The role of the device for participants impacted on how autonomous they appeared. However, though in some way related, '*Knowing the body'* was noted as a distinct 'understanding'.

Phase 3/3a: Shared Meanings/Shared Meanings in context

As individual meanings became clearer, shared meanings were then sought. An interpretive summary was drafted at this point to identify links between meanings identified within and across participants' narratives. Initial drafts were re-written and phenomenological reflection continued. As this phase continued, I also explored and incorporated the perspectives of other stakeholders to illuminate the patient context.

Nov / Dec / Jan / February 2012

I sat with; all patient data, individual interpretive summaries, using the 4 existentialist categories as overarching themes (this later proved unwieldy as analysis continued and the thematic headings were altered). I drew out a heuristic device on a large sheet of paper to 'plot' all shared understandings in a structured way. I discussed this with work colleagues, supervisors and others outside the formal supervision process, to elaborate the understanding of '*Knowing the body*', as a sub-theme of '*Corporeal understandings of autonomy and self-testing in chronic illness*', Frances's story linked with Betty, Deirdre and Bart. Bart's earlier words regarding his experience of his body, and Deirdre's comments re 'awareness' were more salient in light of Frances's story. As per the research protocol, patient interviews were analysed in association with healthcare professional (HCPs) interviews and the scientific community participants (SCPs) focus group. These stakeholder interviews were analysed seeking salience in terms of the shared meanings emerging from patient participants. Notes on analysis of transcripts from both stakeholder groups note links with '*Knowing the body*'. At this point an interpretive summary was produced which included '*Knowing the body through self-testing*' (its original title) as a separate sub-theme. The perspectives of the HCPs and SCPs community were interwoven with the patient stories, and relevant literature/philosophy, to aid understanding. Related understandings, as noted above, concerning the '*Instrumentality of the device*' and '*Autonomy continuum*' were incorporated within developing sub-themes. [Analysis journal extracts from this period detail how I revisited early lines of enquiry and constructed/ altered sub-themes through an iterative process of reflecting, reading, writing and listening. The initial intention to group themes in accordance with the existential themes (relationality, corporeality, spatiality, and temporality) was altered to allow a more seamless account of patient experience. Also Heidegger's concept of 'technology as revealing' was developed during this time to explain how exploring the patient's use of the device revealed wider understandings related to the experience of chronic illness].

*Phase 4: Final Interpretations***:** In-depth interpretations of central concerns and summaries were produced. Phenomenological reflection and writing continued resulting in numerous drafts in association with the supervision process.

Phase 5: Dissemination of the Interpretation: Final reports were refined and the thesis was written in its current format.

Appendix J: Interpretive guide to support analysis

My interpretive questions for analysis:

Initially – Telling the story

1. What is salient here?
2. What makes it salient? Are there other ways I could think about this data?
3. What is being revealed about the experience of self-testing?
4. What exemplars or specific stories from the patient's account best represent the patient's experience
5. What is this patient's experience of 'being-in-the world' as a diabetic who self-tests?
6. Are there any understandings that can be developed from *listening* to the participant's story again?
7. What does the 'I' listening guide reveal to assist in keeping close to the patient experience?

Moving to interpretation . . .

8. How do I interpret this experience?
9. What understandings are emerging?

Further interpretation - Heideggerian and other philosophical concerns. . .

10. This story reveals the self-testing device 'as' what in this patients engagement with the device?
11. Are there references to existential modes of being – temporality, relationality, corporeality, spatiality?
12. What philosophical literature and other texts can inform my interpretation?
13. Are there insights from others within an interpretive team?
14. What fore-structures have informed my interpretation?
15. What shared meanings are emerging from analysis of other interviews?
16. What does this participant express regarding the idea of an *Autonomy Continuum* as revealed by the self-testing device? (Idea put forward during early lines of enquiry)

Link to interviews with other stakeholders to illuminate context and temporality

17. What does this story suggest I ask healthcare professionals?
18. What does this story suggest I ask designers?

Developed from work of Crowther and Smythe as discussed at the Indianapolis Institute for Heideggerian Methodologies (2012) and the model of interpretive analysis outlined by Crist and Tanner (2003)

Appendix K: Knowledge building - Knowledge dissemination

Publications

Greaney A.M., O'Mathuna D. & Scott P.A. (2012) Patient autonomy and choice in healthcare: Self-testing devices as a case in point. *Medicine, Health Care and Philosophy*, 15(4):383-95.

Conference Presentations

Greaney A.M. (2013) *'Being-with' interpretive research: The analysis process in Heideggerian Phenomenology.* Paper presented at Royal College of Nursing Research Conference, Belfast.

Greaney A.M. (2012) *What is it with nurses and Heidegger?* Paper presented at Hastings Bioethics Centre, Garrison, New York.

Greaney A.M. (2012) *To the things themselves! Heideggerian Phenomenology as a tool to explore patients' experiences of self-testing technology*. Paper presented at RCSI Annual Nursing Research Conference, Royal College of Surgeons.

Greaney A.M (2012) *Patient Autonomy within the self-testing process: Conceptual and Contextual Perspectives.* Paper presented at Dublin Graduate Philosophy Conference, Trinity College.

Greaney A.M. (2011) *From Hume to Harris: Revisiting the 'is-ought' debate three hundred years post Hume's birth.* Paper presented at 15th International Philosophy of Nursing Conference, Leeds.

Greaney A.M. (2010) *Reflections on diagnostic self-testing and patient autonomy.* Paper presented at 14th International Philosophy of Nursing Conference, Vancouver, Canada.

DCU Graduate Training Elements

Philosophy of Social Science Module 2011/2012 (5 GTE credits)

School of Nursing Qualitative Research Summer School 2011 (5 GTE credits)

School of Nursing Qualitative Research Summer School 2010

Summer Schools / Visiting Studentships[84]

Institute for Heideggerian Hermeneutical Methodologies Summer School, University of Indiana, June 2012

Visiting Scholar at Hastings Centre for Bioethics, New York, June/July 2012

Vising Student at Centre for Philosophy of Technology and Engineering Sciences University of Twente, February 2010

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[84] Shorter seminars/conferences not included here

Appendix L: Ethical approval letter from Dublin City University

Dublin City University
Ollscoil Chathair Bhaile Átha Cliath

Dr. Donal O'Mathuna
School of Nursing

22nd July 2011

REC Reference: DCUREC/2011/087

Proposal Title: **The ethical assessment of self-testing technology: A philosophical and contextual analysis of autonomy within the self-testing process**

Applicants: Dr. Donal O'Mathuna, Ms. Anne-Marie Greaney

Dear Donal,

This research proposal qualifies under our Notification Procedure, as a low risk social research project. Therefore, the DCU Research Ethics Committee approves this research proposal. Should substantial modifications to the research protocol be required at a later stage, a further submission should be made to the REC.

Yours sincerely,

pp Fiona Brennan

Dr. Donal O'Gorman
Vice-Chair
DCU Research Ethics Committee

Appendix M: Invitation letter, plain language statement and informed consent for patients

September 2011

Re: Invitation to participate in a research study[85]

Dear Sir/Madam

I am involved in research towards a PhD at Dublin City University. As part of this study I am undertaking a research project. The title of this component of the research is:

An ethical assessment of self-testing technology: The patient's experience, and healthcare professionals' views of the self-testing process

The particular piece of my research which I am asking you to participate in involves interviewing patients about their experiences of self-testing their blood sugar levels. Your participation would involve being interviewed by me about what you like and dislike about self-testing. The interview would last for no more than 1 hour and will be recorded so I can review what you say. After going back over all the interviews, I may ask some people to return for a second interview. A detailed account of the study is attached which includes any benefits and risks to which you may be exposed if you decide to participate. *The study has received approval from the Clinical Research Ethics Committee of _____*

I invite you to read the attached information and participate in the study if you so wish. Your participation in the study is entirely voluntary and you may withdraw from the study at any time. Should you decide to participate, or wish to find out more information, my contact details are included on the information sheet and above. If you decide not to participate this will in no way impact on your treatment in the hospital.

Whatever you decide, the research team wishes you well and thank you for taking the time to read this material.

Yours sincerely,

_____

Anna-Marie Greaney (co-investigator)

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[85] Any identifying or personal details have been omitted from ethics documentation within appendices

INFORMATION SHEET FOR PATIENT PARTICIPANTS

Title of research: **An ethical assessment of self-testing technology: The patient's experience, and healthcare professionals' views of the self-testing process**

In order to decide whether or not you want to be a part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This letter gives detailed information about the research study. If you are interested in participating please contact the researcher at the details below who will meet with you to answer any questions you may have. Once you understand the study, you will be asked to sign a consent form if you wish to participate.

NATURE AND DURATION OF PROCEDURE(S):

What is this research study about?
This study is interested in finding out what it is like for patients to self-test their blood glucose levels. This will provide information about the use of self-testing devices and the effects of self-testing on patients. Participation in the study *is not* required as part of your diabetes treatment. The research is funded by Science Foundation Ireland.

Why is it important?
There are a growing number of self-testing kits available for sale in the community. These testing kits allow individuals to test for a variety of diseases without the involvement of healthcare professionals. Similarly, more patients with long-term illnesses are now in a position to monitor their own condition at home due to the development of self-testing devices. Previous research has indicated that some patients prefer *not* to take a lead role in the management of their health. This appears to go against the emphasis on patients taking greater control of their health, which self-testing technology encourages. The Department of Health and Children recognises that we need to assess the usefulness of new technologies in healthcare. This study can provide some of that information.

How will the study be carried out?
This particular part of the study will involve interviews with diabetes patients to explore their personal experiences of self-testing. The wider study will investigate the views of different people involved in the self-testing process. This includes nurses, doctors and those who develop self-testing tools.

What will be required of me if I agree to participate?
You will be asked to attend for interview to talk about your experiences of self-testing your blood sugar levels. You will be asked about the things you like and don't like about self-testing and how you manage self-testing in the context of your daily living. The interview will take no longer than 1 hour and will be arranged for a time and place that is convenient for you. Interviews will be recorded so that the researcher will have access to your responses after the interview. You may be invited to attend for a second interview to discuss further particular issues of interest raised in the initial interview.

You may decide to end your participation in the study at any time. This is entirely your decision and will not impact on your treatment in the hospital in any way.

POTENTIAL RISKS AND BENEFITS:

Benefits: The research will have no direct therapeutic benefits to you at this time other than an opportunity to discuss your experiences of self-testing. Any queries about your diabetes should be directed towards the nursing and/or medical staff. The researcher can assist you in this regard if required. However, the information which you provide will enable the researcher to add to the knowledge currently available regarding what it is like for patients to be involved in self-testing. This information has the potential to impact on future decisions regarding patients' participation in their care and the use of self-testing in diabetic, and possibly other, patients.

Risks: The study does not require you to receive any experimental treatment and therefore involves minimal risks only. You may have concerns regarding the information you share with the researcher and what happens to it. You may also become distressed during the interview if you are relating past experiences regarding your diabetes management which you find unsettling.

Precautions to minimise risks: The researcher will ensure that, apart from exceptional circumstances, for example if you said something in the interview that suggested a potentially life-threatening situation, any information you share, including the tape recording, will remain confidential and that the final research report or any material published about the research will not identify you in any way. The researcher takes her responsibilities for your welfare very seriously. If you do become upset, the researcher will cease the interview if required and assist you in accessing any necessary support from the nursing and/or medical staff.

POSSIBLE ALTERNATIVES:

This study does not involve any form of treatment therefore there are no alternative treatment options to outline to you. It is totally your decision to decide to be involved. You can stop your involvement in the study at any point.

WHO TO CONTACT FOR FURTHER INFORMATION:
Please contact the co-investigator, Anna-Marie Greaney at _____

Consent form for patient participants

Title of research:

An ethical assessment of self-testing technology: The patient's experience, and healthcare professionals' views of the self-testing process

The research study the procedures associated with it, and any risks and benefits have been fully explained to me. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved. I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me, or impact on my relationship with the healthcare professionals at the hospital in any way. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner.

I, the undersigned, hereby consent to participate as a subject in the above described project conducted at _____. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the researcher listed below. If I have further queries concerning my rights in connection with the research, I can contact the Clinical Research Ethics Committee of _____

Signature of research participant: _____

Signature of co-investigator: _____

Date: _____   Time: _____

Co-investigator, Anna-Marie Greaney is contactable at _____ for any additional queries regarding the study.

Appendix N: Invitation letter, plain language statement and informed consent for healthcare professionals

Re: Invitation to participate in a research study

September 2012

Dear Sir/Madam

I am involved in research towards a PhD at Dublin City University. As part of this study I am undertaking a research project. The title of this component of the research is:

An ethical assessment of self-testing technology: The patient's experience, and healthcare professionals' views of the self-testing process

This is part of a wider study involving a theoretical and empirical analysis of patient autonomy within the self-testing process. You have been invited to participate because you engage with diabetic patients who self-test in a nursing or medical capacity. The particular piece of the research which I am asking you to participate in involves interviewing you about *your views* of the self-testing process in diabetic patients. A more detailed account of the study is attached which includes any benefits and risks to which you may be exposed if you decide to participate. These are minimal. *The study has received approval from the Clinical Research Ethics Committee of* _____. The study is funded by Science Foundation Ireland.

I invite you to read the attached information and participate in the study if you so wish. Your participation in the study is entirely voluntary and you may withdraw from the study at any time. Should you decide to participate, or wish find out more information, my contact details are included on the information sheet and above.

Whatever you decide, the research team wishes you well and thank you for taking the time to read this material.

Yours sincerely,

_____

Anna-Marie Greaney (co-investigator)

Information sheet for healthcare professional participants

Title of research: *An ethical assessment of self-testing technology: The patient's experience and healthcare professionals' views of the self-testing process*

In order to decide whether or not you want to be a part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This detail is included below. If you are interested in participating please contact the researcher at the details listed who will meet with you to answer any questions you may have. Once you understand the study, you will be asked to sign a consent form if you wish to participate.

NATURE AND DURATION OF PROCEDURES

What is this research study about and what is involved?
This particular study is part of a wider research project. The wider study seeks to undertake a theoretical and empirical analysis of patient autonomy within the self-testing process, and will also involve interviews with the stakeholders who design self-testing devices. Empirical enquiry in the context of this protocol will involve interviews with 10-12 diabetic patients who self-test, and approximately 8 healthcare professionals who interact with the patient group. The process and purpose of the interviews is quite different. The overall research design is Hermeneutic Phenomenological Enquiry (HPE). The patient interviews will be conducted in accordance with this methodology and involve mostly open-ended questioning in order to elicit their lived experience of self-testing. The interviews with healthcare professionals will occur after the patient interviews. The patient data will be used to formulate semi-structured interview questions for the healthcare professionals. In this sense the patient experience can be interpreted in light of the data obtained from healthcare professionals. The context of the patient experience is essential to a hermeneutic understanding and the healthcare professional's views can help illuminate this context.

Why is it important?
There are a growing number of self-testing kits available for sale in the community. These testing kits allow individuals to test for a variety of diseases without the involvement of healthcare professionals. Similarly, patients with long-term illnesses are now in a position to monitor their own condition at home due to the development of self-testing devices. Previous research has indicated that some patients prefer not to take a lead role in the management of their health, and value the support and advice which healthcare professionals can provide. This appears to go against the emphasis on patients taking greater control of their health, which underlies developments in self-testing technology. Self-testing kits are one example of how technology impacts on the way healthcare is managed. The Department of Health and Children recognises that we need to assess developing technology to determine its appropriateness for use in healthcare delivery. This study aims to provide this type of information. In addition, the evidence regarding the benefits of self-testing among the diabetic population,

particularly those with type 2 diabetes, is inconclusive. This study can provide some qualitative data to contribute to this debate.

What will be required of me if I agree to participate?
You will be asked to attend for one interview to talk about your views of the self-testing process in diabetic patients. The interview will take *no longer* than 30 minutes and will be arranged for a time and place that is convenient for you. Interviews will be recorded so that the researcher will have access to your responses after the interview. You may decide to end your participation in the study at any time.

POTENTIAL RISKS AND BENEFITS:

Benefits: The research will have no direct benefit to you at this time other than an opportunity to discuss your views. However, the information which you provide will enable the researcher to engage in a richer analysis of patient data, and therefore, add to the knowledge currently available regarding what it is like for patients to be engaged in self-testing. This information has the potential to impact on future decisions regarding patients' participation in their care and the use of self-testing in diabetic, and possibly other, patients.

Risks and precautions to minimise them: Essentially as sensitive data is not sought the researcher does not envisage any particular risks to you as a participant. You may have some concerns about confidentiality. However, the researcher assures you that, apart from exceptional circumstances, for example if you said something in the interview that suggested a potentially life-threatening situation, any information you share, including the tape recording, will remain confidential and that the final research report, or any material published about the research, will not identify you in any way. In addition, the research takes place at two sites which will assist in assuring the anonymity of participants in the final thesis and any future publications.

WHO TO CONTACT FOR FURTHER INFORMATION:
Please contact the co-investigator, Anna-Marie Greaney at _____

Consent form for healthcare professional participants

Title of research: *An ethical assessment of self-testing technology: The patient's experience and healthcare professionals' views of the self-testing process*

The research study the procedures associated with it, and any risks and benefits have been fully explained to me. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved. I am aware that participation is voluntary and that I may withdraw my consent at any time. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner.

I, the undersigned, hereby consent to participate as a subject in the above described project conducted at _____. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the researcher listed below. If I have further queries concerning my rights in connection with the research, I can contact the Clinical Research Ethics Committee of _____.

Signature of research participant: _____

Signature of co-investigator: _____

Date: _____   Time:_____

Co-investigator, Anna-Marie Greaney is contactable at _____for any additional queries regarding the study.

Appendix O: Plain language statement and informed consent for scientific community (BDI) participants

Plain Language Statement - Information for BDI Participants[86]

In what context is this research being undertaken?
This study is being undertaken as part of my PhD studies within the School of Nursing and Human Sciences at DCU. Dr. Dónal O'Mathúna is supervising the research. The research is partly funded by Science Foundation Ireland (in accordance with the Biomedical Diagnostics Institute at DCU) and the School of Nursing, DCU. The research has received ethical approval as a low risk project from the DCU ethics committee and gatekeeper approval from BDI director Professor Berndt.

What is this research study about and what is involved?
The study is titled: *The ethical assessment of self-testing technology: A philosophical and contextual analysis of autonomy within the self-testing process*
The study involves a theoretical and empirical analysis of patient autonomy within the self-testing process. The theoretical component consists of a philosophical analysis of what it means to be autonomous, through a critical review of the philosophical literature regarding patient autonomy. Empirical enquiry involves in-depth interviews with diabetic patients who self-test. Additional interviews involve healthcare professionals who interact with the patient group. This final component of the project seeks to ascertain the perspective of those who are involved in the scientific development of potential self-testing technology within BDI. All phases of the research process will collectively contribute to creating an understanding of the meaning of autonomy within the self-testing process.

What will be required of me if I agree to participate?
You will be asked to attend for a focus group interview to talk about your views of self-testing in healthcare, and the impact that you envisage this technology can have on patient care and patient autonomy. **No prior preparation is required on your part**. The interview will take *no longer* than 50 minutes and will be arranged at a suitable location within the BDI environment. Interviews will be recorded so that the researcher will have access to your responses after the interview. Participation in the study is entirely voluntary and you are free to withdraw at any time without penalty.

What potential benefits or risks exist?
Benefits: The research will have no direct benefit to you at this time other than an opportunity to discuss your views. However, participating in this type of discussion may facilitate some reflection on the social and ethical dimensions of technological developments which you may not have the time to engage with in normal working practices. It is envisaged that the wider study will have potential benefits for patients through a more elaborate understanding of the realities of the self-testing process.

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[86] Invitation was via e-mail October 2012 to BDI community with assistance of gatekeeper

Risks and precautions to minimise them: Essentially as sensitive data is not sought the researcher does not envisage any particular risks to you as a participant. You may have some concerns about confidentiality. However, the researcher assures you that any information you share will be reported anonymously in any future publication. The final research report, or any material published about the research, will not identify you in any way. In addition, the specific job titles of any BDI members will not be listed in any outputs to prevent identification within a small community. The tape recording will be protected by the researcher in accordance with good research practice. As the data is collected via a focus group the researcher will stress the importance of confidentiality within the group participants prior to discussion. **The researcher is aware of specific IP considerations with in the BDI community and has signed up to the necessary agreements.**

Who can I contact if I require additional information?
Please feel free to contact the researcher Anna-Marie Greaney at:_____

If participants have concerns about this study and wish to contact an independent person, please contact the following: *The Secretary, Dublin City University Research Ethics Committee, c/o Office of the Vice-President for Research, Dublin City University, Dublin 9. Tel 01-7008000*

Informed Consent form for BDI participants

Title of research: The ethical assessment of self-testing technology: A philosophical and contextual analysis of autonomy within the self-testing process

Researcher: Anna-Marie Greaney, PhD Student School of Nursing, DCU
Supervisor: Dr. Dónal O' Mathúna, School of Nursing, DCU
Ph: 01-7007308 E-Mail: donal.omathuna@dcu.ie

I have read details of the research study, the procedures associated with it, and any risks and benefits in the form of a plain language statement. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved. Any queries have been appropriately addressed. I appreciate that the study seeks to examine patient autonomy in healthcare in the specific context of self-testing technology. I understand that participation involves attending for a focus group interview and that the interview will be taped. I am aware that participation is voluntary and that I may withdraw my consent at any time. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner in accordance with legal limitations.

I, the undersigned, hereby consent to participate as a subject in the above described project. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the researcher listed below. If I have further queries concerning my rights in connection with the research and wish to contact an independent person I can contact *The Secretary, Dublin City University Research Ethics Committee, c/o Office of the Vice-President for Research, Dublin City University, Dublin 9. Tel 01-7008000*

Participants Signature: _____

Name in Block Capitals: _____ _____

Witness: _____

Date: _____

Anna-Marie Greaney is contactable at _____ *for any additional queries regarding the study.*