

A Sociology of Medical Innovation

Deep brain stimulation and the treatment of children with dystonia



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Abstract

This project explores the dynamics of medical innovation using the development of deep brain stimulation therapy in paediatric neurology as a case study. Ethnographic research was conducted with a multidisciplinary clinical team developing a novel clinical service that uses deep brain stimulation (DBS) to treat children and young people with movement disorders. Interviews and observations were carried out to identify key challenges encountered by team members, and to explore the way in which team members attempt to manage these challenges in day-to-day clinical practice.

Four key challenges were identified: coordinating multidisciplinary teamwork, identifying suitable candidates for deep brain stimulation; managing the expectations of patients and families; and measuring clinical outcomes. By exploring the strategies used by team members to overcome these challenges, this thesis develops the *Complex Model of Medical Innovation* which challenges prevalent, linear 'bench-to-bedside' understandings of innovation. While scientific 'discovery' is one source of medical innovation, new therapies in medicine also emerge from technology transfer (the transfer of technology from one sector into another) and clinicians' learning-in-practice (the ability of clinician to learn 'on the spot').

Importantly, this thesis demonstrates that technology transfer, learning-in-practice, and medical innovation in general are shaped by various socio-political trends. The activities of the multidisciplinary team and their novel DBS service, for example, have been shaped by the evidence based medicine movement, commercial interests, and a movement that promotes multidisciplinary approaches to paediatric service provision. A consequence of these influences is that the team subjects their patients to a *broad clinical gaze*. Adopting the Complex Model of Medical Innovation has important consequences: First, it draws attention to the innovative activities of clinicians, activities that may be worth disseminating in other contexts. Second, it highlights the role of existing social and material factors in shaping the development of new clinical services. The social impact of new technologies will be influenced by these contextual factors and cannot be attributed to the technology alone.

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Preface

This project was first conceived within the London and Brighton Translational Ethics Centre (LABTEC). Established in 2008 and funded by a Wellcome Trust grant, the LABTEC initiative aims to explore the various social, ethical and clinical challenges arising from the translation of biomedical research into viable medical treatments (from ‘bench to bedside’). Two key principles underlie the LABTEC initiative. The first is a commitment to interdisciplinarity: the individuals that constitute LABTEC come from diverse disciplinary backgrounds, including sociology, philosophy, law, and various health sciences. The second principle is a commitment to “sociology in bioethics”: a conviction that an empirically-derived, in-depth knowledge of a clinical practice can inform more appropriate and more useful normative statements about such practices.

Thus, the LABTEC initiative cultivates interdisciplinary research that has a substantial empirical component. Four PhD studentships were created in this vein, two to be hosted at King’s College London and two at the Brighton and Sussex Medical School. Reflecting a recent surge in interest among the social sciences, all of the studentships explore topics related to the neurosciences. While the specific topics of these studentships were being decided upon, a LABTEC co-applicant suggested that a particular paediatric team using deep brain stimulation would provide an excellent case-study. After my first and second supervisors approached the head of this team and secured his provisional approval, the studentship that has become this project was formally established. The studentship was titled “Deep brain stimulation and the treatment of children with dystonia” and was described as a project that would explore “clinicians’ perspectives on the clinical, social and ethical challenges of using deep brain stimulation”.

In 2010 I was awarded the studentship. Although the scope of the project was set, I was granted a considerable freedom: For better or worse I was permitted to adopt a theoretical perspective that I felt would be most appropriate, and I was given the freedom to decide which specific aspects of the team’s work I would focus on. After a great deal of thinking and consultation, I decided to explicitly frame the project as an exploration of innovation in medicine.

Preface (continued)

A brief note on nomenclature

While putting this thesis together I have had to make a decision on how I would refer people receiving healthcare services. The available terms “patient” and “client” are both laden with symbolic baggage: each imply a particular mode of health care and a particular form of relationship between receivers and providers. (“Patient” is reminiscent of an earlier, ‘paternalistic’ era of health care, while “client” is associated with the move towards consumerism and individual choice.) Ideally I would have simply employed the same terminology used by the clinicians that feature in this project. For the most part, however, the clinicians in this project referred to their patients/clients by name, and during those few instances when a general term was required, clinicians switched between “patient”, “client” and “children” without any apparent logic. I did consider using “children” but some of the patients would be more appropriately described as “young adults”. So, in order to avoid clumsy and awkward phrasing, I have settled for the all-age-encompassing “patient”. When referring to individuals I have used pseudonyms.

Acknowledgements

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I would also like to thank my student colleagues at King's College London and Brunel University, London. At both institutions I have been surrounded by a warm group of students who have provided encouragement, support and coffee. I would particularly like to thank James Porter and Gabby Samuel.

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My family has also given me endless support and encouragement. I thank my father, Peter, for reading sections of this thesis and for his very useful comments. (I apologise to him for my failure to purge this work of all split-infinitives).

I'm forever grateful to my partner, Matthew. Many of the ideas in this thesis are the product of discussions that we have had. He has helped me to make sense of my fieldwork findings and he has reviewed every chapter of this thesis. More importantly, he has provided me with constant encouragement and care, particularly when I have felt exhausted by it all.

Finally, I would thank my participants for their time, curiosity, and tolerance. They have shared a part of their professional and personal lives with me and they have exposed their activities to the scrutiny of an outsider. Consenting to do so would have seemed risky and they could have easily said 'no'. By saying 'yes', they have provided me with a wonderful opportunity. I hope this thesis has made the most of this opportunity.

List of abbreviations

ADL	Activities of daily living
ANT	Actor-Network Theory
AMPS	Assessment of Motor and Process Skills
BFM/BFMDRS	Burke-Fahn-Marsden Dystonia Rating Scale
CDT	Child development teams
COPM	Canadian Occupational Performance Measure
DBS	Deep brain stimulation
EBM	Evidence-based medicine
FDA	Food and Drug Administration
GAS	Goal Attainment Scale
GMFM	Gross Motor Function Measure
GPi	Globus pallidus interna (palladium)
HDE	Humanitarian Device Exemption
HTA	Health Technology Assessment
IMPACT	Initiative on Methods, Measurement and Pain Assessment in Clinical Trials
LABTEC	London & Brighton Translation Ethics Centre
MDT	Multidisciplinary team report
MRI	Magnetic resonance imaging
NBIA	Neurodegeneration with brain iron accumulation
NHS	National Health Service (UK)
NICE	National Institute of Health and Care Excellence
PCT	Primary Care Trust
PI	Principal Investigator
PIL	Participant information leaflet
PMDS	Paediatric Motor Disorder Service
QoL	Quality of Life
R&D	Research and Development
REC	Research Ethics Committee
STN	Subthalamic nucleus
STS	Science and Technology Studies
UPDRS	Unified Parkinson's Disease Rating Scale

Participant abbreviations

Adm	Administrator of the PMDS team
CD	Ex-Clinical Director of Paediatric Services
CRF	Clinical research fellow
Dr M.	Dr Martin, Paediatric neurologist (head of the PMDS team)
JG	John Gardner (author)
Mm	Patient's mother
Neur2	Second paediatric neurologist
Nur	Specialist paediatric nurse
OT	Occupational therapist
Psy	Clinical psychologist
PT1	Senior physiotherapist
PT2	Junior physiotherapist
S&L	Speech and language therapist
TA	Therapist's assistant

Introduction

1.1 Novel neurotechnologies: “Where great need meets great uncertainty”

In 2003 the medical device manufacturer Medtronic gained regulatory approval to market their deep brain stimulation technology as a therapeutic intervention for dystonia. Other, more standard interventions for managing dystonia, a neurological disorder characterised by painful, crippling body postures, are generally considered to be crude and ineffective. Medications provide some relief for a small number of sufferers, but for many they are ineffective or the side-effects are intolerable. Ablative surgery, which involves carefully destroying a specific section of brain tissue, may have some therapeutic effect, but this is often short term: the surgery will need to be repeated, and as more brain tissue is incrementally destroyed, important functions will be irreversibly impaired. As the Nuffield Council on Bioethics’ recent report *Novel Neurotechnologies* (2013) states, dystonia is one of many neurological conditions for which there is “a great need” for new, safer and more effective therapies. There is a considerable hope among clinicians and sufferers, then, that deep brain stimulation will prove to be such a therapy. According to proponents it is adjustable and reversible (unlike ablative surgery), and it has proved to be remarkably effective in managing the symptoms of other neurological disorders such as Parkinson’s. Indeed, the Nuffield Council’s report identifies deep brain stimulation as one of several highly promising novel therapeutic innovations in neurology.

The report also highlights the “great uncertainty” surrounding these promising innovations. Despite having undergone clinical trials as part of the regulatory approval process, there is a lack of useful data concerning the efficacy and safety of deep brain stimulation for dystonia. For example, while some sufferers have experienced a dramatic reduction in dystonic movements with deep brain stimulation, some experience no benefit whatsoever, and there is currently no body of literature that can be used to predict how an individual candidate may respond. And while the incidence of serious short-term adverse effects appears to be low, there is some uncertainty over the long-term effect of stimulating areas of the brain that may be implicated in cognition and mood. For these reasons, the Nuffield Council’s report suggests that the deep brain stimulation technique occupies a

tenuous half-way point between experimental therapy at one extreme and routine clinical intervention on the other.

For clinicians who wish to provide deep brain stimulation therapy as a routine clinical intervention these uncertainties present considerable challenges. This thesis is based upon a study, using observations and interviews, of a specialist team of clinicians as they attempt to overcome such challenges. The team, which I will refer to as the Paediatric Motor Disorder Service (PMDS), is based in the UK and is one of a few teams worldwide that are currently providing deep brain stimulation therapy to children and young people with dystonia. This thesis explores several specific challenges encountered by PMDS team members, and it explores how team members attempt to manage and overcome these challenges during their day-to-day clinical work. The premise of this thesis is that the team's response to these challenges is a vital part of the innovation process. The structure of the team is unique within a hospital setting, and team members engage in what could be called 'learning-in-practice': they devise novel routines and practices that, they hope, will enable them to successfully utilise deep brain stimulation technology within a clinical service for children and young people with dystonia. The activities of the team, then, represent an innovative attempt to address 'a great need' while managing 'a great uncertainty'.

Obviously such learning-in-practice does not occur in isolation. PMDS team members are situated within a particular social and material context which constrains their activities, as well as providing them with various affordances. An aim of this thesis is to illustrate how the PMDS deep brain stimulation service has been shaped by such contextual factors, and thus to provide some insight into the dynamics of contemporary medical innovation. Specifically, this thesis will identify several key factors that have shaped the development of a deep brain stimulation service for dystonia. These include the evidence-based medicine and rationalisation of healthcare movement, commercial interests, pro-multidisciplinarity healthcare policy, the patient-centred healthcare movement, and a trend towards shared-decision making in health care. Using the PMDS as a case study, I will illustrate how these factors can influence the way in which 'promising' new technologies become part of novel clinical services.

The research questions of this thesis will be clearly stated towards end of this introduction. In the meantime I will provide a more thorough overview of deep

brain stimulation and demonstrate why I believe it is worthy of sociological investigation. I will also provide a more thorough overview of the PMDS team that is the focus of this thesis, and the current policy climate as it relates to deep brain stimulation. I will then introduce a model of innovation developed by Piera Morlacchi and Richard Nelson (2011). This model provides a conceptual basis for this thesis, as reflected by the research questions. It also provides a useful starting point for developing what I will argue is a more comprehensive conceptualisation of medical innovation, which I will refer to as the Complex Model of medical innovation.

1.2 Deep brain stimulation

Deep brain stimulation (DBS) is a technique that reduces the symptoms of various neurological disorders by using a pacemaker-like device to deliver constant electrical stimulation to areas deep within the brain. According to current models of the brain, such neurological disorders are the consequence of pathological or damaged brain structures which induce abnormal levels of neural activity. This activity disrupts normal signaling pathways within the central nervous system, leading to uncontrollable motor symptoms such as rigid and stiff muscles or shaking and flailing limbs (Montgomery & Gale, 2008). The exact way in which DBS alleviates such symptoms is not known. One explanation is that by swamping the problematic brain structures with electrical noise it essentially masks the pulsating, cyclic neural activity that would otherwise trigger the motor symptoms (Montgomery & Gale, 2008). DBS is not, then, a cure. It does not repair abnormal brain structures and it does not prevent the progressive degradation of brain tissue associated with some neurological disorders. So while it may be effective in enabling patients to regain some control over the movement of their body, when electrical stimulation ceases, so does its therapeutic effect.

DBS is currently being used in several movement disorder therapies. Within the European Union and North America, regulatory agencies have permitted DBS therapies for Parkinson's, essential tremor, and dystonia. Generally, due to the perceived risks and the high-cost of DBS, it is reserved for severe cases of these conditions where other, more usual treatments have failed to provide adequate therapeutic relief. Parkinson's is by far the most common disorder treated with DBS: diagnoses of Parkinson's are prevalent in developed countries, it is

progressive, and long-term medicinal treatment fails in up to two-thirds of patients (Marsden & Parkes, 1977: 348); hence, according to the device manufacturer Medtronic over 80,000 people world-wide are using DBS to manage the motor symptoms of Parkinson's (Medtronic 2014).

Figure 1.1: DBS system, implanted components

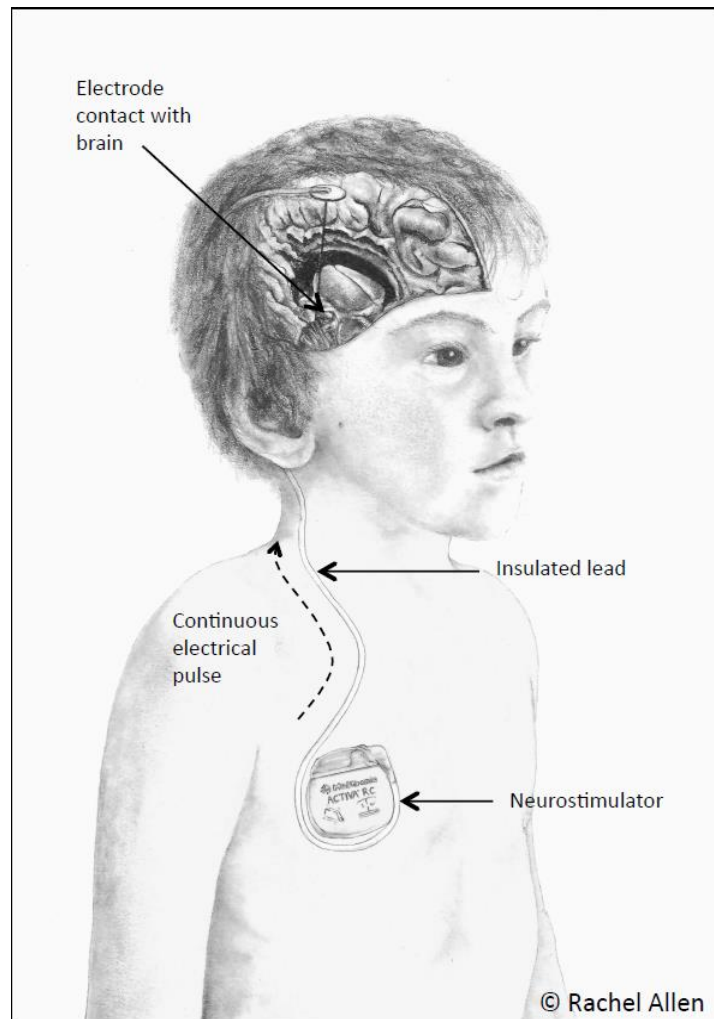


Figure 1.1: An illustration showing the positions of the implanted DBS system components, including neurostimulator, extension wire, and lead (implanted into basal ganglia region of the brain).

Some cases of epilepsy are also being treated with DBS, and recently researchers began exploring the ability of DBS to treat severe cases of psychiatric illnesses: in Europe, DBS has been approved for the treatment of severe obsessive compulsive disorder, and in both Europe and the US, pilot trials assessing DBS as treatment for depression have recently been completed. In the past, severe cases of these motor

and psychiatric disorders that failed to respond to medicine-based therapies would have been treated with ablative surgery. Proponents of DBS argue that unlike ablative surgery, DBS does not cause irreversible damage to brain structures and adverse effects are therefore less likely, or easier to manage if they do arise (Benabid et al., 1991; Limousin et al., 1995).

Specialised technology is needed to deliver DBS. Electrical stimulation is delivered to the target areas within the brain by at least one lead. A neurosurgeon carefully threads the lead into the brain so that the electrodes at one end are placed within the target area. The other end of the lead is attached to a flexible extension wire, threaded under the skin from the top of the scalp, down the side of the neck to the chest (See figure 1.1, page 4). At this point it is attached to an implantable pulse generator (IPG), or neurostimulator, implanted under the skin (Talan, 2009: xiii). DBS therapies are either monopolar, where one lead is inserted on one side of the brain, or bipolar, where two or more leads are used to stimulate both sides of the brain. The specific brain area where the electrodes make contact depend on the condition being treated, but in motor disorders the target area is one of several structures that make up the basal ganglia region.

Figure 1.2: Deep Brain Stimulation hardware



The neurostimulator (figure 1.2) is very similar in appearance and function to a cardiac pacemaker, producing a constant electrical pulse, albeit at a much higher frequency than that used to regulate the beating of a heart. A battery makes up most of the bulk of the neurostimulator, and depending on the model is either

rechargeable or non-rechargeable. In rechargeable models the battery is recharged transcutaneously: the patient (or a caregiver) presses a recharging 'paddle' against the area of skin that covers the neurostimulator, ideally once a day for half an hour. Non-rechargeable models tend to be used for patients who may have difficulty adhering to a recharging schedule. These batteries last between two and four years, after which the entire neurostimulator is surgically replaced.

Once the components have been implanted within the patient, a clinician can programme the IPG via remote control: it can be switched on and off, the frequency of stimulation can be altered, and specific electrodes can be activated. It may take several weeks of trial and error adjustment before the most efficacious stimulation parameters for each particular patient have been determined (Ostrem & Starr, 2008: 322). In many cases (particularly with PD) the patient will be given a remote programmer enabling them to have some control over the implanted device. Importantly, after the device has been implanted and the initial optimal stimulation parameters have been identified, DBS patients require long-term skilled clinical attention: six-monthly follow-up assessments are necessary to ensure that stimulation parameters are indeed still optimal (they often require fine tuning); hardware failures, such as broken or migrating leads are not uncommon; and of course, for those patients with non-rechargeable stimulators, a neurosurgical team is needed to replace the stimulator at least every four years.

The emergence of deep brain stimulation therapies offers an excellent opportunity to explore some of the tensions associated with biomedicine and society. On the one hand, as the Nuffield Council report states, DBS therapies have shown a great deal of promise. DBS therapy for Parkinson's in particular is currently viewed as a sensible and generally effective intervention for patients who fail to respond to medicine-based therapies (Bell, Mathieu, & Racine, 2009; Deuschl et al., 2006: 578). Most Parkinson's patients experience a reduction in the severity of the symptoms, and some patients have had dramatic improvement in their condition. Indeed, some commentators have heralded DBS as providing 'a new life for people with Parkinson's' (Chou et al., 2012), and stories of previously housebound patients with debilitating symptoms subsequently regaining independence and self-confidence with DBS are not uncommon. Proponents also emphasise that because it does not damage brain tissue it is a favourable alternative to ablative therapies (Ardouin et al.,

1999). And, despite the high cost of DBS, there is also emerging evidence to suggest that for the long-term treatment of Parkinson's it is more cost-effective than the best alternative treatments (Bell, et al., 2009; Fraix et al., 2006). For these reasons, a great deal of hope and high expectations surrounds DBS (Talan, 2009).

On the other hand there are, as I stated earlier, significant challenges for health professionals working with DBS therapies. First, despite the apparent success of DBS for treating motor disorders, it is associated with a range of adverse effects, some of which can be severe. There are those adverse effects that relate to the implantation of the components, such as intra-operative cerebral hemorrhaging and post-operative infection, and there are those related to the actual therapy itself, such as slurred speech and a range of so-called 'psycho-social' effects. In DBS therapy for Parkinson's these include mood elevation, anxiety, aggression and cognitive dulling (Synofzik & Schlaepfer, 2011: 3-4). In the longer term, some DBS patients have experienced feelings of aimlessness, despair over the years lost to their illness, marital problems resulting from mood changes, and suicide (Agid et al., 2006; Schüpbach et al., 2006). It is not clear whether these long-term effects are directly linked to electro-stimulation itself or if they are the consequence of the major life changes resulting from the rapid transition from a severely impaired state to an able-state. (Bell, et al., 2009). Second, there is a perceived lack of information regarding the efficacy of DBS therapies and the frequency and severity of these adverse effects. As I stated earlier, while many patients with Parkinson's or dystonia will respond positively to DBS, some patients experience no benefit whatsoever, and currently it is not possible to identify into which of these two groups a prospective patient will fall (Schlaepfer & Fins, 2010; Synofzik & Schlaepfer, 2011).

And third, like many novel biomedical developments, DBS is subject to a fair amount of media-generated hype. The media has tended to produce "over-optimistic portrayals" of DBS, focusing on positive outcomes and dramatic, individual cases while neglecting to explore the actual, more subtle benefits for the majority of those undergoing treatment. (Gilbert & Ovadia, 2011: 2). Racine and colleagues (2007) argue that by reporting predominately on DBS 'miracle stories', the media is creating unrealistic expectations among the public and prospective patients, and thus producing additional pressures for clinicians delivering DBS therapies. This is particularly problematic with DBS as it often represents the last

hope for people with debilitating symptoms who have failed to improve with other available treatments (Bell, et al., 2009).

Some commentators have also drawn attention to the role of commercial interests in disseminating DBS technology. The major producer of DBS equipment is the Minneapolis-based medical device manufacturer Medtronic. According to their most recent annual report, world-wide sales of DBS technology constituted a sizeable chunk of their USD 1.8 billion in net revenues in their neuromodulation division for the financial year (Medtronic, 2013). Fins and Schiff (2010) argue that the interplay of market forces and scientific inquiry within DBS research has resulted in potentially dangerous conflicts of interest. Medtronic, for instance, has been accused of misusing a regulatory exemption in order to facilitate the dissemination of their DBS technology into a range of therapies (Fins et al., 2011). And, from a more philosophical perspective, DBS has been implicated in the 'continuous march of technologies that invade and transform the body', bringing us closer to an era of ethically contentious intelligent design, cyborgs and mind/machine interfaces (Hester, 2007: 255). Such accounts render DBS a small but definite movement towards neurotechnologies with a potential to significantly effect that which we think of as 'human' (McGee and Maguire, 2007).

Thus, DBS is not only the source of a great deal of hope, it is also the subject of apprehension. It exemplifies important tensions associated with biomedicine in contemporary society more generally: a conviction in technology-orientated solutions, a drive to alleviate suffering, a suspicion of commercial interests, doubts over the ability of regulatory initiatives and anxiety over a precarious future. For these reasons DBS is an excellent topic of sociological investigation. For those of us who are interested in exploring the dynamics of medical innovation, such as how the social and technical aspects of medicine may shape one another, the relationship between developments in medicine and wider social and political context, and the ethical challenges presented by new medical technologies, DBS provides an illuminating case study.

1.2.1 Deep brain stimulation in social science research

A small body of work has explored the 'social' aspects of DBS. Much of this has been conducted by French clinical teams as part of their post-operative long-term surveillance of patients receiving DBS for Parkinson's (Agid, et al., 2006;

Schüpbach, et al., 2006). These follow-ups have involved standardised Quality-of-Life and psychological assessments, along with "qualitative psychological observations backed-up by a semi-structured psychiatric interview" (Agid, et al., 2006: 410). It has been these studies that have identified the various 'psycho-social' problems encountered by some "successfully" treated patients: marital problems, feelings of despair over the years lost to the illness, persistent negative anticipation of the future, and a loss of aim in life. Some patients, the authors note, have also experienced a sense of being dehumanised due to their reliance on a foreign, implanted mechanical technology; a feeling of being "an electronic doll" (Agid, et al., 2006: 412). Some of these same patients were interviewed by the sociologist Elsa Gisquet. Gisquet's short report in *Social Science & Medicine* (2008) also highlights the day-to-day challenges faced by people with Parkinson's whose motor symptoms are being successfully managed by DBS. Some, she noted, lamented their reliance on a specialised medical technology, others experienced troubling changes in mood which they attributed to the therapy, and some were frustrated that DBS was not providing greater relief. Gisquet goes on to suggest that DBS therapies may pose "a unique form of biographical disruption" for patients, and suggests that "a period of adaptation is required so that patients become used to their new capacities and accept the limits of the treatment" (Gisquet, 2008: 1850).

The experiences of these patients, and clinicians' responses to them, have been more carefully interrogated by Baptiste Moutaud as part of his ethnographic study of one of the French clinical centres providing DBS (Moutaud 2011). Moutaud paid close attention to the way in which clinicians drew upon various explanatory models to make sense of their patients' responses to DBS. He notes, for example, that the clinicians were able to carefully delineate patients' psycho-social problems as being a consequence of their inability to reintegrate into 'normal life', rather than being a direct side-effect of the stimulation. This enabled them to frame DBS as 'successful', and in the process they effectively drew upon and perpetuated a model of personhood characterised by a mind/body rupture (2011: 186). Patients, in other words, were understood as having a successfully-managed neurological disorder, and as having a distressed mind that necessitated further psychological care. Moutaud also explored how patients themselves drew upon various models of personhood to make sense of their experiences. In contrast to their clinicians, some people with Parkinson's attributed their psycho-social

problems to DBS and its direct effects on the brain. Moutaud argues (2011: 190) that these patients are, in effect, buying-into and reinforcing a naturalistic, neuroscientific discourse that equates behaviour and emotion with neural structures. Similarly, patients undergoing DBS for OCD (who were also included in Moutaud's study) employed biological models to understand their illness. These patients made sense of their OCD in terms of pathological brain circuits rather than, say, drawing upon psychoanalytic models that relate OCD to obsessional neuroses. Moutaud's study, then, illustrates an interesting social consequence of DBS: it can influence how human actors make sense of health, illness and personhood. Indeed, like other neurotechnologies (as I will discuss further on), it has been implicated in perpetuating brain-based explanations of the self.

Moutaud's work demonstrates the value of an ethnographic study of a DBS clinical team. It provides the researcher with an opportunity to explore how DBS patients and their illnesses are rendered intelligible within actual clinical practice. It provides an opportunity, in other words, to witness how a medical innovation is implicated in the reshaping of self-perception, identity and notions of personhood.

Morrison and Bliton are conducting similar sociological research with clinicians offering DBS to people with Parkinson's at Vanderbilt University Medical Centre in Nashville, US. As yet very little work has been published from this study, but Morrison and Bliton published an article in the *American Journal of Bioethics* (2011) in which they argue that such research can provide important insights into the ethics of new neurotechnologies. Empirical research, they state, is necessary in order to identify those aspects of DBS that are ethically problematic. Indeed, they warn ethicists against presupposing which particular issues are ethically problematic without taking into account "the crucial dimensions of patient experience" (Morrison & Bliton, 2011: 27). Both Morrison and Bliton, and Gisquet (2008), argue that extensive examination of the perspectives of DBS patients is needed to guide future development of the therapy: "by focusing on outcomes important to patients, we become more sensitive to effects patients consider beneficial to their lives" (Morrison and Bliton, 2011: 28). For these authors, then, there is a clinical and ethical imperative for conducting qualitative empirical research into DBS therapies.

This project will supplement this small body of work on the social aspects of DBS. In a similar vein to the study of Moutaud, this project will use ethnographic methods to explore, among other things, the ways in which patients

and their illnesses are rendered intelligible during clinical practice. And, in response to Morrison and Bliton's argument, this project will also draw on empirical observations to reflect upon current discussions on the ethics of deep brain stimulation. However, rather than focusing specifically on the experiences of patients (as suggested by Morrison and Bliton), this project will focus on the perspectives of clinicians, and it will explore their clinical interactions with patients.

1.3 The Paediatric Motor Disorder Service: A multidisciplinary DBS service

The case study for this project is the Paediatric Motor Disorder Service (PMDS). As stated earlier, it is using deep brain stimulation technology to provide a therapy for children and young people with severe forms of dystonia at a large children's hospital in the UK. The team was established in 2007 by Dr Martin (pseudonym), a consultant in paediatric neurology. Dr Martin had become familiar with DBS therapy for dystonia via his association with a French team that at the time was providing DBS for a range of motor disorders in adults and a small number of children (It now also conducts DBS for psychiatric disorders in adults.) Dr Martin was awarded a substantial grant from an NHS hospital trust which provided sufficient funding to establish a team that could specialize in the management of complex motor disorders, and could offer DBS as a key therapy. By the time this pool of money was exhausted the service was receiving enough referrals to become self-sufficient.

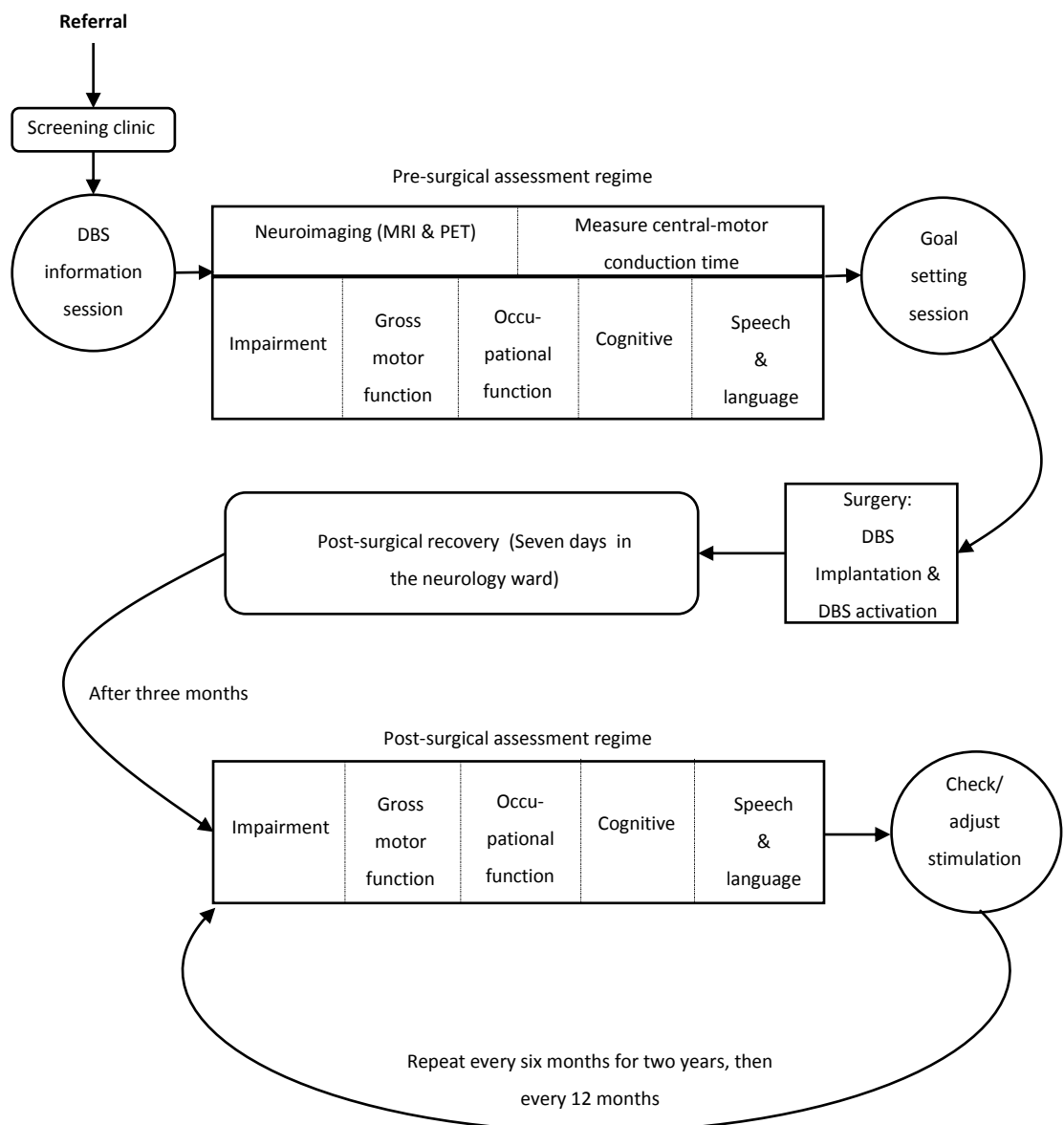
The initial NHS grant provided Dr Martin with the sufficient degree of financial flexibility to create a team structure that he felt would be most appropriate for offering DBS for dystonia in a paediatric context. Consequently, the PMDS was established as a multidisciplinary team, and during the duration of this project it included nine team members in addition to Dr Martin. These were:

- An additional neurologist (a clinical fellow in paediatric neurology)
- A clinical nurse specialist
- Two physiotherapists (PTs)
- An occupational therapist (OTs)
- A clinical psychologist
- A speech and language therapist (S&L)

- A therapy assistant
- A clinical research fellow (training to become a paediatric neurologist)

Aside from Dr Martin and the clinical research fellow, all members of the team are female. This 'core' team also worked closely with two neurosurgeons at a nearby hospital (where the DBS system implantation is carried out), and with several MRI and PET imaging specialists.

Figure 1.3: Paediatric Motor Disorder Service patient pathway



There are several centres worldwide that have provided DBS therapy for paediatric motor disorders (such as the French team that originally inspired Dr Martin), but

currently the PMDS is one of only two groups that specializes in providing DBS exclusively for children and young people with dystonia. It is also the only group that has this multidisciplinary structure: the other prominent specialist team (based in Fort Worth, Texas) does utilize the services of a physiotherapist, an occupational therapist, a neuropsychologist and a 'child life specialist', but their specific roles differ from those of the PMDS members. The PMDS is therefore unique, and along with the Texan team, it is perceived to be pioneering DBS therapy for dystonia in children and young people. More specifically it is pioneering the use of DBS to treat a particular category of dystonia, secondary dystonia (which will be described further on), that is more common in children than adults.

The normal patient pathway through the PMDS (see figure 1.3, page 12) is as follows. First, the families of new referrals are sent a questionnaire that explores the patient's level of disability, their medication regime and history of clinical interventions. Next, the patient and supporting family members attends a screening clinic at the hospital, during which one of the neurologists and several other members of the team (generally the occupational therapist and a physiotherapist) undertake a preliminary assessment of whether or not the patient is a suitable candidate for DBS. This may involve undertaking diagnostic procedures if the patient arrives with an unclear diagnosis. If they are a good candidate the patient will return at a later date to undergo a series of scans (MRI and PET imaging), an information session about DBS, and a regime of pre-surgical assessments, which may take several days to complete. These assessments are used to confirm that they are indeed a suitable DBS candidate, and to produce a 'baseline' measurement of the severity of their condition which can later be used to determine the effectiveness of the intervention. A range of features are assessed:

- Impairment: the degree to which different regions of the body are affected by the motor disorder);
- Gross motor function: the degree to which the disorder affects the patient's ability to perform 'major' movements, such as standing, walking, sitting upright;
- Occupational performance: the ability of the patient to undertake common, day-to-day tasks, like brushing teeth;
- Cognitive: the ability of the patient to perform basic cognitive tasks;

- Speech and language: the ability of the patient to verbally communicate. This may also include assessing the patient's ability to chew and swallow food items.

The assessment regime is then followed by a goal setting session involving the patient, their supporting family members, and most members of the PMDS team. During this session the team attempts to identify the family's goals and to ensure that such goals are realistic. The patient and their family are then given several months to decide whether or not, in light of these 'realistic goals', they would like to continue to proceed with DBS. If they do, the patient will undergo surgery to have the device implanted at a nearby linked hospital, before being brought back to the PMDS for a week of post-surgical recovery as an inpatient in the neurology ward of the children's hospital. It is during this time that the stimulator device is activated. From then on the patient and their supporting family members will be required to regularly return to the PMDS so that the stimulator parameters can be 'fine-tuned' and the assessment regime can be repeated.

Let me now provide a brief overview of the roles of each of the PMDS team members (more substantial descriptions will be provided during the course of this thesis). The neurologists are responsible for assessing the various MRI and PET images in order to determine whether the structural and functional features of the patient's brain will permit the use of DBS: is there, for example, an appropriate, intact target area for the electrodes? The neurologists will also work with the surgeon to plan the surgical insertion trajectory for electrodes. Again, this involves consulting the MRI and PET images. During the patient's post-operative follow-ups it is usually the neurologists who decide upon the stimulation parameters. Additionally, the neurologists are also responsible for prescribing and managing the patient's medication from the time of their initial screening: generally, patients are on a plethora of medications to manage the symptoms. During the patient's time with the PMDS the specialist nurse is largely responsible for liaising with families and helping them to manage their child both before and after the surgery, liaising with the surgical team, and coaching the neurology ward staff on how to manage DBS inpatients. The nurse, together with the neurologists, is responsible for managing any infections that occur. The nurse also leads the DBS information session with families. The regime of pre-surgical and post-surgical assessments are

carried out by the therapists: the physiotherapists assess gross motor control, the occupational therapist assesses the patient's ability to undertake various activities of daily living (self-feeding, hygiene, etc), the speech and language therapist assesses the patient's ability to eat (chew and swallow) and to verbally communicate, and the psychologist assesses the patient's cognitive abilities. The psychologist will also work with patients and their families to help manage anxiety, stress and depression throughout their time with the PMDS. The therapy assistant provides support to the therapists, often helping to set up assessments and record information. In addition to carrying out the assessments the therapist will also consult with families on how to manage their home life. This may involve helping them work with appropriate technologies such as assistive communication devices or mobility aides. Importantly, within the PMDS, it is the therapists who direct the goal setting session with patients and their families: during the regime of assessments they become familiar with the family; a familiarity which they draw upon when helping families to set realistic expectations.

The clinical research fellow is training to become a specialist in paediatric neurology, and to this aim, he works alongside the neurologists as an 'apprentice'. His training also requires him to complete a PhD (in addition to his already-completed medical degree), which involves conducting a research project with the team. His particular project involves determining whether or not there is a correlation between electrode placement within the target structure of the brain and symptom control.

Thus, the team is roughly divided into two sections: the 'medical section', which involves the neurologists, the nurse and the clinical research fellow, and the 'therapy section', which includes the therapists, the therapy assistant, and the clinical psychologist. The 'official' domain of the former group is brain structure and brain function assessment, DBS hardware management, and infection management, while the domain of the latter is assessing and assisting the patient's day-to-day functional abilities, and managing the expectations of patients and families.

1.3.1 *Dystonia and the PMDS cohort*

Dystonia is defined as "a neurological syndrome characterized by involuntary, sustained, patterned, and often repetitive muscle contraction of opposite muscles, causing twisting movements or abnormal postures" (Jankovic 2007). It can occur

seemingly at random in people of any age. While in many cases it may be limited to a specific region of the body (focal dystonia, such as cervical dystonia that affects the muscles of the neck), in some cases it affects large sections of the body (generalized dystonia). And, in some people dystonia is 'brought on' only when they attempt particular movements, while in others dystonic movements are present at rest. It is often exacerbated by stress and anxiety (Geyer and Bressman 2006). In more severe cases, the twisting movements and the resulting abnormal postures are intensely painful and severely debilitating. Although the exact pathology of dystonia is unknown, dystonia, like other movement disorders, results from abnormal neural activity in the structures that make up the basal ganglia, a region deep within the brain that is responsible for motor control.

Generally dystonia is classified as either 'primary dystonia' or 'secondary dystonia'. Primary dystonia is used to describe cases where the dystonia (either focal or generalized) is the only neurological condition present (Geyer and Bressman 2006). It is characterized by an absence of any identifiable brain lesion or structural abnormality, and in many cases it is associated with one of several specific genetic mutations, such as the DYT1 or DYT6 mutations (although it is not known how these specific mutations result in dystonic movements). Primary generalized dystonia is often 'early-onset', appearing in children who, up until that point, appear to have had normal motor system development. At first, dystonic movements are restricted to a particular area of the body, often the feet, before 'spreading' to other regions of the body over a period of several years until it appears to plateau (Marks et al. 2009). As this happens the child becomes increasingly disabled (especially as dystonia spreads to the trunk and upper limbs) and the child will require a great deal of care and assistance. Estimates of the prevalence of early on-set primary dystonia range from 24-50 cases for every million people (Defazio 2010). In this chronic form the dystonia itself is not life threatening, but it is not uncommon for such individuals to enter into a seizure-like state called status dystonicus. In this state, which can last anywhere from a few hours to several months, dystonic movements become so severe that life-threatening complications may ensue, such as renal and respiratory failure. Patients with status dystonicus often require management in an intensive care unit (Manji et al. 1998).

Secondary dystonia is used to describe cases where the dystonia results from some sort of brain injury. It is characterized, then, by the presence of a brain lesion

that is rendered visible with MRI or PET imaging techniques. Depending on their exact location these brain lesions can interfere with a number of brain functions, so it is not unusual for individuals with secondary dystonia to have a number of neurological conditions such as spasticity and cognitive difficulties. A common cause of secondary dystonia is brain trauma received around the time of birth. In these individuals (who are classified as having a 'cerebral palsy'), dystonia will often present alongside spasticity, muscular-skeletal abnormalities and low muscle tone, leading to what clinicians refer to as a 'complex motor disorder'. Generally secondary dystonia is not progressive. In children, cerebral palsy is the most common cause of dystonia (Marks et al. 2009).

There is a subset of secondary dystonia that is progressive however. This is hereditary degenerative dystonia, where dystonia is one of manifestation of a genetic abnormality that results in the slow and progressive destruction of the structures that make up the basal ganglia area of the brain. A large proportion of these are metabolic disorders referred to as Neurodegeneration with Brain Iron Accumulation (NBIA). Here, the individual's inability to produce an essential enzymatic protein results in the build-up of particular metabolites within structures of the basal ganglia. These metabolites destroy the brain tissue, leading to a gradual increase in neurological conditions such as dystonia and spasticity until the point of death, which may occur several decades after the original diagnosis (Gregory and Hayflick 2005). Generally as afflicted individuals progressively deteriorate and their bodies become increasingly contorted and disfigured, they experience prolonged periods of intense physical pain. These NBIA conditions are incurable. Thankfully, they are very rare.

Both primary and secondary dystonia, particularly less severe cases, can be adequately managed with medicine-based therapies (such as benzodiazepines and anticholinergics), but there is subset of cases where medicines fail, or where the individual is unable to tolerate medication side-effects. It is this subgroup that will be considered for deep brain stimulation. At this point in time clinicians believe that the most efficacious electrode target area for managing the symptoms of dystonia is the globus pallidus internus (GPi) structure within the basal ganglia (Ostrem and Starr 2008).

Table 1.1: The PMDS patient cohort

	Primary dystonia	Secondary dystonia	Heredodegenerative
Proportion of PMDS cohort (approx.)	25%	50%	25%
Cause	Genetic (usually), or unknown	Brain trauma (often associated with cerebral palsy)	Genetic, resulting from metabolic disorder
Coexisting neurological conditions	None	Can include low tone, spasticity, contractures, cognitive difficulties.	Include spasticity, low tone, contractures, cognitive difficulties.
Progressive or static?	<i>Focal:</i> Static, limited to local body region <i>Generalised:</i> Progresses from specific region to major muscles group. Plateaus.	Static: does not worsen	Progressive until death
General response to DBS	Dramatic improvement in some cases. Many cases experience useful functional improvements. Some cases experience no improvement whatsoever.	Most cases experience modest functional improvements. Some cases experience no improvement.	Some reduction in dystonia and thus alleviation of pain in many cases. Some cases experience no improvement.

The Dystonia Medical Research Foundation states that by 2010 around 1000 individuals worldwide had received DBS therapy for dystonia (Dystonia Medical Research Foundation 2010). Most of these are adults with primary dystonia, and according to the small number of reports within published literature DBS has proven to be effective in managing their condition. Some of these patients have experienced a dramatic improvement, regaining their ability to walk unaided after being wheelchair bound for several years (Ostrem & Starr, 2008; Vercueil et al., 2001). As with other DBS therapies, however, there is considerable variation in

improvement rates, with some patients receiving no beneficial effects whatsoever. Generally dramatic improvements are far less likely in patients with secondary dystonia – according to the very small number of available reports. In these patients, if the dystonia itself is alleviated the presence of additional neurological disorders such as spasticity and contractures (which do not improve with DBS) will limit the degree of functional gain experienced by the patient (Marks et al. 2009).

By the end of 2012 the PMDS had provided DBS therapy to approximately 80 children and young people with dystonia. Approximately half of this cohort are patients with secondary dystonia, a quarter have primary dystonia, and a quarter have some form of hereditary degenerative disorder (see table 1.1, page 18). In line with the predominantly adult DBS outcomes reported in the literature, the primary cases have tended to respond better than secondary cases and several have regained their capacity to walk unaided after having been wheelchair bound. DBS is offered to patients with a hereditary degenerative disorder as part of palliative care: it is intended to help alleviate some of the intense pain caused by dystonic contortions rather than enable the patient to regain some function. Because that PMDS is the only service of its kind within the UK it receive referrals from around the country, including Northern Island, Wales and Scotland. The costs of the procedure, as we will see below, are covered by the NHS. Each year the team also accepts a small number of 'private' patients from overseas, a high proportion of whom are from the wealthy Gulf states.

1.4 UK policy on DBS therapy for dystonia

In 2003 DBS therapy for primary dystonia was approved in the US, and therapies for both primary and secondary dystonia were approved in the EU. In both jurisdictions the therapies are approved for individuals who are seven years and older and who have failed to respond to medicine-based therapies. In the US the therapy was approved under the US Food and Drug Administration's (FDA) Humanitarian Device Exemption (HDE). This form of approval is granted to device-based therapies for conditions that affect a small population of individuals; populations that are too small to warrant the lengthy and expensive clinical trials required to obtain 'full' approval. HDE approval, then, does not depend upon the demonstration of efficacy but device manufacturers must nevertheless conduct small clinical investigations in order to demonstrate that their device 'does not pose

an unreasonable or significant risk of illness or injury' (U.S. Food and Drug Administration 2010). In the EU DBS therapy for dystonia does have 'full' approval, but the criteria for 'full' device approval differ from those of the FDA. Indeed, 'full' approval does not require a demonstration of efficacy: in addition to demonstrating a device's safety, manufacturers must demonstrate that the device performs satisfactorily (i.e, that it does not malfunction)(NCoB 2013: 134). Hence, despite obtaining regulatory approval there is as yet no substantial body of evidence that demonstrates the efficacy of deep brain stimulation therapies for both primary and secondary dystonia.

Nevertheless, the UK's National Institute for Health and Clinical Excellence (NICE) supports the use of deep brain stimulation therapy for dystonia (both primary and secondary). Referring to the small number clinical reports in the literature, existing NICE guidelines state:

Current evidence on the safety and efficacy of deep brain stimulation for tremor and dystonia... appears adequate to support the use of this procedure (NHS: National Institute for Health and Clinical Excellence 2006: 1).

Thus, the NICE guidelines have contributed to the establishment of a context that is largely supportive of those who wish to offer DBS therapies for dystonia in the UK. In December 2013 the NHS Commissioning Board published a National Clinical Commissioning Policy for DBS for movement disorders in adults for the population of England. The policy affirms that the evidence supporting DBS is sufficient, and states that funding for DBS (including DBS for dystonia) will be provided by the Commissioning Board via the appropriate Health Resource Group (NHS Commissioning Board 2013).

This national policy has followed a heated debate over the effectiveness of DBS. Prior to the national commissioning policy, the decision about whether or not to fund DBS for dystonia was made by regional Specialist Health Commissioning Groups. These groups were responsible for recommending which specialist services would be funded by the Primary Care Trusts (which have since been replaced by Clinical Commissioning Groups) within their jurisdiction. Most regional groups followed the NICE guidelines and released policy statements stipulating their

willingness to support DBS therapies for dystonia. As with the NICE guidelines these statements drew on the available data produced by the small number of clinical investigations to justify their support, but they also stipulate the limitations of such data, and state the need for further evidence. The following quote from the Specialist Services Commission Group of Wales exemplifies this:

“Whilst all of the studies demonstrate the benefits of DBS in the treatment of dystonia, all of the studies have relatively small samples, and limited evidence is available on the long term outcomes of dystonia.” (Health Commission Wales (Specialist Services): 2009: 10)

One specialist service commissioning group, however, stated that these same studies did not provide sufficient grounds for recommending DBS for dystonia. The East Midlands Specialist Service Commissioning Group policy on DBS stated: “the use of DBS for non-Parkinson’s tremor, dystonia and pain disorders is not supported due to a lack of robust evidence.” (East Midlands Specialised Commissioning Group 2011: 2). Since most Primary Care Trusts (PCTs) within the UK did provide funding for their patients to receive DBS therapy for dystonia, the policy of the East Midlands Specialist Service Commissioning Group led to what The Dystonia Society (which actively supports DBS therapies) described as a DBS “postcode lottery” (The Dystonia Society 2013). The issue became the source of some controversy and was the subject of a Channel 4 News Item (4 News 2012). The Dystonia Society enrolled Lord Macdonald and several MPs including Stephen Dorrell, the chair of the Health Select Committee, in a campaign pushing for a National Commissioning Policy that would force all PCTs to align their position on DBS. The campaign appears to have been a success. Now, all adults who meet eligibility criteria will receive funding for DBS for dystonia, Parkinson’s, or essential tremor. The total cost of DBS for dystonia is around £80,000 per patient over ten years.¹ £35 000 of this covers hardware and surgical costs, and the remainder covers pre and post-surgical assessments.

¹ This cost of £80,000 pertains to paediatric cases receiving a non-rechargeable neurostimulator which requires replacement every two-to-four years. For adult cases, the cost is around £5,000 less (over ten years). This is because adults undergo a less rigorous, and thus cheaper, regime of pre- and post-surgical assessments. (Medical Services Advisory Committee 2008; Yianni et al. 2005).

As yet there is no national commissioning policy for paediatric DBS, so the PMDS receives their revenue directly from individual Clinical Commissioning Groups. New referrals will only be accepted if they are accompanied by a letter of guarantee from their Commissioning Group stating that the funding for the therapy has been approved. In the past, Primary Care Trusts within the East Midlands area had refused to provide funding, and several families that were wishing to peruse DBS with PMDS had moved postcodes in order to fall within another jurisdiction.

Thus, while the NHS policy environment is generally supportive of DBS therapy for dystonia, this 'postal code lottery' controversy highlights that potentially precarious position of DBS services, particularly a service that provides DBS to children. There is still some doubt as to the reliability of the small amount of evidence of the efficacy of DBS.

1.5 Conceptualising innovation in medicine

It is because of this tenuous evidence-base and the associated uncertainty that the Nuffield Council's report described DBS as occupying a realm that is somewhere between established clinical therapy and clinical research. Indeed, deep brain stimulation therapy can be described as an innovation in-progress, and for this reason the novel PMDS provides an excellent case study by which to explore the dynamics of innovation in contemporary medicine. In this thesis I use this case study to build upon a model of medical innovation proposed by Piera Morlacchi and Richard Nelson (2011). Their model provides a useful starting point for this thesis, and as we will see in this section, the research questions of the project derive from it. There are, however, limitations with the Morlacchi-Nelson model. It is by addressing these limitations and thus building upon their model that this thesis makes a novel theoretical contribution to medical sociology. I will introduce the Morlacchi-Nelson model by way of a critical overview of a prevalent understanding of medical innovation.

The linear, 'bench-to-bedside' model of innovation

Several commentators have argued that an oversimplified, inadequate understanding of medical innovation is common among members of the public, various policy circles, and parts of the biomedical community (Gelijns and Rosenberg 1994; Hopkins et al, 2007; Morlacchi and Nelson 2011). According to this understanding

medical innovation is largely a linear process that begins with basic science and culminates with a diagnostic or therapeutic application. Here, scientific research generates novel knowledge about the body or a disease that leads to the development of (or is translated into) a new drug or device. This drug or device then progresses through various stages of clinical trials (during which it is incrementally modified), gains regulatory approval, and is subsequently incorporated into clinical practice as a finished product (see figure 1.4).

Figure 1.4: A linear model of medical innovation



Adapted from Gelijs and Rosenberg (1994)

Morlacchi and Nelson (2011) argue that prevalence of this unidirectional, 'bench-to-bedside' understanding of medical innovation has several unfortunate consequences. First, the linear model implies that useful therapeutic and diagnostic advancements ultimately have their genesis in basic biomedical research. Consequently basic biomedical research has received vast amounts of funding from governments and agencies, while "other important activities like clinical and health services research have been largely neglected" (Morlacchi and Nelson 2011: 512). Second, the linear model assumes that clinicians will adopt a drug or device in a uniform and predictable manner, as intended by the drug or device's manufacturer. The model does not account for the various ways in which the local specificities of clinical contexts may influence how a drug or device is used, and while it presumes that clinicians must acquire a new skill set to use the tool, it does not account for clinicians' 'learning-in-practice' as a generator of novelty. Learning-in-practice as a source of innovation in its own right, is overlooked (Morlacchi and Nelson 2011).

We can add more criticisms to those of Morlacchi and Nelson. The model assumes something akin to what economists have referred to as demand-pull. Here, the innovation process is perceived to be driven by and oriented towards a pre-identified market demand for, say, a therapy for a particular illness. Innovation, then, is perceived as a means of producing solutions to known problems. The wider transformative implications of medical innovation processes, such as their impact on the professional and institutional structures within medicine (c.f. Pasveer 1989)

and their capacity to shape understandings of disease, illness and the body (c.f. Martin 1999; Joyce 2006), are disregarded. As the economist de Laat argues, markets are the result of the innovation enterprise, rather than an a priori determinant (de Laat 2000: 190). The linear model, in other words, ignores the fact that medical innovation may entail a constant re-conceptualisation of the problem being addressed and often involves an ongoing negotiation of what constitutes a satisfactory endpoint. As Brown and colleagues have demonstrated, prospective 'endpoints' are actively constructed and often contested during innovation processes (Brown et al. 2000).

In a similar vein to Morlacchi and Nelson, other scholars have criticized what they refer to as the narrative of a 'biotech revolution' (Nightingale and Martin 2004; Hopkins et al. 2007). According to this narrative (which presupposes a linear model of innovation) biotechnological advancements have the potential to produce a vast array of new, highly effective drug therapies and thus "bring about radical changes in healthcare" (Nightingale and Martin 2004: 564). Yet, as Hopkins and colleagues argue (2007), the available empirical evidence suggests that the narrative is overblown. While there have been considerable changes in the way in which the pharmaceutical industry is organized, there has not been a significant, corresponding rise in the emergence of useful new drug-based therapies. Indeed, Nightingale and Martin argue that the perpetuation of the biotech revolution narrative is itself part of the innovation process: it has a performative function as it is used to create high expectations and facilitate the formation of pro-biotech alliances, thus enabling innovators to gain access to valuable resources such as funding, people, and intellectual property (2004: 566).

The Morlacchi-Nelson model of medical innovation

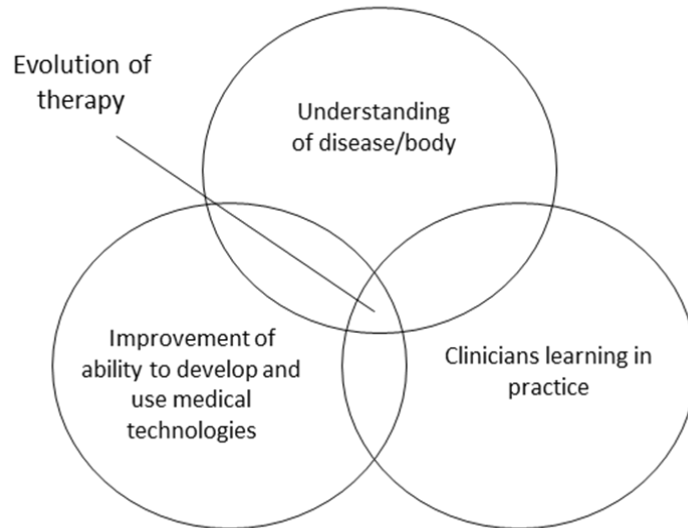
Based on their empirical exploration of the development of the Left Ventricular Assist Device (LVAD), Morlacchi and Nelson (2011) have put forward an alternative model of the development of new medical therapies (see figure 1.5, page 26). They state that while the generation of new knowledge regarding a disease or the body is an important component, medical innovation is also the result of two other factors: an *improvement in the ability to design and use new medical technologies*, and the ability of health professionals to *learn-in-practice*. Improvements in the ability to design and use new medical technologies often results from technology transfer: the

horizontal movement of a technology, perhaps from an area of industry into healthcare, or within healthcare from one clinical specialty to another. 'Exogenous' advances in electronics, computing and composite materials, for example, have brought about considerable changes in diagnostics and clinical therapies. Learning-in-practice refers to the new skills and knowledge acquired by healthcare workers as they attempt to integrate a technology or a drug into an actual, useful, day-to-day therapy or diagnostic tool. This is not, however, just a matter of becoming a 'competent' user via familiarisation with an instruction manual or protocol. Learning how to use a technology often entails acquiring tacit knowledge or embodied 'know-how' that can only be learned through day-to-day clinical practice.

Learning-in-practice is also a source of novelty in its own right. Successfully integrating a technology into a useful therapy or diagnostic tool in clinical contexts that are inevitably 'messy' often requires health professionals to make impromptu, ad-hoc adjustments and thus to learn 'on-the-spot'. Indeed, many of the day-to-day challenges associated with integrating a technology or drug into clinical practice will be unforeseen. Thus, as Hopkins and colleagues state "the benefits of new technologies do not come from only possessing firm specific assets or competencies, but instead require the dynamic capability to effectively transform them." (2007: 568)

Morlacchi and Nelson point out (2011: 523) that while the relative influence of technology transfer, learning-in-practice, and knowledge on the innovation process will differ according to the medical therapy in question, all three elements interact strongly. While learning how to work with the technology, for example, healthcare workers may provide feedback to the manufacturer on how it could be improved (2011: 516): via a process of constant communication between healthcare workers and manufacturers the technology undergoes a series of incremental adjustments. Additionally, while working with new technologies, healthcare workers may acquire a new understanding of the underlying disease. This may subsequently inform further learning-in-practice and developments in the technology (2011: 520-21). According to Morlacchi and Nelson's model, then, medical innovation is a cumulative and incremental process involving ongoing negotiations between clinicians, those involved in designing and manufacturing the technology or drug, and those working on advancing understandings of disease and the body.

Figure 1.5: The Morlacchi-Nelson model of medical innovation



Adapted from Morlacchi and Nelson 2011

This 'Morlacchi-Nelson model' provides a useful starting point for a sociological conceptualization of medical innovation and it is a useful starting point for this thesis. First, it draws attention to the role of local specificities in shaping how a technology or drug is actually implemented in a clinical service. Technologies, for example, are immersed in "relations of other technologies, practices and know-how, and it is through their localization in heterogeneous networks that they emerge and evolve" (Morlacchi and Nelson 2011: 523). In other words, the way in which a newly introduced technology or drug is understood and is implemented will depend on the pre-existing material and social context (Callon 1987; Latour 1987; Berg 1998). As a result, a technology or drug will seldom be adopted in a uniform and predictable manner across clinical contexts.

Second, the complex model also takes into account the transformative nature of innovation. Technologies and practices are mutually constituting and interdependent (Morlacchi and Nelson 2011: 521). Health professionals, for example, may respond to the challenges and opportunities presented by a new technology by bringing in additional complementary tools and protocols, thus actively altering the material and social context within which they work. The introduction of a technology, then, can prompt further changes within a particular

clinical context. Additionally, Morlacchi and Nelson illustrate that the process of innovation often involves the formation and consolidation of novel alliances between various professions: the development of the LVAD, for example, involved the formation of close ties between cardiac surgeons and engineers (2011: 516).

A third reason why Morlacchi and Nelson's model provides a useful starting point for a sociological conceptualization of innovation is that it portrays innovation as being what complexity theorists have referred to as an 'emergent property' (Antonelli 2009; Antonelli and Ferraris 2011). An emergent property is generated by the numerous interactions within a collective (or an assemblage) of agents. All agents within the collective contribute to the emergent property, and the property cannot, therefore, be reduced to the activities of any one agent. As Morlacchi and Nelson illustrated, the evolution of useful LVAD-based therapies has been a collective process involving a network of clinicians (cardiologists, and cardiac surgeons), engineers and industrial scientists. The resulting therapy cannot be attributed to the activities of any one of these groups, but has, rather, emerged out of and has been shaped by, the various and ongoing interactions between them. Innovation, then, is a collective process, involving what is often an extensive network of agents from a range of disciplinary and professional backgrounds.

1.6 Research questions

Morlacchi and Nelson's model provides a conceptualization of medical innovation that avoids both technological determinism and social determinism. Progress in medicine cannot solely be attributed to either technological (or pharmaceutical) advancements or the dissemination of particular understandings of a disease and/or the body. Rather, innovation entails what Science and Technology Studies (STS) theorists have referred to as the mutual co-construction of both the technological-material and social domains: technological artefacts both shape, and are shaped by, the social relations within which they are embedded (Faulkner 2009). In this thesis I adopt a version of Morlacchi and Nelson's model of medical innovation in order to provide a conceptual framework for exploring deep brain stimulation in paediatric neurology. We can, therefore, conceptualize the development of a DBS service for children and young people with dystonia as involving: the transfer of DBS technology from one clinical area (Parkinson's therapy) into another; the learning-in-practice activities of PMDS team members as they learn to adapt the technology

into a clinical service for dystonia; and particular understandings of dystonia and the motor system, which influence how the technology is adopted, and may also evolve or change in the process. By adopting this model, we are drawn to specific areas of inquiry if we want to explore the development of a DBS service for dystonia.

In addition to noting how particular understandings of dystonia and the motor system are, along with development of deep brain stimulation technology, implicated in the development of novel a service, we are also encouraged to explore the role of PMDS clinicians' learning-in-practice; how it is that they identify and learn to manage the challenges in their day-to-day clinical activities. Thus, this leads to the first three research questions of this thesis:

- 1) What factors have shaped the development and dissemination of DBS technology?**
- 2) According to PMDS team members, what are the challenges associated with the integration of DBS technology into a therapy for children and young people with dystonia?**
- 3) How do members of the PMDS team attempt to overcome these challenges in clinical practice?**

The first of these questions relates to the development and transfer of technology and the second and third relate to learning-in-practice. Addressing these will enable us to explore how a specific group of clinicians perceive and manage the 'great uncertainty' associated with a promising neurotechnology as they attempt to meet a 'great need'. For example, it will enable us to see how a team of clinicians develop a clinical service when there is a lack of information regarding the efficacy of DBS, and where media hype has tended to generate unrealistic expectations among patients and families. Importantly, addressing these questions will also enable us to see the various types of day-to-day work that are entailed in medical innovation; work that is necessary to create a service from a newly available technology but is generally overlooked in accounts of medical innovation. By doing this we will also see how it is that social and technical change can occur in medicine; how it is that

the introduction of a technology into a clinical service can entail wider social and technological changes.

However, in the process of addressing these questions, this project will also reveal what I believe to be a limitation with the Nelson-Morlacchi model. While the model does account for the role of local contextual social and material factors in shaping the way in which new clinical therapies emerge, it does not account for the influence of what could be called 'macro' factors. Indeed, it gives the impression that the 'innovative' clinical sites in which new clinical services are being developed are independent of wider social and political trends, examples of which could be healthcare policy initiatives, emerging health-related movements, or prevalent approaches to thinking about and dealing with ethical dilemmas in medicine. Such socio-political trends tend to traverse individual clinical and research sites, and while they will seldom influence each site in a uniform or predictable way, they may nonetheless encourage particular patterns of innovation. As Faulkner has put it (2009: 24), such trends can constitute "powerful structuring forces that affect the capacity of groups to shape a technology" (And we can infer their capacity to integrate technologies into new therapeutic or diagnostic services). Faulkner gives several examples of these structuring forces relating to device innovation: the close intermeshing of the medical device industry and the healthcare state (or what Clarke and colleagues (2003) have referred to as the BiomedicalTechnoService Complex), the emergence of assertive user-groups and the associated framing of patients as active, autonomous citizens, and medical device regulation and device classification systems. State policies related to health service provision may also be an example: Stuart Blume has illustrated how changes in the US Medicare system facilitated the growth of cochlear implants (Blume 2010). The 'culture of images' identified by Kelly Joyce in her account of the development of MRI is also an example of a socio-political trend (Joyce 2006). Joyce argues that the popularising of images brought about by the emergence of television, film and computers in the 1970s encouraged engineers to produce diagnostic machines that displayed biomedical data as images rather than sets of numbers. Another example of a 'macro' trend which relates to clinical innovation more broadly is what Keating and Cambrosio (2003) have referred to as the transformation of medicine into biomedicine. This trend manifests in the emergence of what they refer to as biomedical platforms: configurations of healthcare policy, architecture, machines, infrastructure, reagents,

protocols and 'ways of thinking' that render disease (and health) intelligible in terms of an array of biological entities (cellular markers and oncogenes, for example). They argue that these platforms have become common place in Western medical settings such as hospitals and have a structuring effect on clinical research and innovation.

In light of this limitation I recommend that an amendment to the Morlacchi-Nelson model of medical innovation is necessary. In addition to technology transfer, learning-in-practice, and understandings of disease, we can add what could be termed the 'socio-political climate' to the list of interacting factors that generate and shape the innovation of new therapies. Here 'socio-political' is used in a very broad sense, referring to trends that are not limited to particular, discrete clinical settings. Generally (but not necessarily) such trends will have become macro 'structuring forces' by being encoded in some sort of policy, perhaps in national healthcare policy, or in a regulatory agency classification system for example. I will refer to this amended Morlacchi-Nelson model as the Complex Model of Innovation. By exploring the history of the development of deep brain stimulation and the 'learning-in-practice' activities of the PMDS, this project will expose several socio-technical factors that are shaping medical innovation as it relates to deep brain stimulation. As the economist Cristiano Antonelli argues, learning is only possible in the "limited spectrum of techniques and conditions, both external and internal" to the locale of clinicians, and an analysis of their learning process "makes it possible to appreciate the role of a variety of contextual constraints in shaping the process." (Antonelli 2009: 631). So, in the process of addressing the first three research questions, this project will also address the following:

4) What socio-political trends influence the development of the PMDS's deep brain stimulation service?

By demonstrating how the activities of the PMDS are influenced by socio-technical trends, this project will validate The Complex Model of Medical Innovation and thus make an original theoretical contribution to medical sociology.

Additionally this project will also shed some light on current discussions regarding the impact of new medical technologies. Some commentators have

suggested that new medical technologies tend to reify reductive, biomedical model-based understandings of disease and the body (Corea 1985, Klein 1991; Brown and Webster 2004). As Webster states, many new medical technologies have enabled the medical gaze to peer deeper into the body, thus facilitating the emergence of health identities based around biomedical criteria (Webster 2002). Commentators have also associated new neurotechnologies with this 'reification' of the biomedical model. As Singh states, new neurotherapies have been implicated in the emergence of brain-based explanations of the self (Singh 2013), or what some commentators have referred to as the creation of 'cerebral subjects' (Ortega 2009; Vidal 2009). Moutaud's (2011) observation that some patients receiving DBS made sense of their own behaviour and emotion in terms of their neural networks (and the effect of DBS on these networks) is an example of this 'neurologisation of personhood'.

Indeed, a significant body of social science work has explored the recent rise of neuroscience and its cultural impact (c.f. Pickersgill and Van Keulen 2011; Rose and Abi-Rached 2013). As Pickersgill and Van Keulen argue, the neurosciences have become an influential and prestigious branch of biomedicine. The tools of neuroscience (particularly neuro-imaging technologies) and neuroscientific models are increasingly influencing the way in which the 'classical questions' (such as the nature of human agency and the demarcation between normal and pathological) are being addressed (Pickersgill and Van Keulen 2011: xii).

Sociologists exploring this cultural impact have suggested that a plurality of neurological-based understandings of the self and personhood are being constructed and drawn-upon in various clinical settings. Rose, for example, has traced the emergence of the *neurochemical self*, in which individuals are rendered intelligible in terms of their brain chemistry (2003; 2007). According to this understanding, the brain (and thus the individual) is malleable and open to improvement via carefully administered psychopharmacology. Indeed, this model of the individual is implied (and perpetuated by) psychopharmacological interventions. Fein (2011) argues that there has also been an emergence of contrasting brain-based explanation of the self: the *neurostructural self*. Drawing on her study of people diagnosed with an autism spectrum disorder, she argues that this particular brain-based understanding of personhood equates the self with a brain that is largely a fixed material system governed by physical laws. The neurostructural self is

predictable, and in contrast to the neurochemical self, it is "not open to intervention and optimisation" (Fein 2011: 27).

Such work has shown that the neurosciences, neurotechnologies and neuro-interventions have spawned various brain-based explanations of the self, health and illness. The tools and models of neuroscience have the capacity, then, to substantially influence the way in which people make sense of themselves and the world around them. In this particular project I will be studying a team that relies heavily on neuro-imaging technologies; a team which also puts electrodes into the brains of patients. It therefore represents an excellent opportunity to explore the social impact of the neurosciences in a particular context. More specifically, it provides an opportunity to explore how bodies, patients and illnesses are actually 'constructed' and rendered intelligible within a clinical setting providing a novel neuro-therapy. Are PMDS patients, for instance, 'reduced' to biomedical entities? Are PMDS patients and their illnesses rendered intelligible in terms of neural networks? This leads us to the fifth research question of this thesis.

5) How are dystonia and patients rendered intelligible during their time with the PMDS?

A fruitful way to address this question is to explore the nature of the clinical gaze of PMDS team members. Do they, for example, exercise the objectifying medical gaze identified by Foucault (1963), whereby a patient - and ultimately 'health' and 'disease' - are rendered intelligible in terms of their body's (or brain's) inner shapes, forms and textures? Or do they exercise a more extensive gaze that takes into account a patient's experiences and interpretations, for example?

1.7 Summary of thesis chapters

Using Morlacchi and Nelson's work as a precedent this thesis is based on a methodology that includes both historical and ethnographic methods. It includes an historical overview of the development and dissemination of deep brain stimulation and I use interviews and observations to explore the day-to-day activities of PMDS team members.

In the following 'Methodology' chapter I provide an overview of these methods (including their limitations) and I justify why they were chosen. I will state that the methods reflect a particular theoretical approach to exploring and making

sense of the social and technical world known as material semiotics. I outline the basic tenets of material semiotics, describe the implications of these tenets for sociology, and then illustrate how they entail a set of ethnographic methods: observations and interviews. Importantly, I argue, a material semiotics approach requires the researcher to explore the role of non-human actors, such as objects, instruments and the built environment, in shaping, constraining, enabling and transmuting human action. Additionally, I describe the range of factors that shaped the overall scope of this project. These include the process of gaining site access and the NHS Research Ethics Committee approval process - both of which placed constraints on the data collection process. I conclude this chapter by outlining the major challenges encountered by the PMDS that were identified during data collection, each of which becomes the focus of subsequent chapters.

The remainder of the thesis is loosely structured according to the research questions outlined above. Chapter 3, 'A History of Deep Brain Stimulation'², addresses the first research question. It provides an historical account of deep brain stimulation, illustrating the plurality of interests involved in the development and stabilisation of deep brain stimulation technology. In doing this, I identify several key socio-political trends which have influenced the innovation process and which have also shaped the environment within which the PMDS team operates.

Chapters 4, 5 and 6 address the second and third research questions. Using data from the interviews and observations each of these chapters focuses on one specific challenge encountered by the team and illustrates how members of the team attempt to overcome that challenge. We will see that these challenges and the team's responses to these challenges reflect particular socio-political trends. These chapters will also illustrate how, in order to manage the challenges, the team has brought in tools, protocols and perspectives from different professions, most notably, physiotherapy and occupational therapy. Chapter 4, 'Coordinating Multidisciplinarity', explores the first challenge: coordinating multidisciplinary teamwork. There has been a trend within healthcare policy to encourage multidisciplinary service provision with healthcare. Yet as various commentators have illustrated, overcoming disciplinary and professional boundaries is challenging.

² The bulk of this chapter has been published as: Gardner, J. (2013). A history of deep brain stimulation: technological innovation and the role of clinical assessment tools. *Social Studies of Science* 43(5): 707-728.

In this chapter I illustrate how the team attempts to overcome these challenges. Specifically I will explore the role of the built environment of the hospital, their use of a collective diary and regular team meetings. We will also see that the PMDS exercises what could be called a 'broad' clinical gaze, aspects of which will be examined in the following chapters.

Chapter 5, 'Body work & identifying dystonia', explores the challenge of identifying suitable candidates for deep brain stimulation. I illustrate that for the PMDS this challenge involves differentiating dystonia (which does respond to DBS) from other manifestations of neurological pathology, such as spasticity and muscle weakness (which do not respond to DBS). In order to do this the team relies on what I refer to as the body work of the physiotherapists: the ability to use their own bodies as a means of generating useful clinical information. Such work, I argue, requires the careful construction of an ensemble involving bodies, objects and texts, and is an important part of the innovation process.

Chapter 6, 'Managing expectations', explores how the team attempts to manage the expectations of patients and supporting family members. I will begin this chapter by providing some background on the emergence of patient rights and 'respect for autonomy' in healthcare. These have placed a burden on health professionals to disclose information in a way that is accessible to patients, and to respect patient's wishes. I will illustrate how, in an attempt to overcome this challenge, team members use a goal setting session with patients and supporting family members. This goal setting session is based around the use of a specific tool adopted from occupational therapy which works very much like a script: it delegates particular roles to team members, the patient, and family members; and in doing this, it encodes particular power relations. Importantly it does this in a way that generates what could be considered an ethically favourable mode of communication.

In Chapter 7, 'Measuring Clinical Outcomes', I explore the challenge of generating 'robust evidence' on the safety and efficacy of DBS. I will begin by stating that in an era increasingly dominated by evidence-based medicine (a socio-political trend), clinicians and researchers are required to generate 'objective' evidence of a therapy's efficacy and safety. For the PMDS team, measuring the impact of DBS is particularly challenging due to what team members feel is the inadequacy of the widely-accepted clinical assessment tool in neurology for

measuring dystonia. In order to overcome this challenge the team has adopted what they believe to be a more appropriate tool from occupational therapy. I compare the two tools, illustrating how each of them enables data to be extracted from patients, and I argue that they encode different understandings of disease. I will argue that the team's adoption of the tool from occupational therapy reflects a general shift in many areas of clinical practice towards tools such as Quality of Life measures that attempt to measure the 'social' aspects of illness.

In the final chapter I argue that the team's strategies for managing these challenges can be seen as innovations in their own right; they are, I will argue, examples of strategies that are vital to establishing new therapeutic or diagnostic services but are often overlooked in accounts of medical innovation. I will also argue that they provide a specific illustration of how the emergence of new technologies can prompt wider social and clinical changes in medicine. Bringing together the findings from each chapter, I will then discuss the key socio-political trends which have influenced the development of deep brain stimulation and the team's attempts to produce a clinical service. From this I will outline the "The Complex Model of Innovation. I will then relate my observations on the 'broad' clinical gaze of the PDMS to current discussions on the relationship between new neurotherapies and biomedical-model derived understandings of disease and the body. PMDS patients, I will argue, are 'enacted' in multiple ways. I will then discuss how the findings from this thesis can be used to 'guide the future of DBS', referring to recommendations put forward by the Nuffield Council and a group of neuroethicists. I conclude the thesis by outlining some fruitful avenues of further research that could build upon the findings of this project.

2 Methodology: Exploring innovation in medicine

2.1 Introduction

Several schools of thought within the social sciences, particularly those that have been inspired by ethnomethodology, maintain that social order is the accomplishment of everyday interactions between individuals. Through talk and action, individuals make sense of, and compose group activities, and from these activities emerges what we refer to as 'society'. Thus, society is a product; it is the ongoing consequence of the heterogeneous interactions between numerous and diverse individual agents. From this perspective, then, cohesion and social order (and disorder) are the effect of the practical reasoning and actions of negotiating individuals. Accordingly, scholars such as Harold Garfinkel and Harvey Sacks argued that if we wish to gain insight into how and why particular social patterns exist, we must observe the everyday, often mundane interactions of individual agents.

I adopt a conception of society that is similar to that of Garfinkel and Sacks and consequently the methodology of this project reflects their commitment to exploring the every-day, mundane interactions of individuals. The advantage of such an approach is that it enabled me to see the 'messiness' of using deep brain stimulation as a therapy in paediatric neurology. As John Law states (2004: 18-19) ethnographic methods allow the researcher to see the diverse, 'ragged', and contingent ways in which knowledge is created and decisions are made, rather than having to rely upon the 'clean' narratives of fact-finding and discovery often perpetuated in prepared accounts. And importantly, according to the Morlacchi-Nelson-derived model of innovation that underpins this project, such ethnographic methods (in addition to historical methods) enable us to explore the activities that constitute medical innovation. In particular they enable us to explore Learning-in-practice: how clinicians perceive the challenges associated with their work, how they bring together a host of tools, resources and knowledge to overcome such challenges, and how, in the process, they contribute to the construction of emergent phenomena. (Ethnographic methods, then, enabled me to address the second, third and fourth research questions, and provide some insights to address the fifth research question).

While this project has much in common with other ethnographic studies, it differs in one major respect. Traditionally, ethnographic studies have tended to focus on the interactions of human actors (it is the ‘communicative, perceptual, judgemental and other accommodative work’ of ‘persons’ that ‘establish, maintain, restore or alter society’, as Garfinkel puts it (1963: 187-188)). When non-human elements are included, they tend to be rendered as tools that simply facilitate human action, or as blank canvases upon which humans impart meaning. In this project I explore the materially-situated nature of human action. Rather than seeing objects and the built environment as mere tools for human action or receptacles for meaning, I am assuming that human action is prompted, transmuted, hindered and transformed by non-human objects in ways that cannot be reduced to the intentions of other human agents. This assumption reflects a particular ontological stance which, following John Law (2007), I shall refer to as material semiotics. Again, this also aligns with the co-constructionist perspective that underpins the Morlacchi-Nelson-derived model of innovation (and thus this thesis).

This chapter will provide an outline of material semiotics and will illustrate how a material semiotics ontology entails a set of ethnographic methods. It will also illustrate how such methods have been used in the field of medical sociology. The methodology and design of this project is not informed by my material semiotic conception of the world alone, however. Like all knowledge-forming endeavours, this project has been shaped by a host of influences, most notably the NHS research ethics committee approval process and the specific research site, which have imposed restrictions on the specific methods of data collection that can be used. Thus, before outlining the ontological justification of the design of this project, this chapter will describe how these various factors have shaped the design of this project.

As I have alluded to several times thus far, this project also includes a historical research component. This enabled me to identify the various factors that have influenced the development and dissemination of DBS technology, and thus address question one. This chapter, however, deals with the ethnographic methods and practicalities of accessing the field site: I have reserved the discussion of the materials and methods of the historical research for the following chapter, where the results of the research are also presented.

2.2 Gaining site access

The PMDS is based at a large children's hospital in the United Kingdom – it is this hospital that is the research site for this project. In order to maintain anonymity of the team and my participants, I cannot provide too many details about the hospital. Suffice to say it is a multilevel complex that contains staff workstations and meeting rooms on the top floor, outpatient clinics on the ground floor, and various wards in between, one of which is the neurology ward (more details about the hospital built environment are provided in chapter four). All clinical work with patients takes place within the various spaces of this hospital, except for the surgical procedure to implant the DBS system: this takes place at a nearby linked hospital with the appropriate neurosurgical facilities.

Luckily securing provisional access to this case-study site did not prove to be too difficult. This is largely due to the work of my first and second supervisors who, during their initial scouting of the team as a possible case-study site for the studentship, were able to establish something of a rapport with the head of the team and 'gatekeeper', Dr Martin (pseudonym). During this time, Dr Martin indicated that he would be happy for the members of his team to be involved in the project (pending the consent of individual team members).

While securing provisional access to the site was not difficult, it was still necessary to negotiate the specific terms on which site access would be granted. Shortly after I began the project my first supervisor took me to the field site to meet Dr Martin. During this meeting Dr Martin voiced a couple of concerns about the project. First, he was concerned that the findings of the project could misrepresent the activities of the team, and that he, or some of his staff, could be misquoted. To allay these concerns I told him that my intention was not to assess the team's activities, and that he and other members of the team would have some control over the data that would be used in the project. Specifically, team members could ask to have any data pertaining to them withdrawn after three months of their participation (no participants made such a request). We also agreed that it would be appropriate for Dr Martin to act as my clinical co-supervisor. In this role he was able to clarify any queries I had regarding clinical details of DBS and dystonia, and he was able to guide my access to his team members and patients. We felt at the time that such a compromise would not prevent me from exploring the team members' perspectives of their work, nor would it prevent me from addressing the

research questions. As Hammersley and Atkinson point out, such adjustments to project design are often necessary to secure access from even the most cooperative of gatekeepers (2007: 59).

Like all gatekeepers Dr Martin was bound by his own commitments, and as a result he was impelled to direct the scope of the research. Aside from expressing a commitment to protecting the reputation of his team, Dr Martin also expressed a concern for the wellbeing of his patients. It was important, he stated, that my data-collection methods did not unnecessarily interfere with this team's ability to work, or place undue stress on patients and their families. After some discussion we agreed that two data-collection methods would be feasible: interviews with team members and observations of specific interactions, including interactions with patients. While this is not the ideal methodology entailed by a material semiotics conception of the world (as I will illustrate further on), we nevertheless felt that these methods would enable me to collect the data necessary to address the research questions of this project. Thus, during this initial meeting, the data collection methods of the project had been set.

Several months later my supervisor and I returned to the fieldwork site to meet with other members of the PMDS team. Eight members including Dr Martin turned up (two could not be pulled away from clinical duties). I introduced my supervisor and myself and I then gave a brief presentation to the team on what it was that I was hoping to do. I made a point of emphasising that, if they agreed to participate, they would have some control over the data they contribute, and that the design of the project would ensure that as little as possible of their normal work would be disrupted. After the brief presentation I asked team members if they had any questions or concerns. The only concern that was raised was about time. One member asked if my project was going to take up much of Dr Martin's time, adding: "we already have enough difficulty getting hold of him when we need him". I replied that it should take up very little of his time, and repeated that aside from the interviews, the project as a whole should not take members away from their normal work duties. Generally team members seemed interested and curious in the project and said that as long as it didn't take too much of their time, they would certainly consider participating. At this stage, then, I was ready to begin putting together the various documents required to get ethics approval

2.3 The NHS Research Ethics Committee approval process

Because this research was taking place within the National Health Service the project required a “favourable opinion” from an NHS research ethics committee (REC). Once I had some idea of the data collection methods I would use and PMDS team members had indicated that they would consider taking part, I compiled the documents required for REC approval. Within this documentation I was able to argue that the specific data-collection methods that had been selected would not, according to a specialist health professional (Dr Martin), unnecessarily disrupt the team’s work, nor cause undue stress to patients and their family/caregivers. It was also necessary to explicitly stipulate the aims of the fieldwork. Thus, I stated that my aims were to explore the challenges encountered by team members, and to explore how they attempted to overcome these challenges in day-to-day clinical practice (these later became the first and second research questions of this thesis) I felt at the time that such aims were specific enough to satisfy the research committee but sufficiently general that I could explore any issues that arose during the fieldwork. In total, I was required to submit twenty-one different documents to the Research Ethics Committee. These included:

- A REC application form outlining the project design, the ‘scientific justification’ of the project, the main ‘ethical issues’ arising from the project design, how the informed consent of participants would be obtained.
- A project protocol/overview (around 6 000 words), which was an abridged version of the above.
- Participant information leaflets (PILs) for each of the data collection methods (interviews, and observations), including specialized participant information sheet for participants less than 16 years of age (Appendix 2, pages 240-251).
- Consent and forms for participants involved in each of the data collection methods, including as assent form for children and young people under 16 (Appendix 3, pages 252-256).
- The CVs of my supervisor and myself.
- Proof of Brunel University’s indemnity/insurance coverage, proof that Brunel University was my ‘sponsor’, and a letter from the Wellcome Trust proving that they were funding the project.

It took just over six months to compile this documentation. I was able to model my participant information leaflets (PILs) and consent forms for adults on those produced by other members of the LABTEC team. The PIL for participants under 16 years of age was based on the model prescribed in Alderson and Morrow's *The Ethics of Research with Children* (2007). As a consequence, the PIL reflects Alderson and Morrow's belief that children as young as five can make informed decisions regarding participation in research (and that children 16 years and under can legally give their informed consent), and that such decisions should be guided by their parents or caregivers. Consequently the PIL for children and young people contains all information necessary for informed consent to be obtained, and is intended to be read by children and their parents together.

Several weeks after the above documentation was submitted my first supervisor and I met with the NHS REC. Committee members asked us to clarify a few points, and we were informed that the committee had granted the project provisional approval. A few minor changes would have to be made before a 'favourable opinion' would be granted: pictures would have to be added to the PIL for participants under 16, and assent, rather than consent, was to be obtained from all participants under 16 years of age. Aside from these minor recommendations the REC had no problem with the design of the research or the data-collection methods being used, probably due, at least in part, to Dr Martin's support. A month later I resubmitted the amended children's PIL containing cartoon pictures that I drew myself. Full approval from the REC was obtained on the 13th of February 2012 (the letter of REC approval confirmation is appended to this thesis – Appendix 1, pages 237-239). I was therefore permitted to conduct interviews with health professionals and observe specific interactions including consultations involving young patients.

Once I had been notified of REC approval I had to obtain clearance from the Research and Development Department (R&D) of the specific NHS Trust overseeing the hospital where the research was taking place. In short, while the REC assessed the overall project, the R&D assessed me: In order to gain clearance I had to undergo an enhanced police check and obtain Occupational Health Clearance, the latter requiring me to receive an assortment of vaccinations to ensure I would pose no biological risk to patients. R&D clearance also required the project to have a Principal Investigator (PI) who was employed by that particular Trust. The

role of the PI was to ensure that I adhered to the Trust's policy and that all necessary reports were completed. Luckily, Dr Martin agreed to this role, and on the 4th of April 2012 I was informed that I had an 'Honorary Research Contract' with the Trust and I was permitted to begin conducting research within the children's hospital.

The honorary contract, however, did not enable me to conduct research at the hospital where the actual surgical implantation of the DBS system takes place. This hospital was under the jurisdiction of a different trust and would therefore require the approval of a separate R&D department. A local PI employed within that particular trust would also be required. The only possible contender was the neurosurgeon, but due to his workload he was reluctant to undertake this role. Unfortunately this meant that I was unable to include the neurosurgeon and his interactions with patients in this project. (I was, however, able to discuss neurosurgical issues with the neurologists, one of whom would often sit in on the neurosurgical operation, and the clinical research fellow, whose PhD was exploring the placement of DBS electrodes within the brain). In effect, then, the necessity of having R&D department approval defined the research site and limited the scope of the project.

The design and focus of this project, therefore, is the product of multiple influences. Before I discuss the data collection methods in more detail and describe the actual data collection process, I will now outline what could be called the material semiotics 'metaphysics' of this project. This, as we will see, has implications for the specific methods used.

2.4 An ethnography of every thing: material semiotics

Material semiotics has emerged from two domains of enquiry: Science and Technology Studies (STS), particularly in the form of Actor-Network Theory, and Deleuzian-inspired assemblage-theory, which is most clearly articulated in the work of Manuel DeLanda (2002, 2006). It has no heritage in the work of Marx, Weber or Durkheim, and consequently many of its key tenets seem at odds with more traditional sociology: 'social' is simply the association of any entities; non-human objects can be 'actors', and spatial and temporal scale are the consequence of associations between actors, to name a few oddities. The goal of this section is not to give an exhaustive account of material semiotics, but rather to explain its key

tenets and outline how it can be used in sociology. In order to do this I will rely heavily on the work of three proponents. Using Manuel DeLanda I will articulate what could be called the underlying metaphysics of material semiotics, and with the work of Bruno Latour, I will illustrate how this metaphysics translates into a sociology methodology. Referring to the work of Annemarie Mol, I will then illustrate how this approach can be applied to medical sociology.

2.4.1 *The ontology of material semiotics*

The central tenet of material semiotics is a commitment to *relationality*. The intelligibility of an entity, or how we come to perceive and understand an entity, is not the result of some inner essence or nature, revealing itself to the objective observer. Rather, the intelligibility of any entity (an inanimate object, an individual, a social institution) is the consequence of its interaction (or association) with numerous other entities. Each entity has *capacities for interaction*; qualities that become perceptible only when it is prompted, jostled, or moved by another (DeLanda 2006). As associations form, particular capacities of interaction are realised or enacted, and thus the associating entities become intelligible. It is only by being immersed in an assemblage with other entities, therefore, that an entity acquires a perceptible form. In *Laboratory Life* (1986), Latour and Woolgar argue that the process of scientific ‘discovery’ that takes place within a laboratory involves noting how an entity of interest (such as the hormone Thyrotropin Releasing Factor, or TRF) responds when placed within various, carefully arranged material assemblages. Laboratory technicians attempt to create a list of the entity’s qualities by enacting its various capacities for interaction.

Importantly, the intelligibility of an entity will differ depending on the assemblage in which it is immersed. Each entity has innumerable capacities for interaction, only a few of which will be enacted, or realised, in any one assemblage. We might think of an individual as having a capacity to act rationally (however we may define the term), a capacity to experience a range of emotions, and innumerable capacities to physically engage with the material world: to move bipedally, for instance. The combination of capacities that are enacted will depend on the individual’s wider context. A supermarket may prompt an individual to rationally appraise a food product according to its cost and perceived value; a theatre production may prompt particular emotive responses among members of the

audience; and a set of stairs will induce an individual to move bipedally. Generally, an entity is defined according to a few of its qualities for convenience (such as colour, shape, mass), but its potential for expressing other qualities means that it will always escape any attempt to determine its essence (DeLanda 2006). We may define a human as a 'rational actor' for pragmatic or political purposes, but any definition will reflect, at most, only a select set of a human's capacities for interaction. Any intelligible entity, then, possess perceivable characteristics that are the result of being immersed within a particular assemblage, and it will have an indefinite number of un-actualised capacities that may later be realised, or enacted, if the entity becomes part of a novel assemblage (DeLanda 2006; 2002: 72).

DeLanda refers to this as relation between an entity and the assemblage in which it is immersed as *relations of exteriority*. While each entity is rendered intelligible through its association with other entities, it cannot be reduced to this relationship. Its potential to express qualities, its capacities for interaction, will always exceed those that are actually being expressed at any one time. An example are the amino acids that combine to form the hormone TRF: the same amino acids have the capacity to combine in other combinations creating hormones or peptides with different effects. We might also think of the ability of an individual to adopt different roles within different social contexts or professional organisations. An individual's potential, then, always exceeds any one of the various roles that they may undertake. To put this another way, component parts cannot be reduced the function they may have within a larger structure. DeLanda contrasts this relations of exteriority with *relations of interiority*, a conceptual relationship between the social 'whole' and its 'parts' that has been prevalent in social sciences, most blatantly in representations of society as an organism (DeLanda 2006: 9). Here, each part is constituted by the relations it has to the social whole. In its crudest, functionalist manifestation, it is only because of its relationship to the social whole that a part exists. With the relations of exteriority model that underlies material semiotics, society is not a seamless whole, nor does it determine the shape, activity, or intelligibility of its constitute parts. Society is, rather, the consequence of numerous, heterogeneous assemblages: it is the temporal product of the enactment of an enormous number of capacities for interaction and the elision of many more.

This does not entail methodological individualism, however. Structures can possess properties that cannot be reduced to their component parts. As multiple

entities assemble, many expressed capacities combine and interact, and subsequently come to have a novel affect that cannot be attributed to any one entity. These are *emergent properties* (DeLanda 2002). Emergent properties are not logically necessary: they do not exist because they serve a particular function. Rather, they are continually obligatory: they are the consequence of complex dynamics and relations between parts (and within parts) that do not necessarily have a specific higher order objective (DeLanda 2006). They are, essentially, unintended consequences. Thus, it is possible for assemblages to act or express properties that differ from the actions and intentions of the individuals and components that constitute them.

This holds true for all assemblages, whether they be nation-states, institutions, individuals, the body, organs, or DNA. Obviously DNA possesses capacities for interaction (such as inducing the formation of proteins) that cannot be reduced to its constituent nucleotides. An individual, too, can be seen as the emerging product of an assemblage of what could be called subpersonal components (DeLanda 2006): acquired beliefs, prejudices and ideas, learned embodied-dispositions and habitual responses, ambiguous desires, and a host of various biological processes. Different combinations of these will be enacted in different contexts, and the overall effect of a combination (the individual) cannot be reduced to any one constituent component. The individual is the emergent product of an assemblage, and the individual is also a component in other assemblages (such as social or professional organisations). And by participating in 'larger' assemblages, the individual may of course be prompted to adopt new, or hone existing, subpersonal components: they may acquire an additional set of political beliefs or develop new practical skills that resonate with their existing beliefs, skills, desires (or fears) (DeLanda 2006). In this light, socialisation can be seen as a process of immersing individuals within assemblages that configure their various subpersonal components.

Individuals, then, are both networks in themselves, and 'actors' in other networks; they are the 'effect' of associations between entities, and subsequently they come to have an 'affect' on others. Any intelligible entity is both the consequence of a network or assemblage of components (other entities), and a component in other assemblages or networks. They are an 'effect', that can subsequently have an 'affect'. And while an entity may contribute to the perpetuation and delineation of a larger assemblage, its capacities for interaction (its

potential, enabled by its constituent components) will exceed this role, or any other one role. According to a material semiotics perspective, society is constituted by these heterogeneous actors that are both actors and networks (or actor-networks).

2.4.2 A sociology informed by material semiotics

If intelligibility is the effect of an assemblage, then the sociologist should refrain from making a priori assumptions about the nature of entities that constitute society. Instead sociologists should explore how such entities are rendered via their associations with other entities. According to Latour (2005) this is achieved by identifying the ‘actors’ within a network. Here, however, an ‘actor’ does not refer to the origin of an action, nor does it refer to a subject possessing intentionality. ‘Actor’ refers to an entity that is made to move, to have an affect, by other actors; it is a point of confluence where a series of actions is translated into another type of action (Latour, 2005: 46). Michel Callon’s example of the *space of calculability* within a strawberry market illustrates this (Callon, 1999). In the Salogne region of France, text-book neo-liberal economic theory was used to guide the formation of a market: merchandise was physically arranged so that its weight and quality were clearly delineated and comparable, yet information pertaining to its production and origin were deliberately hidden and partitions were constructed between growers and buyers. Transactions were displayed on a large electronic board, formal measurement standards were adopted, and digressive bidding was used. Consequently, buyers had little choice but to base their decisions on the data displayed to them and engage in decentralised and ‘rational’ exchange. The resulting ‘rational’ buyer was not the cause of the action; they were prompted to act in this way by a wider network of electronic display boards, physical partitions, formalised measurement tools and so on. These cannot be called the ‘cause’ of the resulting action either: they were carefully arranged by other actors, such as the graduate in economics who had been employed by local authorities to create the market and who, in turn, would also have been prompted by others. Each actor was made to move (or to express a capacity for interaction), to have an affect, by other actors, and consequently action was transferred, altered, distributed, and translated along a concatenation of actors.

Importantly, as Callon’s example illustrates, this definition of ‘actor’ does not exclude non-humans. Physical, inanimate objects, transmute, constrain, guide,

and prompt the action of other entities, including humans. As Annemarie Mol puts it, human action is not just culturally and historically situated, it is also materially situated (Mol, 1999: 75). Consequently, the sociologist should refrain from making a priori judgments about which type of entity can have agency.³

Latour has advocated a ‘follow the actors’ approach to sociology (Latour, 2005). Rather than presupposing the existence of particular structures, such as the individual, class, the state, the sociologist should seek to explore how these are enacted in networks, that is, how they emerge in specific contexts. If social structures are not the result of some higher function they may serve, (that is, if they are continually obligatory rather than logically necessary), then ‘thought’ alone cannot explain their existence and form. Here, then, Latour proscribes an empiricist method for exploring the social world that is not dissimilar to that of the ethnomethodologists; a commitment to exploring how every-day practices generate those things that constitute society. The key difference, as we have seen, is that the sociologist must not focus exclusively on the interactions between humans.

2.4.3 Material semiotics and medical sociology

For the sociology of medicine this method can be used to illustrate how medical practices, often laden with technologies and material objects, collectively generate

³ This entails a notion of ‘social’ that differs from that usually adopted in the social sciences. For a sociology informed by material semiotics, ‘social’ is defined as the associating of entities: It is the transferring and translating of action from one entity to another. As Latour has noted (Latour, 2001), this conception was articulated by a contemporary of Durkheim, Gabriel Tarde, who made no distinction between the social and the material: when two or more things are brought together, it is a social phenomenon: “everything is a society and that all things are society” (Tarde, quoted Latour 2005: 218). This is perhaps the most significant point of difference between material semiotics and more traditional sociology. Traditional sociology has tended to posit the existence of a social realm that is distinct and a priori to the world of material things. For Durkheim, social reality is constituted by ‘social facts’. These have an independent existence beyond the actions of individuals: they inform individual behaviour, they can explain collective behaviour, and they provide society with some rigidity (Durkheim, 1982). Here, society is seen as the cause of associations between people. Although Weber may have rejected this type of positivism, he nonetheless reified the existence of a distinct social realm with his neo-Kantian notion of *verstehen*: if social change is to be explained, then it is necessary to understand the rationale of human actors. Tarde, however, argued that if sociologists postulate the existence of a distinct social realm, they will overlook much of the stuff that society is actually made of (Tarde, 2010).

many of those things that interest the sociologist: the body and body-parts, agency, the individual, and so on. The work of Annemarie Mol (2002) is perhaps the best example of an account that explores how both human and non-human actors collectively participate in the production of intelligibility in medical practices, and it is her work that will form the basis of the argument here. Importantly she has used this method to illustrate not only how intelligibility is produced, but also how multiplicity and conflict can arise; different material and/or cultural contexts (assemblages) can generate distinct renderings of an entity, as different capacities for interaction are realised. In some cases, this can result in conflict.

Employing the approach proscribed by Latour, Annemarie Mol undertook what she referred to as an ‘ethnography of atherosclerosis’. This became the basis of her book *The Body Multiple* (2002). Here she reports on her observations of specific interactions that rendered lower-limb atherosclerosis intelligible within the hospital. She noted that even within the one hospital, the intelligibility of atherosclerosis varied: in different sites, distinct assemblages of humans and non-humans would enact⁴ a distinct atherosclerosis. In consultation room, atherosclerosis is the inability to walk a certain length on flat ground without pain. In the pathology lab, atherosclerosis is a thickening of deposits on the inside of blood vessels, but only after the construction of a delicate assemblage: the preparation and staining of a blood vessel cross section on a slide, carefully placed under a microscope. And in the vascular clinic, atherosclerosis was rendered intelligible as restricted blood flow and a loss of blood pressure, as enacted by the ultra-sound emitting Doppler apparatus and accompanying pressure cuff. Each of these sites contained a different assortment of human and non-human actors, and each, then, enacted a distinct atherosclerosis. In other words, different capacities for interaction were realised in different locations.

⁴ Mol uses the term ‘enactment’ to replace ‘social construction’. The problem with the latter, she argues, is it implies that the ‘constructed’ entity has obtained a degree of durability. ‘Enact’ conveys the short temporality of such ‘constructions’: a body might be constructed as a biomedical entity in one specific context, but this may have very little influence in other contexts were it is enacted differently (Mol 2002; 32-33). By emphasizing the generally short temporality of enactments, sociologists are encouraged to explore how it is that some enactments do actually become more durable than others; how it is, for example, that some enactments come to be seen as more ‘valid’ than others.

Mol argues that far from being unified and homogenous, medical practices are complex, divergent and messy, and tend to produce multiple entities (Mol, 2002). What may be considered the same disease can, in fact, multiply in various parts of the hospital. Often this multiplicity is unproblematic, particularly if the various enactments remain tethered to the site in which they are produced. But alongside this multiplicity, however, are practices that seek to produce an overall singularity and coherence: Mol notes how some renderings of atherosclerosis were discarded or ignored by clinicians (if they appeared contradictory), how narratives were used by health professionals to link, say, the pain in the leg with arterial deposits, and how some enactments were simply ‘translated’ into others. Some assemblages, then, become more durable than others. An ‘informed’ patient may be presented with a singular, coherent account of their affliction, but such an account is an achievement; the consequence of ordering and sorting, ranking and prioritising.

Mol, then, draws attention to the way in which disease and the body are rendered intelligible in medical practices, how potentially conflicting accounts can be produced, and how such conflict is overcome. She has illustrated how assemblages produce an intelligible body, how the body can be rendered intelligible differently by various assemblages, and importantly, she has illustrated how particular renditions may supplant others in order to give the impression of a singular, coherent reality. Reality is the product of assemblages, and if such a reality appears singular and coherent, it is because multiplicity has somehow been elided.

2.5 Material semiotics and the collection of data

Many of the assumptions underlying material semiotics are synonymous with the key tenets of Garfinkel’s approach and ethnographic inquiry, such as: a rejection of positivism (the idea that universal laws, or an appeal to a transcendental reality, can be used to explain social phenomenon); a commitment to studying practices ‘in situ’ (rather than in some sort of artificial or experimental setting); a tendency to conduct in-depth small scale studies involving a few cases/contexts; and a commitment to prioritising agents themselves and the meanings they attribute to their actions and their surrounding world (Hammersley and Atkinson 2007: 3, 7). These tenets reflect a belief that human action is culturally and historically situated, and that social forms

and structures emerge from such action. Understanding such action therefore requires exploring the rich, complex and messy milieu in which it takes place.

This project employs these key tenets of ethnographic inquiry. As I have argued, however, this project also assumes that human action is materially situated: So for this project, to the above list of tenets common to ethnographic inquiry, I append a commitment to including within this sociological exploration the interactions between human agents and non-humans. In this project such an approach can be used to explore: how, in the process of developing a DBS service, PMDS team members bring together a range of tools, bodies and knowledge into an assemblage; how these assemblages render various entities (such as the dystonic patient) intelligible, thus enabling the production of useful clinical knowledge; and how potentially conflicting renderings of an entity are negotiated or managed.

2.5.1 Methodology issues with material semiotics in practice

Before I outline the specific data collection methods it is necessary to introduce two potentially problematic issues arising when a material semiotics-informed methodology (or an adjusted ethnography) is put into practice. The first potentially problematic issue relates to the specific methods of data collection. Ideally the researcher would immerse themselves in the field for a long period of time, 'living with the tribesmen', to quote Latour and Woolgar (1986: 28). In collecting the data that became the basis for *Laboratory Life* (1986), Latour undertook a twenty-one-month programme of participant observation within the selected laboratory. He was employed as a research assistant, enabling him to participate in, and experience first-hand, practices within the lab. He was also granted free access to the laboratory's archive, papers and documents, many of the scientists' discussions, and he undertook formal interviews with scientists (1986: 39). Latour and Woolgar argue that such prolonged immersion within the field enabled them to witness the 'craft' of science; that is, the actual day-to-day, often mundane, often messy practices that constitute the production of scientific facts. In situ observations are necessary, as many aspects of this 'craft of science' are not presented in scientists' own presentations of their work (1986: 28-29). Interviews and documentary analysis alone, then, are insufficient. Similarly, Mol's *The Body Multiple* is based on data collected from over 300 observations of consultations (2002: 2).

Ideally for this project I would have undertaken a similar quantity of fieldwork. I would have immersed myself within the field site for a long period of time, observing members of the medical team as they interact with each one another, their patients and their material environment. I would have viewed communications between the team and other agents, and I would have accessed the medical records, clinical assessment tools and so on that members of the team use to diagnose and manage children with dystonia. As Pawson has stated (1999), however, there is often a divergence between what is 'ideal', and what is possible (the 'real') in research practice, and as I illustrated earlier, the practicalities of doing fieldwork with the PMDS prohibit the sort of prolonged field-site-immersion undertaken by Latour. However, although I did not 'live with the tribesman', I believe that the my methods nevertheless enabled me to witness the 'craft' of using deep brain stimulation to treat children with dystonia. The observations in particular (as we will see further on) were particularly useful in this regard.

This brings me to the second potentially problematic issue regarding a material-semiotics informed methodology. Latour implies that the role of sociologist is to create a sociological account via extrapolation from the field alone. The sociologist, he argues, must refrain from making a priori assumptions about the nature of entities in the world, or what constitutes 'reality', as these are being generated and negotiated 'in the field'⁵. Ideally, if I were to have followed suit, I would have immersed myself in the research site, having jettisoned prior assumptions about the body and the brain, the roles of clinical staff, dystonia and the deep brain stimulation technology. Much like the romanticized version of a mid-20th century anthropologist, I would approach the research site as if it were a strange and exotic culture where various artefacts are produced and become implicated in wider systems of exchange and meaning. I would extrapolate all that is important to the inquiry from the field itself. Indeed, in their seminal *Laboratory Life*

⁵ "Your task is no longer to impose some order, to limit the range of acceptable entities, to teach actors what they are, or to add some reflexivity to their blind practice... You have 'to follow the actors themselves', that is, try to catch up with what the collective existence has become in their hands, which methods they have elaborated to make it fit together, which accounts could best define the new associations that they have been forced to establish... sociology has to be fully relativist." (Latour, 2005: 11-12)

(1986), Latour and Woolgar claim that this naïve, intrepid researcher is the basis for their ‘anthropology of science’.

We envisage a research procedure analogous with that of an intrepid explorer of the Ivory Coast, who, having studied the belief system and material culture of “savage minds” by living with tribesman, sharing their hardships and almost becoming one of them, eventually returns with a body of observations which he can present as a preliminary research report. (Latour and Woolgar, 1986: 22)

I argue that such an ultra-relativist position, however, is problematic. If it were possible to thoroughly purge oneself of all a priori assumptions, the world would appear as an incomprehensible mess. As Silverman puts it, without a prior conceptual orientation, “one would not recognize the ‘field’ one was trying to study” (Silverman, 2001: 72). At the very least a researcher requires a starting point, some sort of focus to anchor their initial inquiry. A realistic goal is not to dispense with prior knowledge of the topic area, but to be aware of, and reflect upon, any bias that such knowledge may entail (Dey, 1993: 63-64). What might seem like a sensible starting point for the researcher may turn out to be highly contested by those within the field, or completely irrelevant. The key, then, is to approach the field with an “open mind”, not an “empty head” (Dey, 1993: 63). For Mol, ‘atherosclerosis’ provided an initial starting point and a means of discerning which particular phenomena would be the focus of her inquiry. By entering the field with some ideas about what atherosclerosis is and what it might be, she equipped herself with a means of engaging with those within the field and a means of keeping her project to a manageable size (Mol had received basic training in medical school and studied text books and journal articles on atherosclerosis while undertaking the study (Mol, 2002: 1,3). And obviously, as Mol demonstrates, adopting atherosclerosis a priori as an initial starting point did not mean that it was taken to represent an unproblematic aspect of nature, nor did it render her insensitive to the divergent ways in which actors in the field understood atherosclerosis. Indeed, it was her ontological starting point and not a naivety of the topic matter that compelled her to be attentive to the ways in which such seemingly taken-for-granted concepts could be contested, disrupted, or reified by practices within the field.

My goal, then, was to enter the field with as much knowledge of the topic matter as possible. Prior to beginning fieldwork I attempted to read as much material on deep brain stimulation as I possibly could (some of this material has featured in the introduction of this thesis). From this material I acquired some understanding of the DBS technology, the regions of the brain and the pathology of various neurological disorders, and I became familiar with at least a few of the seemingly infinite number acronyms used by members of the team. My familiarity with the literature, then, meant that my participants and I had at least some common points of understanding, and it meant (I assume) that I had some credibility in their eyes. To borrow a term from Collins and Evans, I acquired (or attempted to acquire) an *interactional expertise*: a sufficient level of “expertise to interact interestingly with participants and carry out sociological analysis” (Collins and Evans 2002: 254)⁶. My primary research questions were also particularly important in this regard: they provided me with an initial framework for determining which participants to include in the project, which particular practices might be worth focusing upon, and in the case of interviews (as I will explain further on), which questions to ask. I tried my best, then, to avoid entering the field as a naïve, intrepid researcher. Before I provide a description of fieldwork activities, let me address some of the methodological issues of the specific data collection methods that I used.

2.5.2 Methodological issues relating to interviews and observations

Interviews and observations each have their limitations as data-collection methods. By using both in-depth semi-structured interviews and observations I hoped to sufficiently overcome the limitations specific to each method. Obviously, like all data collection methods, interviews do not provide the researcher with a transparent view of reality or a set of truths. Interviews elicit participants’ perspectives on their world, and during the course of interviews, participants actively shape their responses according to commonsense devices for making sense of their environment. On this point I adopt what Silverman refers to as the constructionist perspective on interviews (Silverman 2001: 95); during an interview, both the

⁶ Interactional expertise is in contrast to no expertise, which is insufficient for undertaking sociological analysis, and contributory expertise, which is the expertise required to contribute to that field which is being studied (Collins and Evans 2002).

researcher (interviewer) and the participant (interviewee) actively engage in the construction of an account of the world. The interviewer brings a set of concerns to the interview (which reflects their worldview and background knowledge of the topic), and prompts the interviewee to address these concerns through a particular line of questioning. The interviewee responds by offering details of their experiences, but in doing so, constructively adds to, takes away from, and transforms the facts and details (Holsteim and Gubrium, in Silverman, 2001: 95). To adopt a material semiotic parlance, interviews are a means where interviewer and interviewee actively construct an assemblage. Both prompt and respond to each other, bringing together and relating a range of semantic elements within an account that subsequently provides intelligibility to the aspect of the world in question. Importantly, in the process of co-producing an account, both the interviewer and interviewee share and draw upon common, learned tools for interacting and communicating meaning (Cicourel, 1964: 100). Latour refers to such tools as ‘plug-ins’ (2005: 207): circulating clichés, gestures, turns of phrase and so on that actors can ‘plug-into and download’ in order to articulate themselves and the world around them. Here, then, familiarity with the topic matter, a shared understanding of such ‘plug-ins’, and an ability to relate to, and engage with participants are not hindrances to the collection of data (as is implied by the ‘intrepid researcher’ fallacy), but necessary prerequisites.

Thus, during interviews I attempted to prompt participants into articulating their perspectives on various aspects of using DBS to manage children with dystonia, enabling me to address the research questions. Additionally, a key component of participants’ perspectives was not just ‘what’ they said, but also ‘how’ they said it. I used interviews to explore how members of the PMDS team and associated health professionals employed circulating tools, points of reference, and norms in order to convey their understandings of their work.

While interviews enabled me to see how participants thought about their work, observations enabled me to see what they actually do. Observation as a method reflects the theoretical position that social forms and structures emerge from the every-day activities of actors: people do not ‘come to terms’ with phenomena; they actively constitute them (Silverman, 2001: 74). From a material semiotics perspective, observations enable the researcher to explore how routine and mundane practices assemble various entities, and how the resulting assemblages

enable the expression of particular capacities of interaction (while preventing the expression of many more). Observing consultations enabled me to witness first-hand the practices that assemble the patient in a wider network of entities: health professionals, medical technologies, clinical assessment tools, and so on. Just as Annemarie Mol observed (2002) how various practices rendered atherosclerosis intelligible within the consultation room, I used observations in order to see how the body, dystonia, and the patient are ‘enacted’, or rendered intelligible, in everyday clinical practice. (Additionally, Dr Martin stated that in order for me to gain a coherent insight in the way in which his team works it would be necessary to observe several consultations involving patients.)

2.6 Conducting fieldwork: Observations and interviews

I began my fieldwork with the PMDS immediately after I received an Honorary Research Contract from the R&D department of the hospital trust. My strategy was to undertake five or six observations of team meetings before conducting interviews or observing any interactions with patients. As we will see, I used these initial team meetings to identify some of the various challenges encountered by PMDS team members. I was then able to explore these challenges in detail during subsequent interviews, and I was able to request to observe specific interactions with patients where these challenges are addressed

2.6.1 Observing team meetings in the field

In the second week of April 2012 I began undertaking observations of team meetings. For the first six months I attended as many as I could. I would arrive five minutes before the scheduled start time and sit in one of the many chairs lining the perimeter of the room. During meetings I used hand-written field notes to record data. The reason for this is that I suspected an ethics committee would object to the taking of audio or video recordings on the grounds that these would be too invasive: with handwritten field notes I could easily omit any data that could be used to identify participants, and I would more easily ‘blend-in’ with other members of the team.

My rough strategy for taking notes was based on a few points of guidance provided by Hammersley and Atkinson (2007: 141-147). My goal was to record as much activity as possible, in as much concrete detail as possible, particularly during

the initial observations. In order to do this, I created my field notes in two stages. The first stage took place during the observation. Here, I made very concise notes comprising key words and phrases and brief descriptions: “jottings, snatched in the course of action” (2007: 143). These were intended to trigger my memory during the second stage of note taking which took place immediately after the observation. Generally this first stage was not too challenging and I was able to check my brief jottings against the comments added to the agenda/minutes that were displayed on the wall and were being created as the meeting progressed. But the informality of the meeting did present challenges. Sometimes, on occasions when several team members were talking at once, I became perplexed and failed to note anything at all. Often a ‘course of action’ had been added to the meeting minutes but I could not follow how the team actually arrived at that decision.

I used the brief notes made in stage one to “trip-off a string of images in the mind” (Hammersley and Atkinson 2001: 143), enabling me to write a more substantial and detailed reconstruction of the observed interaction (stage two). The advantage of this two-stage process is that by delaying the extensive note taking until after the observation I was less likely to miss details of the interaction. For this strategy to work, however, it was necessary that the second stage take place immediately after the observation while the rich detail of the interaction was still accessible in my mind. This was not difficult: I wrote-up my field notes immediately afterward in a café near the hospital. Generally I found that for every one-hour of observation, It took me a further two hours to write up my field notes in full.

As Hammersley and Atkinson point out, as ethnographic research progresses emerging themes become apparent and the project becomes more focused as a result (Hammersley and Atkinson, in Silverman, 2001: 70). From very early on in the meetings I was able to discern the key challenges encountered by the team in their day-to-day work and thus hone my fieldwork as a result. Much of the discussion revolved around several key issues. One of these was the coordination of the team itself: a great deal of meeting-time was taken up discussing what could be referred to as “coordinating multidisciplinary”. Others included: deciding which patients were suitable candidates for DBS, managing expectations of patients, managing infection, measuring the effectiveness of DBS, and disseminating the clinical outcomes and research of the team to the wider clinical community. These were similar to the challenges that had been identified in the literature on DBS and

no doubt my attention had been drawn to these by my background reading, but given the amount time the PMDS team spent discussing these issues, I decided that I could indeed delineate them as being ‘major challenges associated with the day-to-day application of DBS into paediatric neurology’. I honed my fieldwork strategy to explore how these challenges manifested in the clinical practice of the team, and how the team managed these challenges in their day-to-day work (thus addressing my first and second research objectives). As I will illustrate further on, I decided to use the interviews and the observations of interactions with patients as a means to explore these specific issues in more detail.

Aside from ‘routine’ team meetings I also had the opportunity to observe ‘academic’ team meetings (a full list is displayed in table 2.1, page 58). This term was used by team members to describe either a meeting with a visiting clinician working in a related area (usually an area of paediatric neurology), or a meeting to review a potentially useful academic paper. Both types were especially useful to observe. In the former, the team and the visiting clinician would compare services, discuss difficult clinical cases, explicitly state the challenges they faced, and provide detail on how they managed these challenges in practice. In the latter type of meeting the team identified papers for review that could shed light on a particular clinical challenge: a team member would present the paper, and the team would then discuss its merits and its applicability to the team’s day-to-day practice. In both types of academic meetings the challenges encountered by the team and their methods for overcoming these challenges were explicitly articulated. These meetings provided vital data and confirmed that I had, indeed, chosen to focus on the correct issues. By the time I had observed five or six meetings I had created the list of challenges that I would focus upon in more depth and consider as specific topics for the substantive chapters of this thesis: coordinating multidisciplinary teamwork, selecting candidates for DBS, managing expectations of families, and measuring clinical improvements.

Table 2.1: Observations of team meetings

Observation	Meeting type	Duration (min)	Comments
1	Routine	120	
2	Academic	150	With paediatric neurologist from Texas
3	Routine	70	
4	Academic	90	Discussion on paper on DBS for childhood dystonia written by another centre
5	Routine	100	
6	Routine	80	
7	Academic	60	With obstetrician from Australia. Discussion about causes of cerebral palsy
8	Routine	80	
9	Routine	60	
10	Routine	60	
11	Routine	75	
12	Routine	60	
13	Routine	45	
14	Routine	55	
15	Routine	60	
16	Academic	60	Review of paper detailing new clinical outcome measure
17	Routine	60	
18	Routine	180	First team meeting after three week delay
19	Academic	60	Discussion of two complex clinical cases
20	Routine	90	
21	Academic	180	Discussion of alliance with statisticians
22	Routine	60	

2.6.2 Observing interactions with patients and family members

Thus, once I had identified the challenges, I asked team members if I could observe interactions, including interactions with patients and family members, where these specific challenges were addressed. Team members identified two patients who would be involved in PMDS activities in the coming months, one of whom would undergo a full pre-surgical assessment regime. Here I will describe the process of obtaining consent and assent from these patients before describing my method for capturing data during the interactions. All names provided below are pseudonyms.

The first patient was Kyle, a twelve-year old with dystonic cerebral palsy. At that time he had recently had the DBS system implanted and was an inpatient in the neurology ward. The neurologist suggested that I observe her working with Kyle and his parents as she showed them how to operate and recharge the DBS system. On the day of the interaction I arrived at the neurology ward an hour before this

scheduled meeting and Dr Martin introduced me to Kyle's mother and father who were sitting in a private room. Kyle, I was told, was attending the hospital school and would return in thirty minutes. Dr Martin left me to speak with Kyle's parents alone, and after initial introductions I provided them with an adult's and young person's participant information leaflets (PIL), explained the purpose of my project, and described, specifically, what participation would involve. I then asked them if they had any questions, if they were interested in participating, and if they would be happy for me to ask Kyle if he would like to participate. They both stated that they were more than happy to participate, and that Kyle usually enjoyed having extra people around. I gave them copies of consent and assent forms and said that I would collect them just prior to the upcoming consultation (thus giving them additional time to read the PIL). I then left the private room where I was met by the occupational therapist (OT) and Kyle who had just returned from school. The OT introduced me to Kyle, and I explained my project (in simple terms) to him and asked if he would like to participate. He smiled, and using the communication device attached to his motorised wheelchair indicated 'yes'. I asked him if he had any questions (to which he indicated 'no'), and as we accompanied him back to his parents, I told him that he could talk about it more with his mum and dad, and that if they did want to participate, they could sign the forms that I had given them. I left Kyle with his parents and I returned around fifty minutes later with the neurologist (not Dr Martin) to see if they were happy to participate. They were, and they handed me their signed consent and assent forms.

The second patient, Carl (pseudonym), was a sixteen year-old with suspected but undiagnosed secondary dystonia. He was a candidate for deep brain stimulation and would be undergoing all necessary pre-surgical assessments and a goal setting session: the team decided this would provide me with an excellent opportunity to observe them as they attempt to manage some of the challenges I had identified during team meetings. I first met Carl on the morning of his first set of assessments. He was sitting in the waiting area of the outpatient clinic, typing on his laptop, with his mother seated next to him. The psychologist had introduced us, and said that one of the other team members would return in twenty minutes to collect them for the first assessment. Carl and his mother had been told of my project several days earlier and they had said they were interested in participating. I provided them with PILs, described my project and what participation would entail,

and asked if they had any questions. Carl had no problem with speech and was articulate, and said that he would be happy to participate. Both him and his mother signed consent forms, and I waited with them before we were collected for the first of his assessments.

Again, during my observations of the interactions involving Kyle and Carl, I used the ‘two-step’ process of creating field notes (Hammersley and Atkinson 2007). In addition to capturing what was ‘said’ by participants, however, I also wanted to record as much of the non-verbal action as possible. Indeed, an observational method informed by my particular theoretical stance (material semiotics), necessitated that I capture the interactions between bodies, objects, technologies and the physical, built-environment. Although there is a significant body of ethnographic studies focusing on interactions between humans, non-human objects, and the build environment, very little guidance is provided within sociology literature on how the researcher can record such interactions. The design theorist John Zeisel (2006) provides some useful guidance. He states that maps and accompanying notation are a convenient way to analyze several people in one setting (2006: 200-203). Following suit, I created annotated maps of the physical setting in which the observed scenes take place. During the interaction I created a quick floor plan of the setting, noting the location of tables and chairs, the position of various participants (PMDS team members, patients, family members), and the position of various equipment and tools that were used. I also used ‘trigger’ words or concise phrases to note how and when various tools, equipment and other non-human objects were used. During stage two of the note-taking process these initial scribbles were expanded into a more coherent and detailed account.

Zeisel also suggests that researchers should stay attentive to several types of ‘physical traces’ that indicate how participants interact with their environment. These include various *displays of the self*, where objects are employed to personalize a space or associate a space with a particular group; *adaptations for use*, where participants add props to enable a space to be used in a particular way; *public messages*, such as official signs or graffiti which communicate to people how a space should be used; and *by-products of use* such as wear-and-tear of a surface, or physical remnants, which indicate how a space or an object has been used (2006: 170-179). These traces can be used to infer how a material environment shapes particular actions and how human participants mould and utilise their environment. My

original intention was to take note of all of these types of physical traces, but as I undertook the research I found that it was the first two ('displays of the self' and 'adaptations for use') that I tended to notice. Perhaps because I was already near-overwhelmed with data as the interactions took place that I failed to note any instances of 'public messages' or 'by-products of use'.

Using this method of noting and recording data I observed most members of the team as they worked with patients and families. (A full list of the specific interactions that I observed is presented in table 2.2). Observing these interactions enabled me to see how team members, in a 'messy', clinical setting, managed several of the challenges that I had identified during the team meetings: how they selected candidates for DBS, how they attempted to manage the expectations of families, and how they measured clinical improvements. Importantly, it also enabled me to see how various assemblages 'enact' the patient and dystonia.

Table 2.2: Observations of interactions involving patients

Observation	Interaction	Participants	Duration (min)
1	Teaching family how to recharge DBS system	Neurologist Patient Patient's mother Patient's father	30
2	Gross motor function assessment and neurological exam	Two physiotherapists Patient Patient's mother	90
3	Fine motor skills assessment, assessment of functionality (preparing and eating food)	Occupational therapist Therapy assistant Patient Patient's mother	60
4	Speech and intelligibility assessment	Speech and language therapist, patient patient's mother	40
5	Goal setting session prior to DBS surgery	Occupational therapist Physiotherapist Psychologist Patient Patient's mother	60
6	Scoring of impairment	Two physiotherapist Occupational therapist Speech & language therapist	90
7	Scoring of functionality	Occupational therapist	120

Table 2.2 illustrates the observations of interactions that were undertaken as part of this project. Note that several of the interactions involved more than one assessment or exam.

2.6.3 Interviews with clinicians

All members of the PMDS team were interviewed once, except for the clinical research fellow who was interviewed twice. Interviews lasted between 45 and 90 minutes and all participants were happy to have the interviews audio-recorded. To ensure that they did not feel pressured to participate (which was a possibility, given that the leader of their team was also Principal Investigator for the project), all team members were told that their decision to participate would be kept confidential. In addition to members of the team I also interviewed a consultant clinical geneticist who was the Head of Clinical Services at the hospital when the PMDS team was established. In this role she liaised with the head of the PMDS team and had extensive knowledge of the institutional environment in which the team worked. (A full list of interviews conducted is represented in table 2.3, page 63).

By conducting most of the interviews towards the end of the data collection process I was able to address issues that had been raised during both types of observations. Importantly, I was able to address the key challenges I had identified during the observations of team meetings. I also found it particularly useful to recount actions that I had observed during interaction with patients and then ask participants to explain to me what was going on. Thus, the specific interview questions differed for each participant, but in general the interview topic guide that I prepared (and which can be found in Appendix 4, pages 257-259) addressed the following issues:

- The participant's specific role within the team
- The training and experience required to undertake his/her role within the team
- The challenges of identifying candidates for DBS
- Managing patient expectations and getting informed consent
- The challenges associated with measuring clinical improvements
- The benefits and challenges of working within a multidisciplinary team
- Safety and risks associated with DBS implantation
- Working with families
- Communicating with patients.

The interviews were semi-structured and above issues were addressed by-way of open-ended questions. This enabled me to seek clarification, ask for specific examples, and redirect the interview if new, potentially important issues were raised.

Table 2.3: Full list of interviews

Interview	Participant	Duration (min)
1	Ex-head of clinical services of children's hospital	50
2	Clinical research fellow	90
3	Therapy assistant	70
4	Team administrator	60
5	Specialist nurse	55
6	Occupational therapist	80
7	Speech and language therapist	45
8	Physiotherapist – A	45
9	Physiotherapist – B	60
10	Psychologist	45
11	Neurologist – B	55
12	Neurologist – A (Dr Martin)	45
13	Clinical research fellow (2 nd interview)	55

Table 2.3 illustrates all interviews conducted as part of this project. All interviews were audio recorded.

It appeared that participants enjoyed the opportunity to express their points of view, and all stated that they would be happy for me to approach them with further questions if need be. On several occasions after an interview had formally ended the participant would go on to elaborate on issues that had been raised, perhaps feeling more relaxed now that they were no longer recorded. In such instances, I asked participants if it was okay for me to make quick hand-written notes of what they had said. A professional transcriber transcribed all audio recordings. I also read each transcript thoroughly while listening to the audio recordings to correct any errors.

2.6.4 Other fieldwork activities

Aside from the 'formal' methods of data collection outlined above I was involved in other activities on site (table 2.4). These included what I refer to as 'information sessions' with individual team members. One such session involved the nurse who

showed me the presentation she gives to families who are considering undergoing DBS and the presentation on DBS and infection she gives to nurses working on the ward.

Table 2.4: Other fieldwork activities

Activity	Type of activity	Individuals involved	Type of notes taken
1	Demonstration of presentation on DBS given to families	Nurse	Two-stage note taking process
2	Demonstration of presentation on DBS and infection given to ward nurses	Nurse	Two-stage note taking process
3	Demonstration of preparing the weekly schedule	PMDS administrator Nurse	Two-stage note taking process
4	PMDS team away day Feedback session	All PMDS team members	General impressions noted at end of activity
5	Demonstration of props and tools used to communicate with patients	Occupational therapist	Two-stage note taking process

Another session involved the occupational therapist (OT) who showed me the various tools and props they use to communicate with patients with poor speech. The team administrator and nurse also showed me how she put the weekly team schedule together (which was particularly useful to see – as we will see in the following chapter is one strategy for managing the challenge of multidisciplinary). During these sessions I recorded data using the two-stage note taking processes outlined above.

I was also invited to team social events, one of which was the annual ‘away-day’. During this event the team discussed various ‘non-clinical’ issues, such as: the overall direction and goals of the team, possible research projects and collaborations with other groups; and the content and format of their website format. Rather than take ‘full’ field notes using the two-stage process I simply recorded my general impressions at the end of the day. At this event I was allocated 45 minutes to provide a feedback session to the team. Here, I articulated my understanding of the major challenges encountered by the team and how the team was attempting to manage these challenges, and I illustrated how I was using and presenting the data that I had so far collected. Members of the team clarified a few points, and indicated that they were satisfied with the picture I had presented.

2.7 Data analysis and identifying key themes

Analysis was an iterative process and took place as I was collecting data. All interview transcripts and field notes were transferred to NVivo9 data storage/analysis software, which I then used to code the data immediately after it was uploaded. As I indicated earlier, my research objectives compelled me to maintain surveillance of any challenges that the team was encountering in their day-to-day work. After five of six observations of team meetings I had identified what I took to be the major challenges of the team: coordinating multidisciplinary teamwork; selecting candidates for DBS, managing expectations of families, and measuring clinical improvements. I therefore created thematic codes that would enable me to quickly locate any discussions or actions related to these particular challenges. I was able to use the feedback session to check with participants that the challenges I had identified (and that had become the basis for much of my codes), were in fact, representative of their work. As my stock of data increased I quickly noticed that many of my initial codes were too general. So, I had to create 'sub-codes' and subsequently recode data collected earlier. For example, the code 'measuring clinical improvements' was divided into the sub-codes 'BFM scale', 'AMPS scale', 'BADs scale', and several others. This 'enriching' of my codes corresponded to my increased familiarity with the activities of the team.

Indeed, the codes tended proliferate throughout the data collection process. Each additional observation or interview tended to reveal a new theme that might be of interest, and although I became aware that the project would most likely focus on several key challenges encountered by the team, I did not want to preclude any potential avenues of inquiry. In one of the later interviews, for example, I asked a participant if she found it difficult working with children very severe motor disorders. She replied that it was essential to have a good sense of humour. When she said this, I thought about the numerous times I had witnessed team members laughing, often in potentially stressful circumstances. Thankfully I had noted these instances in my field notes even if I had not considered it to be a theme worth coding. I subsequently went back over all my collected data and coded all instances where members of the team were using humour. My analysis, then, involved a continual re-evaluation of earlier data in response to findings from more recently collected data.

Thus, by the end of the analysis period, the data had been organized around the key challenges encountered by the team. Within each of these are a plethora of codes that pertain to participant discussions of that challenge, or specific, practical methods of managing that challenge. I felt that I had sufficient data that all four of these challenges could become the basis for a chapter of this thesis. There is, then, a chapter that explores each of the following challenges encountered by the team:

- Coordinating multidisciplinary (Chapter 4)
- Selecting candidates for deep brain stimulation (Chapter 5)
- Managing expectations of families (Chapter 6)
- Measuring clinical improvements (Chapter 7)

Each will show how PMDS members have ‘innovated’ to overcome the challenge, and together with the chapter on the history of DBS that precedes them (the following chapter), they will provide a comprehensive illustration of medical innovation.

In addition to these challenges I have identified other themes that could be considered to traverse all of these challenges. These included themes such as the role of humour in managing tension, the role of the clinician’s body in generating useful clinical knowledge, and what could be called socio-political factors: the influence of evidence-based medicine, the influence of a ‘patient-centred’ mantra within healthcare, and concerns about how this encourages autonomous decision making among patients.

2.8 Conclusion: producing a sociological account from an irreducible world

In this methodology chapter I have highlighted some of the many factors that have collectively shaped this project (such as negotiations with the gatekeeper, Dr Martin, and the NHS REC approval process). I have also illustrated how the project has been influenced by a set of beliefs about the nature of the world in which we live; a set of beliefs that have been adopted from material semiotics. And, I have also shown how data collection and analysis was shaped by my research questions and background reading on the topic, leading to the identification of four ‘key

challenges' encountered by the PMDS team which form the structural basis for the thesis.

Before we move on however, it is important to keep in mind a caveat. As Law has stated (2004), much of the world does not lend itself to neat sociological accounts. It is naïve to think that the phenomena of the world can be reduced to language and conveyed in text; some phenomena will escape our faculty of comprehension, and even a miniscule aspect of the world contains a near-infinite detail that, if it were to be captured faithfully in an account, would require an enormous amount of time and text (George Luis Borges illustrates the crippling futility of any such attempt in 'Funes the Memorious' 1970)⁷. Inevitably, then, any manageable account of any aspect of the world, even one that seeks to foreground complexity and uncertainty, is stylized in some way. My goal with the proceeding chapters, therefore, was to produce an account that is akin to a useful map. As McGrail puts it in his description of a good Actor-network Theory account:

A good map makes no secret of the fact that it has left-behind a near infinite amount of the detail and complexity of the original terrain, but at the same time it can never be divorced from it – it can never relax its empirical grasp... A map is stubbornly situated, but at the same time it is built upon rigorous, intelligent, and pragmatic abstraction (McGrail 2004: 128-129).

⁷ "Funes not only remembered every leaf on every tree of every wood, but even every one of the times he had perceived or imagined it... I suspect, nevertheless, that he was not very capable of thought. To think is to forget a difference, to generalize, to abstract. In the overly replete world of Funes there were nothing but details, almost contiguous details." (Borges 1970).

3 A history of deep brain stimulation⁸

3.1 Introduction

In order to put the innovative activities of the PMDS team in context, it is necessary for me to describe some of the historical developments that have enabled such a team to exist in the first place. In this chapter I will illustrate how the DBS technology has emerged from an entanglement of various actors and has been shaped by several socio-political trends (In other words, this chapter will be used to address the first research question⁹ and to provide some insights that can address the fourth research question¹⁰). Aside from enabling me to provide a more coherent picture of medical innovation, this foray into the historical development of DBS will also shed light on some of the challenges encountered by the team in their day-to-day activities.

While overviews of the development of DBS are not uncommon in the scientific literature, they are seldom little more than a means of introducing the technology to readers. As such, they tend to be brief, relying on a few key historical events to provide some sense of context. As Hariz et. al. point out (2008), the common narrative of these overviews is that DBS was first developed in 1987 by a team treating patients with tremor at Grenoble, France. Alim-Louis Benabid and his colleagues were using electro-stimulation to identify the correct area of the brain to undergo ablative surgery. In doing this, they noted that high-frequency electro-stimulation was, on its own, therapeutic and subsequently DBS was adopted as a means for treating medically refractory motor disorders in many parts of the world. And as time went on, the narrative goes, the psychiatric side effects identified in some patients encouraged explorations of DBS as a possible treatment of psychiatric illnesses.

⁸ This chapter (with some adjustments to the introduction and discussion) has been published as: Gardner, J. (2013). A history of deep brain stimulation: technological innovation and the role of clinical assessment tools. *Social Studies of Science* 43(5): 707-728.

⁹ Research question 1: What factors have shaped the development and dissemination of DBS technology?

¹⁰ Research question 4: What socio-political trends influence the development of the PMDS's deep brain stimulation services?

While the details of such narratives may not necessarily be wrong, they tend to give a misleading impression of the nature of medical and scientific innovation. Much of the scientific literature presents DBS as if it is an inevitable outcome; the consequence of continuous development driven by good science, beneficent medicine and committed specialists. Consequently, knowledge is presented as something that is discovered, and innovation as the inevitable, neutral incorporation and application of this knowledge (thus reifying the linear model of medical innovation). Many scholars have been critical of such narratives. Generally, such criticisms point out that various social forces shape the development and application of technologies, and such technologies are not, then, value-free and neutral. As Brown and Webster argue (2004), medical innovation is complex and reflects a wide-range of distinct and competing interests. Much of the work undertaken in science and technology studies and the sociology of medicine has sought to identify exactly how particular interests shape the development and application of technology, and how these technologies subsequently reify or disrupt particular norms and institutions. A recent example of such work is Stuart Blume's account (2010) of the development of the cochlear implant. From the late 1960s onwards several groups were attempting to develop an implantable hearing device. These groups had differing views on how such a device should work, faced considerable hostility from their colleagues, and had to compete for funding. Some were not averse to using media hype in order to secure the resources they needed, much to the disdain of other hearing specialists. Competing groups formed alliances with rival device manufacturers, one of which provided the necessary resources to conduct clinical trials and gain regulatory approval. Once approved sales of the device failed to rise, partly due to the high costs associated with its implantation. Competing companies therefore formed an additional alliance to lobby the US government to have the device covered by Medicare. Blume's account highlights the many diverse actors involved in innovation: competing scientists and engineers, the media, industry, regulatory agencies, lobby groups, patient advocacy groups, and governments. As Faulkner states, this plurality of interests, both public and private, is characteristic of medical innovation within neo-liberal economies (Faulkner, 2009: 7). Brown and Webster argue that technologies emerge from, and are an integral part of, heterogeneous networks made up of professions and institutions, users and citizens, governments, regulatory agencies and commercial industry. Technological

innovations have to work within and through these networks by resonating with pre-existing values or interests. Their capacity to do this, to be co-opted, moulded, and perpetuated by various actors, determines their success. No technology “ever speaks for itself” (Brown and Webster 2004: 38).

Indeed, as this chapter will illustrate, this plurality of interests and the formation of alliances is characteristic of the development of deep brain stimulation technologies. Deep brain stimulation has its origin in the neurostimulation techniques developed within a sub-speciality of neurosurgery: stereotactic neurosurgery (also known as functional neurosurgery). During a brief era of intense *learning-in-practice*, neurosurgeons within this speciality produced much of the knowledge and material infrastructure from which deep brain stimulation therapies later emerged. We will also see the importance of *technology transfer* in the development of device-based therapies: the first neurostimulators were modified cardiac pacemakers. As this technology was transferred, alliances were formed between neurosurgeons and commercial industry, particularly with the medical device manufacturer Medtronic. This chapter will suggest that the material qualities of the technology facilitated its rapid dissemination. As de Laet and Mol have illustrated (2000), flexible technologies can disseminate more easily than those that impose a particular type of usership. We will also see that the advent of medical device regulation had a major impact on the development and dissemination of neurostimulation therapies. In effect, it directed the development of neurostimulation technology towards therapies for conditions such as Parkinson’s which could be ‘objectively’ quantified with clinical assessment tools. I will also argue that the commercial utility of such clinical tools in the era of device regulation and evidence-based medicine is one reason why they have become prominent. This has facilitated the diffusion of particular techniques for manipulating bodies to extract data, techniques that are currently employed by the PMDS team. In this chapter, then, we will explore the particular conjunction of circumstances that have enabled the emergence of teams such as the PMDS, and we will see how some of the elements that constitute the context of the PMDS have been shaped by a range of historical actors.

3.2 Materials and methods

The data for this chapter has been gathered from a range of resources. Scientific papers from 1930 onwards relating to electro-stimulation, neurostimulation, neuromodulation and deep brain stimulation were sourced from a range of neurosurgical, neurological, psychiatric journals, as well as engineering and bioengineering publications. Data was also gathered from scientific papers relating to the development of clinical assessment tools for movement disorders published from the 1970s onwards. Newspaper articles, press releases, transcripts of FDA panel hearings and meetings (available online), and secondary historical documents, and accounts produced by engineers (Shatin et al. 1987; Mullett, 1987) Metronic medical advisors (Coffey 2001; 2008) and numerous clinicians, particularly the neurosurgeons Philip Gildenberg (2000; 2005; 2009) and Adrian Upton (1986, Upton & Lazorthes, 1987) were also included. These documents were critically analysed in order adhere to Lampland and Star's proscription for interrogating naive "stories of inevitable technological development" and instead identify how both deep brain stimulation and standardized, clinical assessment tools emerged from, and were shaped by, an entanglement of actors (Lampland and Star, 2009). Thus, these papers were used to identify the various social actors, political and institutional pressures, and biomedical developments involved in the development and stabilization of deep brain stimulation.

3.3 The development and stabilisation of deep brain stimulation

Much of the recent scientific literature on DBS provides a brief overview of the therapy's history. As Hariz et al point out (2010), the common narrative of these overviews is that DBS was first developed in 1987 by a team treating patients with essential tremor and Parkinson's at Grenoble, France. Yet, many clinicians had been aware of the therapeutic effects of electro-stimulation of the brain, or neurostimulation, for several decades prior to this and neurostimulation technologies had been in development since the 1960s.

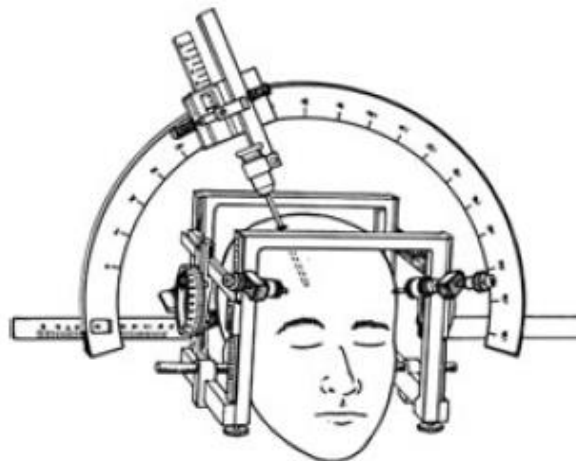
3.3.1 *The rise and near demise of stereotactic neurosurgery*

Since the 1930s clinicians had been using electrodes to explore the function of various areas within the brain and to identify areas for ablative therapy. Ablative therapy involves the deliberate, precise destruction of particular areas within the

brain that are thought to be malfunctioning. The first such procedure, the “Montreal Procedure”, was developed by the neurosurgeon Wilder Penfield in the 1930s to treat epilepsy. Here, patients were kept awake while a surgeon would stimulate different areas of their cerebral cortex with an electrical probe. By noting the patient’s response when stimulating various regions, the surgeon hoped to locate, and subsequently destroy, the particular area of implicated in the patient’s seizures (Penfield, 1936). In 1947 an apparatus was developed that enabled clinicians to use this technique to explore and ablate areas deeper within the brain. The stereotactic apparatus (figure 3.1) brought about the emergence of a new neurosurgical speciality, stereotactic neurosurgery, within which the skills, equipment and knowledge were developed that would later enable deep brain stimulation to emerge and a therapy.

The stereotactic apparatus delineates the brain as a three-dimensional system of Cartesian coordinates. When used in conjunction with imaging technologies, any point within a patient’s central nervous system can be designated as a set of three numbers. Surgeons can then plan their procedure to carefully avoid vital areas and navigate their way to areas deep within the brain (Spiegel et al., 1947). As a result of the apparatus the mortality rate associated with neurosurgery plummeted (from 15% to 1%) and stereotactic neurosurgery went through a period of rapid growth: within ten years it was being practiced in over forty centres worldwide (Gildenberg 2000).

Figure 3.1: A stereotactic apparatus



An artist’s rendition of the stereotactic apparatus. (From Coffey 2008).

This rapid growth was fuelled by a large demand for ablative therapies, the only means available to provide relief from a range of otherwise untreatable neurological conditions. During the period of rapid growth, stereotactic surgery was used to treat various psychiatric disorders (psychosurgery), movement disorders, and chronic pain. Following Penfield's technique and guided by the stereotactic apparatus, surgeons would use electro-stimulation to identify possible target areas deep within the brain that were thought to be implicated in the condition, and if they were satisfied with the corresponding effect on the patient, the area would be carefully destroyed. Prior to the introduction of antipsychotic medications in the mid 1950s, this and the much cruder frontal lobotomy were the only treatments available for patients with psychiatric disorders; disorders that were considered to be a huge financial burden on society, particularly in the US (Mashour et al., 2005). Similarly, prior to the introduction of levodopa in 1968, medicines were largely ineffective in managing the symptoms of Parkinson's, a condition that affects around three in every 1000 individuals. Parkinson's became the main condition treated with stereotactic surgery, with approximately 25 000 surgeries by 1968 worldwide (Gildenberg 2000).

This large body of otherwise untreatable patients provided stereotactic neurosurgeons with a great deal of work and ample opportunity to engage in what Morlacchi and Nelson (2012) refer to as 'Learning-in-practice'. While attempting to identify the most effective means of treating each individual patient, stereotactic neurosurgeons were able to explore the effects of stimulating areas deep within the brain. As the neurosurgeon Gildenberg puts it, it brought about:

A period of unrivalled empirical human experimentation... From the beginning, the philosophy was to use every insertion of an electrode into the brain as an opportunity to study neurophysiology... The information obtained in the operating room was valuable to help localise the electrode position, and the information obtained about pathophysiology was used to develop new indications and targets for stereotactic surgery (Gildenberg, 2000: 299, 301)

Surgeons continued to hunt for more effective target areas for ablation, and in the process they created a body of knowledge based on the effects of stimulating different areas within the brain. In patients with motor disorders it was noted that lower frequency stimulation of particular areas could exacerbate symptoms, while

higher frequencies could reduce symptoms (Munding, 1965; French et al, 1962). In patients with Parkinson's, the subthalamic nucleus (STN), now the main target for deep brain stimulation, was identified as one such area:

The subthalamic nucleus was not readily activated by low frequency stimulation... but there was suppression noted when values of 120 to 300 c.p.s were reached.
(Nashold & Slaughter 1969: 243)

Noting the therapeutic effect of higher frequency stimulation, some surgeons carried out chronic stimulation on their patients. Electrodes were left in situ and protruding from the skull for several weeks, enabling the surgeons to identify and lesion the optimal areas for ablation in an incremental fashion (Sem-Jacobsen 1966; Nashold & Slaughter 1969).

By the end of the decade, however, this era of experimentation, and indeed the stereotactic specialty as a whole, almost came to an end. After the introduction of levodopa in 1968 neurologists were reluctant to refer Parkinson's patients to neurosurgeons: the reservoir of severely affected, otherwise untreatable patients willing to undergo ablative surgery was drastically reduced. Compared to surgical treatments, levodopa was inexpensive, safe (non-invasive), remarkably effective in reducing the severity of Parkinson's symptoms, and it quickly became the first-line treatment for diagnosed patients. Indeed, when it was first introduced it was believed to be a panacea for Parkinson's; a therapy that would control symptoms indefinitely without any major side-effects (Gildenberg 2000). Additionally, neurosurgeons were discouraged from treating psychiatric conditions by a public campaign that lumped their stereotactic procedures with the frontal lobotomy. A figurehead of the campaign, the psychiatrist Peter Breggin, told the US Senate Subcommittee on Health that psychosurgery has "no empirical or rational basis...", "attacks and mutilates brain tissue that has nothing demonstrably wrong with it" and that it can be used to "subject the individual to the control of others" (Breggin, 1972: 381). Using examples of surgically treated restless housewives and hyperactive children, he argued that psychosurgery was a political tool used to placate minorities. Breggin's criticisms were taken-up by US representative Cornelius Gallagher and a commission was established to further investigate his claims. Despite the commission's findings that psychosurgery appeared to be of great

benefit to individual patients the political climate led most neurosurgeons to abandon the field (Valenstein, 1997).

Thus, by the middle of the 1970s levodopa and a hostile political climate had brought about the near-demise of stereotactic neurosurgery. A few academic centres remained open in the US and Europe to provide relief to the small number of patients with chronic, untreatable pain, and those with movement disorders that would not respond to the new levodopa medications. The skills, knowledge and equipment that had been developed during the ‘era of experimentation’ were maintained in these few centres. As the next section will illustrate, it was within these centres that deep brain stimulation therapy would have its genesis. The particular material infrastructure (such as the stereotactic apparatus) and the knowledge-base of these centres, the exploratory ethic of the clinicians working within them, and as we will see, technological developments in cardiac pacemaking, led to the development of the first neurostimulators.

3.3.2 The genesis of the neurostimulator

During the period of ‘unrivalled experimentation’ neurosurgeons had noted the therapeutic effects of high frequency neurostimulation. Electro-stimulation was not a therapy on its own, however. The lack of sufficient technology is no doubt a reason for this: electrodes had to be externalized, protruding from the head in order to link with a power source which at the time were large, cumbersome and certainly not implantable. As Morlacchi and Nelson point out (2011), new medical therapies often arise from the transfer of technological artefacts from one sector into another. This was certainly the case with neurostimulation therapies. In the early 1960s the then fledgling medical device manufacturer Medtronic introduced the first, commercially available cardiac pacemaker. These small, mobile power sources quickly disseminated throughout the US fuelling the company’s rapid growth, and by 1975 Medtronic’s annual turnover was over USD 100 million. From this industry came the components and finance required to produce neurostimulation technologies: in effect, the development of the neurostimulator piggybacked on the success of the cardiac pacemaker.

The adaptability of cardiac pacemaker technology was first demonstrated by neurosurgeons attempting to treat chronic intractable pain in the late 1960s. Although medicines had become the first-line treatment for psychiatric disorders

and Parkinson's, drug-based therapies for various forms of chronic pain remained elusive. This small pocket of patients provided neurosurgeons with an opportunity to continue exploring the effects of neurostimulation and to trial neurostimulation as a therapy in its own right. The Wisconsin based Norman Shealy was the first neurosurgeon to adapt cardiac pacemaker technology into a therapy for chronic pain. Electrodes were implanted within the spinal cord of a group of patients and connected to an implanted Medtronic pacemaker modified to produce the higher frequency of stimulation required to modulate the perception of pain (Shealy, Mortimer, & Reswick, 1967: 490). At that time, standard, battery-powered pacemakers were unable to produce the necessary frequency of electrical pulses required to interfere with the conduction of pain. Shealy used a modified Medtronic "RF" (Radio Frequency) system where energy (in the form of radiowaves) is transferred through the skin to an implanted receiver. Shealy reported his 'promising' results to colleagues at a conference in 1969, many of whom were sufficiently convinced to offer the therapy at their own centres. (Shatin, et al. 1986). Similarly, a Californian team used pacemakers to stimulate areas deep within the brain. Hosobuchi and his team had been using stereotactic-guided ablative surgery to provide relief to patients with chronic pain. Deep brain stimulation was trialled on a few patients who failed to respond satisfactorily to ablative therapy: electrodes were stereotactically implanted within the thalamus and connected to a pacemaker (Hosobuchi et al. 1973). Hosobuchi reported that pain was sufficiently masked in three of his four original patients.

Soon there was sufficient interest among neurosurgeons treating chronic pain to encourage the medical device industry to develop a specific neurostimulator device. Medtronic was the first to do so in 1968, followed by Avery Laboratories in 1972 and then Cordis, the second largest producer of pacemakers behind Medtronic (Rossi, 2003: 10). As Shealy had illustrated, many pacemaker components such the power source, the circuit board, and the device casing could be adapted into neurostimulation therapies, and pacemaker producers were able to use their existing manufacturing skill set to produce many of the neurostimulator components (Stuart, 2012). Companies subsidized the development and production of these components with returns from the highly lucrative pacemaker market (Upton, 1986). Medtronic officially established a neurological division in 1975 and it was while marketing its

device for the treatment of pain that Medtronic trademarked the term “Deep Brain Stimulation” (Coffey, 2009).

During the 1970s these neurostimulators disseminated throughout specialist centres within the US and Europe and were incorporated into therapies for a range of conditions. These were conditions that had previously been shown by neurosurgeons undertaking ablative surgery to respond to electro-stimulation: various motor disorders, cerebral palsy, epilepsy, schizophrenia, and severe depression. Different areas of the nervous system were stimulated: the spinal cord, the cerebral cortex, and within those centres that had retained the ability to carry out stereotactic surgery, areas deep within the brain such as the thalamus. The well-known US neurosurgeon Irving Cooper, for instance, used the newly developed neurostimulators to stimulate the cerebellum and deep brain as treatments for cerebral palsy, epilepsy or dystonia in around 200 patients (Cooper and Upton, 1978, Cooper et al., 1980). Up to 200 patients were treated, the results of which were good and “worthy of immediate notice” (Rosenow et al., 2002). In Germany, Fritz Mundinger used Medtronic neurostimulators to stimulate areas within the thalamus to treat dystonia, arguing that the reversible nature of the treatment made it preferable to ablation (Mundinger, 1977). This statement was echoed by Orlando Andy of Mississippi who was using stimulation of areas within the thalamus to treat nine patients with Parkinson’s who had failed to respond to levodopa therapy (Andy, 1983). At Tulane University Robert Heath adopted Medtronic neurostimulators into his treatments for psychiatric disorders, particularly schizophrenia, reporting that some of these patients subsequently became symptom free (Heath 1977; Heath et al 1980). In Southampton UK during the late 1970s, Brice and McLellan were using DBS to treat a small number of patients with multiple sclerosis-associated intention tremor. They reported that some of their patients improved significantly: one patient initially totally disabled, was subsequently able to “feed herself, light her own cigarettes, fasten her own buttons, and control bed light and radio” (Brice and McLellan, 1980).

In a recent retrospective, Philip Gildenberg, a stereotactic neurosurgeon at the time, gives us some idea as to why neurosurgeons were receptive to neurostimulation technology. The introduction of levodopa for the treatment of Parkinson’s in 1967 had left a work void for functional neurosurgeons with training in stereotactic techniques. Neurostimulation provided an opportunity, for some

neurosurgeons at least, to utilize their skills and equipment and provide potentially effective surgical treatments for other conditions or for those few patients with Parkinson's who could not tolerate levodopa (Gildenberg, 2009: 14). The skills, knowledge and tools that had been developed during stereotactic surgery's earlier period of rapid growth could easily be transferred into deep brain stimulation therapies: the stereotactic apparatus in conjunction with imaging technologies were used to identify target areas and plan the surgical procedure necessary to implant permanent electrodes; intra-operative stimulation was often used to ensure that the correct target area had been located; and these target areas were often the same as those that, in the past, would have been ablated. Neurosurgeons, then, had the necessary skill set, and the technology provided them with a vehicle for intervening in complex neurological conditions in an era when drug-based therapies tended to dominate.

This dissemination was enabled by the flexibility of the technology. As Faulkner argues, the material qualities of a device interact in more or less flexible ways with social actors, impinging upon their possibilities for adoption and usage (2009: 18). The material qualities of neurostimulation technology, such as its small size, its biocompatibility and its ability to deliver precise electrical stimulation to a region decided upon by the clinician, permitted its adoption into a range of therapies. This is not to say that the diffusion of the device was unproblematic. Problems with components were not unusual and these were subject to incremental modifications: the electrodes used in deep brain stimulation could fray and turn on their axis (Siegfried & Shulman 1987); complications arose from lead implantation and the power source could fail (Shatin et al 1986). In the 1980s some of these difficulties were overcome. Lithium batteries enabled the production of a neurostimulator that could be implanted for several years while providing the necessary level of on-going stimulation. New neurostimulator leads were produced based on endocardial (pacemaker) leads, and a device was created that could be programmed via a wireless console programmer. Again, these incremental developments were the result of technology-transfer from the on-going financially lucrative improvements associated with the pacemaker (Shatin et al 1986).

Additionally, it is likely that the diffusion of the neurostimulator was linked to the success of a cardiac pacemaker in a broader sense. As Blume argues, the cardiac pacemaker gave 'the notion of an implantable device legitimacy and appeal'

(2010: 34). It enabled clinicians to significantly improve the lives of a large body of patients and was heralded as a major advancement in modern medicine. This encouraged wider acceptance of implantable devices among the public, and no doubt encouraged those working in neurostimulation to emulate the success of this pacemaker.

3.3.3 Medical device regulation

During this period clinicians reported that many of their patients were responding well to neurostimulation therapies. In 1978 Cooper stated there had been a clinical improvement in the majority of the 700 patients who had undergone cerebral stimulation for the treatment of either cerebral palsy or epilepsy (Cooper and Upton, 1978). Orlando Andy reported that the results of stimulating the thalamus at high frequencies in nine patients with motor disorders were “fair to excellent” (Blomstedt & Hariz, 2010: 431); and Heath, reporting on a study of 38 patients, argued that those with depression, those with “behavioural pathology consequent to epilepsy, and those with psychotic behaviour consequent to structural brain damage” responded well to neurostimulation of the cerebellum (Heath, et al 1980: 243).

Yet in this area prior to medical device regulation it was not exactly clear what constituted a ‘clinical improvement’ or a ‘fair to excellent’ outcome. In effect, the opinion of a clinician was sufficient to determine whether a medical therapy was effective, and thus whether or not the use of a medical device could be justified. This reflected the sentiment of the early 20th century when ‘efficacy’ was considered “a matter of opinion, not a fact” (Bodewitz et al., 1989). With the advent of medical device regulation, however, ‘efficacy’ was delineated as something that should be objectively verifiable, thus necessitating clinical assessment tools and outcome measures that would enable the quantification of a patient’s response to an intervention. Here we will see that there were few such tools for the conditions being treated with neurostimulation, and subsequently, neurostimulation therapies such as deep brain stimulation for chronic pain were not approved in the new regulatory climate.

In 1976 after seven years of political debate, the US Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, thus granting the FDA authority over all medical devices. This was in response to a spate

of device failures: between 1960 and 1970, medical devices were implicated in 10,000 injuries and over 700 deaths, and between 1972 and 1975, over 22,000 potentially defective pacemakers were recalled by manufacturers (Foote, 1978). The intention of the amendments was to provide a “reasonable assurance of safety and effectiveness for all devices” (Foote, 1978). With pharmaceutical regulation the gold-standard for determining efficacy became the double blind trial. With medical devices, which are often not amenable to double-blind trials, the FDA stated that efficacy would be determined “on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience” (Foote, 1978). Consequently, efficacy was rendered as something objectively verifiable: it would have to be demonstrable to an FDA appointed panel of experts that were not directly involved in the treatment in question.

In regard to neurostimulation technology used in deep brain stimulation and cerebral stimulation therapies, the FDA decided that clinical trials would be necessary before it could be marketed (Coffey and Lozano, 2006). Medtronic, Avery, and Neuromed, the three manufacturers of neurostimulation technology, were offered time to perform the necessary trials and produce the required documentation. All, however, eventually declined. The probable reason for this is provided by Adrian Upton, a UK-based neurologist. A major problem in the application of neurostimulation, he stated, was the lack of standardized, quantifiable measures for determining the effectiveness of the treatment (Upton, 1986). Pain, for instance, was especially difficult to measure. In a recent summary of neurostimulation treatments for pain, Coffey and Lozano refer to the:

paradox of pain – its simultaneous reality and subjectivity makes the assessment of pain relief therapies susceptible to observer- or patient-related influences...
Unintentional cues, learned responses, or knowledge that a treating physician... is conducting the assessment can affect how patients rate analgesic treatments
(Coffey and Lozano, 2006).

Irving Cooper’s neurostimulation therapies, including his deep brain stimulation therapies, were also problematic in this regard. Despite Cooper’s belief that they “yielded promising clinical results”, the lack of uniform objective evaluations to quantify and measure clinical improvement meant the “true benefit” could not “be elucidated” (Rosenow et al., 2002).

Thus, DBS and other neurostimulation treatments were not amenable to clinical trials because the conditions being treated were not quantifiable: there were no generally accepted clinical assessment tools that could be used to demonstrate clinical improvement. The clinical trials that were now needed to demonstrate efficacy and safety were also expensive, and Upton stated that the costs of further development would need to be offset by a large market (Upton and Lazorthes, 1987). Upton specifically referred to Parkinson's as a potential market for neurostimulators. The problem with Parkinson's, he claimed, was an over-reliance on medications and the promising findings of earlier neurostimulation treatments for movement disorders were therefore being overlooked (Upton, 1986).

3.3.4 The Unified Parkinson's Disease Rating Scale: generating immutable mobiles

By the mid-1980s neurostimulation was in a precarious position. On the one hand, there was the medical device industry with the manufacturing skill set necessary to produce the neurostimulator technology and there were neurosurgeons with the expertise required to incorporate the technology into working therapies. On the other hand, the new regulatory climate had effectively put a halt on the dissemination of many neurostimulation therapies and the market for the technology was restricted. In effect, medical device regulation established the FDA as what Latour (1987) refers to as centre of calculation. It was endowed with the responsibility of assessing efficacy and safety of therapeutic interventions, and as a result it became a gatekeeper, either preventing or permitting dissemination of new device-based therapies. A distance was created between the point of therapeutic intervention (the clinic or the research site), and the point at which efficacy and safety of those interventions are assessed (an FDA appointed panel of experts). Such distance was deemed necessary to reduce the influence of bias on the assessment of an intervention and thus provide a level of protection to patients and consumers. Yet, as Latour points out, for a centre of calculation to function this distance must be traversed; the two points must, somehow, be brought together. This can be achieved via the production of immutable mobiles: renderings of entities of interest that are capable of circulating between the two locations without losing their meaning in the process (Latour, 1987).

As this section will illustrate, clinical assessment tools are a means of generating immutable mobiles and creating an equivalency of meaning between the sites of intervention and the FDA, thus enabling the latter to act as a centre of calculation. In the mid-1980s such a tool was developed for one particular condition that was known to respond to neurostimulation: Parkinson's. This tool, along with several other developments, encouraged Medtronic to pursue regulatory approval for an application of their neurostimulation technology: deep brain stimulation therapy for Parkinson's.

In the mid-1980s at University Hospital in Grenoble, France, a team led by Alim-Louis Benabid was using ablative therapies to treat cases of Parkinson's, dystonia and a few psychiatric conditions that had failed to respond to drug-based therapies. The team was one of the specialist centres that had retained the stereotactic tools and skill-set developed during the subspecialty's period of growth. For each patient a stereotactic apparatus was used in conjunction with imaging technologies to identify the areas for ablation and to plan the surgical procedure. Additionally, intra-operative electro-stimulation was used to ensure the correct area had been located, and like others before him, Benabid noted that higher frequency stimulation could reduce some of the motor symptoms of Parkinson's. Benabid set about trialling chronic neurostimulation as a therapy in its own right. Importantly, Benabid and his team had been using neurostimulation to treat chronic pain and were familiar with the equipment and methods that would be required to provide chronic stimulation: "We had the method. We had the electrodes. We had the stimulating leads." (Benabid, in Talan, 2009: 41). From 1987 onwards Benabid used Medtronic equipment to trial deep brain stimulation of areas within the thalamus to treat tremor in patients with either Parkinson's or essential tremor, some of which showed complete relief (Benabid et al., 1987). While Benabid and his team were repeating what others had done a decade earlier, a particular conjunction of circumstances meant that Benabid's work was to have a far greater influence.

Firstly, Benabid's team coupled deep brain stimulation to Parkinson's at a time when clinicians were looking for a surgical alternative to levodopa-based therapies. Clinicians were becoming aware that while medications such as levodopa are initially effective in managing the symptoms of Parkinson's, they lose their effectiveness in the long run. By the mid-1980s a reservoir of severely affected Parkinson's patients with symptoms no longer adequately managed with

medications had emerged. Alternative therapies were needed, and neurosurgeons were beginning to revisit pre-levodopa-era stereotactic surgical procedures (Bergman et al., 1990, Laitinen et al., 1992).

Secondly, the accidental discovery of a neurotoxin led to the production of primate models of Parkinson's. The resulting studies enabled Benabid to consolidate particular areas deep within the brain as effective targets for DBS. In two separate incidents (1976 and 1983) recreational drug users inadvertently manufactured and ingested a compound that left them with severe Parkinson's disease-like symptoms. The substance was identified as MPTP (1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine), and an autopsy later revealed that it has destroyed the dopamine producing cells of the substantia nigra, the same area that degenerates in Parkinson's (Porras et al., 2012). Subsequently, MPTP was used to create the first non-human primate models of Parkinson's (Chiueh et al., 1984; Langstorm et al., 1984), enabling new avenues of research into the underlying pathology; research that would have been unethical on afflicted human subjects. One such avenue of research produced a model of a pathological chain of neural activity in which the sub-thalamic nucleus (STN) and the globus pallidus (GPi) are overactive (DeLong, 1990). By surgically ablating these areas researchers at Johns Hopkins University noted that they could reduce the induced-Parkinson's symptoms in primates (Bergman, 1990). The STN had first been identified as an effective target in late 1960s (Nashold & Slaughter 1969), but the resulting model now provided a scientific rationale, prompting Benabid to direct his attention to the area as a target for deep brain stimulation.

And thirdly, Benabid and his team coupled deep brain stimulation treatments to Parkinson's at a time when the disease could be quantified. In 1987, a consortium of movement specialists established the Movement Disorder Society and produced the Unified Parkinson's Disease Rating Scale (UPDRS). Their intention was to create a comprehensive and flexible system that would replace the numerous and idiosyncratic scales being used at various Parkinson's research sites (Fahn and Elton, 1987). The variability of the scales in use at the time made comparative assessments difficult: the unified system would standardize clinical assessment across centres (Goetz et al., 2003). The UPDRS has five parts, each using a scale system to determine the severity of particular Parkinson's symptoms, including mentation, behavior and mood, speech and swallowing, facial expression,

tremor at rest, rigidity and finger tapping. For each symptom a number from 0-4 is used to assess severity (0 being normal or unaffected, and 4 being the most severe), and an overall score for each of the five parts of the UPDRS can be assigned to the patient. The severity of a patient's Parkinson's, therefore, can be represented with a series of numbers. In order to ensure that these numbers are equivalent across contexts, the Movement Disorder Society produced a teaching video-tape, specifically designed to aid new researchers and those conducting multicentre trials (Goetz et al., 1995). The resulting equivalence would enable patients to be compared before and during treatment, across research centres, and would thus permit the calculations required to determine efficacy.

Given there was now a considerable demand for surgical treatments and a tool had become available to quantify Parkinson's, it is not surprising that Medtronic enthusiastically aligned themselves with the Grenoble-based French team. In the early 1990s Benabid presented his results to Medtronic. Engineers at Medtronic had recently conducted studies to assess the use of their stimulation technology to manage pain, but these were abandoned due to the lack of any definitive results (The findings were eventually published in Coffey 2001). Benabid's work illustrated that the same technology could be used to treat Parkinson's and that the results could be demonstrated to regulators: "Changes in movement are pretty obvious... pain is something that is not so obvious" (Medtronic engineer, quoted in Talan, 2009). Subsequently, Benabid was employed by Medtronic to design international (Europe and US), multi-centre clinical trials assessing DBS for the treatment of Parkinson's. The STN or the GPi were to be tested as target areas, both of which were supported by the newly developed model of deep brain function. The trials were funded by Medtronic and the UPDRS was used in all sites. Over the next few years 113 people with Parkinson's and 83 with essential tremor were involved in the trials (Talan, 2009).

3.3.5 Clinical trials & FDA approval

In a laboratory trial, complexity is elided by having a few metabolic parameters 'stand in' for health; parameters that can be measured, counted and used in the construction of factual statements (Latour 1986, Mol 2008.). Similarly, this purification is required in clinical trials involving bodies. The UPDRS (like outcome measures in general) enabled the purification and inscription required to 'construct'

factual statements regarding the efficacy of deep brain stimulation. Because the UPDRS was adopted in all of Medtronic's DBS clinical trials, all patients were subjected to the same standardized regimes of examination, quantification and comparison. Each patient, regardless of their unique personal histories or social context, was rendered as a set of comparable numbers representing the severity of their symptoms.

This quantification and the elision of messy and cumbersome personal detail, therefore, had three important functions. Firstly, it enables calculation: it permits each participant to become a nexus linking the deep brain stimulation technology to a clearly delineated region of the brain in a manner that could be clearly measured: the effect of deep brain stimulation on particular regions of the brain the STN or the GPi could be determined by noting and comparing the numerical changes associated with each body. Secondly, these numerical renderings of the impaired body are mobile: they can be collected, pooled together, charted, graphed, compared and computed, and these resulting inscriptions can then be circulated as 'proof' or 'evidence', with much more fluidity than fleshy bodies. These mobile numerical inscriptions are also immutable: they hold the same meaning across particular centres, enabling the establishment of a common language. Thirdly, as Porter has made quite clear, by eliding personal detail, such renderings are imbued with an authority resulting from their supposed objectivity (Porter, 1994). The UPDRS, therefore, was an essential part of an apparatus for producing facts, in an era when 'efficacy' is institutionally deemed as something objectively verifiable. In effect, through a process of purification and inscription, the UPDRS created the immutable mobiles that bridged the distance between the point of treatment (the clinic) and the point of assessment (the FDA) that had been created with the advent of medical device regulation.

In March 1997 UPDRS-derived data were presented to the FDA's Neurological Devices Panel Advisory Committee by consultants managing the trials on behalf of Medtronic. The intention was to gain approval for the "Medtronic 3382 DBS lead and the Medtronic ITREL stimulation system for the suppression of tremor due to essential tremor or Parkinson's; unilateral or bilateral."(1997). Slides of the results were shown to the panel and explained by a consultant who drew attention to both individual improvements in UPDRS and statistical analyses of overall UPDRS data. He stated that there was a statistically significant reduction in

tremor and global disability and that the efficacy of the treatment appeared to be greater than that of available medications. There was more to the panel hearing than the presentation of numerical data, however. A portion of the hearing was reserved for members of the public to voice their opinion. Four individuals spoke to the panel, all in support of the therapy. The testimony of these four speakers highlighted the day-to-day difficulties of living with a movement disorder, and the hope and expectation that had been invested in the deep brain stimulation therapy. Two were representing patient advocacy groups and two were being successfully treated with DBS therapy as part of the clinical trial (three of the four had also been brought to the hearing by Medtronic).

At the end of the hearing members of the panel expressed their initial impressions. All members believed the efficacy of DBS had been demonstrated. Some, however, said they were not convinced of its safety: although no major safety issues had been identified, potential adverse effects could not be ruled out (1997). As one member put it: “unless the side effect slaps you in the face or is quite profound, you may not find subtle effects like the neurological changes” (Pre-market Notification, 1997). As a result of the panel’s findings the FDA formally approved the use of unilateral deep brain stimulation for the treatment of essential tremor and Parkinson’s. For the latter, however, it could only be used in patients with severe tremor, due to uncertainty regarding possible adverse reactions. Medtronic continued to sponsor trials exploring the longer-term effects of stimulation and in 2002, confident that sufficient evidence of safety had been demonstrated, the FDA approved DBS for more general cases of Parkinson’s. In 1998 the same clinical trials were used by Medtronic to gain the CE mark for their technology, thus permitting the use of DBS to treat Parkinson’s within the European Union.

3.4 Discussion: the shaping of DBS

Within ten years of being approved for the market within the US over 40,000 individuals had been treated with DBS for Parkinson’s or essential tremor (Talan, 2009) and DBS had gone from being a marginal therapy to an “effective”, “standard and accepted treatment for Parkinson’s disease” (Montgomery & Gale, 2008). Currently, Parkinson’s patients can undergo deep brain stimulation therapy at specialist centres in North America, Australia, the UK and much of Europe. In their 2010 annual report, Medtronic highlighted a 9% increase in net revenues from the

previous year in their neuromodulation division (from USD 1.4 billion to 1.5 billion), driven largely by a substantial increase in demand for their DBS technology in both Europe and the US (Medtronic 2010).

DBS for Parkinson's, then, has proven highly lucrative for Medtronic. Medtronic is attempting to replicate some of this success by developing DBS as a treatment of other conditions. While Parkinson's is by far the most common DBS indication, a small number of patients have now undergone DBS for the treatment of dystonia, epilepsy and obsessive-compulsive disorder and depression. Again, the flexibility of the technology has enabled it to be easily adapted to other treatments: as one financial analyst recently put it, "deep brain stimulation provides stimulating a market... because with a single platform, companies can address several diseases with large populations" (Stuart, 2012). In 2003 Medtronic DBS technology was fully approved for the treatment of dystonia within the European Union and partially approved within the US. Like Parkinson's, many of the symptoms of severe dystonia are clearly visible: pathogenic neural activity causes limbs to become rigid and bodies to become painfully contorted. The rate of severe dystonia is significantly lower than that of severe Parkinson's, and so the resulting trials using Medtronic equipment were smaller in scale. As with Parkinson's, standardized clinical assessment tools have been co-opted in order to generate the immutable mobiles necessary to demonstrate efficacy to regulatory agencies. The Burke-Fahn-Marsden Dystonia Rating Scale (BFM), like the UPDRS, uses a series of numbers to indicate the severity of symptoms (Burke et al., 1985). Medtronic sponsored trials assessing DBS for epilepsy and obsessive-compulsive disorder have also adopted clinical assessment tools that produce computable, mobile, impersonal renderings of the patient. Thus, the medical device industry has been, and remains, a major driver of DBS development and stabilization. Indeed, we could say that commercial industry and motivation for profit have been a major socio-political factor in the emergence of deep brain stimulation therapies. (We will return to this point in the final chapter of this thesis).

Professional interests have also driven the innovation process. With the 'rebirth' of DBS neurosurgeons with training in stereotactic techniques are once again gaining access to a pool of patients with conditions inadequately managed with medications. In 1990, stereotactic surgery "was the realm of a relatively small group of subspecialists" (Gildenberg, 2000: 309). By the end of the 1990s "more

stereotactic surgery was being practiced by more neurosurgeons than ever before, and stereotactic techniques made inroads to become needed skills for every practicing neurosurgeon” (Gildenberg, 2000: 309). Importantly, diffusion has been driven by an increasing realization of the limitations of drug-based therapies. As Ackerman points out, neurologists are far more inclined to recommend surgical therapies to patients in the present day. Indeed, in the majority of present day centres offering deep brain stimulation centres, patients are managed by teams that include both a neurosurgeon and a neurologist (Ackerman, 2006: 111).

As this historical overview has shown, the development and stabilization of deep brain stimulation therapies was contingent upon the co-development and diffusion of standardized methods of rendering the affected body. By eliding complexity and foregrounding specific phenomena as ‘significant’, clinical assessment tool, and the immutable mobiles they produce, can have a commercial utility. This particular case study suggests that this utility has facilitated their diffusion. The UPDRS, for example, has been adopted throughout Europe and North America and is now considered the gold-standard reference scale for Parkinson’s. Between 1994 and 2003, out of all articles using a Parkinson’s rating scale well over two-thirds were using the UPDRS, and the scale was used in most clinical trials of both drug and surgical treatments for Parkinson’s. Consequently, US and European regulatory agencies have come to rely on the UPDRS (Goetz, et al., 2003: 740). The diffusion of such tools is part of what several authors have referred to as the rationalization of healthcare of which the evidence-based medicine (EBM) movement is a significant component (Porter, 1995; Hunter, 2003; Wehrens and Bal, 2012). Indeed, EBM and rationalization can be seen as another major socio-political tendency that has, via the redefinition of ‘efficacy’ that occurred with the advent of medical device regulation, influenced the innovation pathway of DBS. Rationalization has involved a move towards pre-defined processes aimed at improving efficiency, an emphasis on quantitative over qualitative characteristics, and creating uniformity over multiple sites (Ritzer; 1996). Proponents of EBM are wary of a clinician’s experience alone and argue that clinical practice should be guided by trials that have objectively determined the effects of an intervention. Timmermans and Berg (2003) state that this process of rationalization in healthcare began in the 1980s, driven by attempts to reduce unnecessary interventions and limit healthcare costs, and facilitated by the emergence of

information technologies. This case study suggests that commercial and professional interests have also assisted this process. The emergence of clinical assessment tools and outcome measures, facilitated by companies in alliance with particular health professionals, is an important part of this rationalization process: they enable ‘efficacy’ to be verified by a third party; no longer is it a clinician’s ‘matter of opinion’ (Bodewitz et al., 1989).

This historical overview has also shown that the necessity of clinical assessment tools in the era of regulation can shunt the development and application of a medical device towards a particular therapeutic intervention. In effect, medical device regulation not only restricts which devices can be marketed, it also limits which illness can be treated with devices. This was the case with the use of neurostimulation to treat chronic pain. Standardized clinical assessment tools did not exist and an evidence-base for the therapy could be produced. Consequently, Medtronic directed its resources towards treatments for other conditions. There is therefore a financial incentive for both the medical device industry and pharmaceutical industry to open up new avenues for innovation by promoting the development of standardized clinical assessment tools. In 2002 a consortium of pain specialists held the first meeting as part of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT). The aim of the initiative was to develop “consensus reviews and recommendations for improving the design, execution, and interpretation of clinical trials of treatments for pain” (Dworkin, 2005). Importantly the initiative has sought to develop a standardized clinical assessment tool, as the current “variability in outcome measures across clinical trials hinders evaluations of the efficacy and effectiveness of treatments” (Dworkin et al., 2005). Johnson & Johnson, Pfizer, Bristol-Myers Squibb and Boehringer Ingelheim sponsored the initiative.

3.5 Implications for the PMDS

In this chapter we have explored some of the factors that have shaped the development and dissemination of DBS technology, thus addressing research question one. In doing so, we have also identified several socio-political factors that have influenced the innovation process. One of these is the influence of commercial interests which has led to alliances between commercial industry and entrepreneurial clinicians. The PMDS team, which was established in 2007 (five years after the

approval of DBS for dystonia) also liaises closely with Medtronic. The team uses Medtronic DBS technology and regularly communicates with Medtronic representatives: Medtronic requests feedback on clinical outcomes and offers advice and support on any technical issues that arise.

The PMDS team is also characteristic of many centres offering DBS therapies in that it involves a close alliance between neurology and neurosurgery. If DBS were not available, many of the PMDS patients would not be considered for a neurosurgical treatment. Indeed the DBS technology has enabled stereotactic neurosurgeons to participate in providing therapeutic relief, via the PMDS, to a group of otherwise untreatable patients. In a sense, then, the PMDS is representative of the new alliances that are forming between neurologists and neurosurgeons as clinicians explore alternatives to medicine-based therapies for neurological disorders.

The second major socio-political factor that has influenced the innovation of DBS is the emergence of EBM and rationalization. As we will see in the following chapters (particularly chapter 7), this has major implications for the PMDS team as they work to develop a DBS service for children and young people with dystonia. They are inclined to demonstrate the effect of DBS using standardized, clinical assessment tools. Given that Medtronic used the Burke-Fahn-Marsden-Dystonia Rating Scale (BFM) when obtaining regulatory approval for DBS as a treatment for dystonia, it is perhaps not surprising that this is one of the tools used by the PMDS. Indeed, the BFM has become the widely accepted means of measuring and comparing the severity of dystonia before and after implantation of the DBS system. As we will see in chapter 7, this creates challenges for the team: the scale was developed specifically for primary dystonia, and team members believe that it fails to capture meaningful improvements in patients with secondary dystonia.

In this chapter we have explored the conjunction of circumstances that enable teams like the PMDS team to exist. In the remaining chapters, we will ‘zoom-in’ on the activities of the PMDS team members as they utilize the DBS technology within an actual clinical service.

4 Coordinating multidisciplinary team work

4.1 Introduction: The challenge of multidisciplinary team work

I began my fieldwork by observing the team's routine weekly meetings and their less-frequent academic meetings. During the very first observation several features of the meeting caught my attention. At that time they struck me as peculiar, but I soon realised that they were characteristic of most of the PMDS team meetings. The first of these was the way in which members of the team referred to, and spoke about, their patients. While there was some talk about MRI images, brains, the basal ganglia, electrodes and stimulation parameters, much more time was devoted to talking about a child's progress at school, their relationship with their siblings and parents, their mood, and their ability to access computers, iPads or assistive technologies. Interestingly, such considerations had a bearing on the decisions that were made during the team meeting; they were certainly not immaterial to clinical decision making. The patients who were being discussed, then, were not the impersonal biomedical entities that have been the subject of so much critical attention from social scientists. Given the various professional backgrounds of those involved in the team, I should not have found this surprising: proponents of multidisciplinary (or 'interprofessionalism') in healthcare have argued that it leads to more 'comprehensive', 'patient-centred' approach.

This brings me to the second feature of the meetings that struck me as peculiar: the seemingly significant proportion of meeting-time that was devoted to discussing what could be called administrative issues. Much of the talk pertained to aligning the weekly schedules of various team members, chiding team members for failing to complete and circulate reports, planning how to secure necessary resources and clinical working space from the hospital, and bemoaning the length of the meeting itself (which was seldom completed within the allocated one-hour slot). My understanding of these discussions is that they reflect the difficulty of coordinating teamwork; a task which is no doubt complicated by the multidisciplinary nature of the team, but is essential, proponents argue, if a 'comprehensive', 'patient centred' approach to healthcare is to be achieved.

So, from very early on during my observations I became aware that multidisciplinary teamwork is not easy, and that certain strategies are used within the PMDS to coordinate the activities of various team members. The product of these

coordinating activities is a particular rendering of the patient: a patient who is understood as more than just a biomedical entity - at least during team meeting discussions. In this chapter, I will flesh out this relationship between the techniques for managing and coordinating multidisciplinary teamwork, collaboration, and a specific way of 'enacting' the patient. Before I do this however, it is necessary to provide some background on multidisciplinary service provision in healthcare more generally.

4.1.1 *Multidisciplinarity in health service provision*

For the last two decades various health professionals and policy makers have actively promoted multidisciplinary team-based service provision within health care. Advocates have argued that multidisciplinary (or 'interprofessional') teams are a means to ensure that safe, efficient and patient-centred outcomes can be accomplished (Department of Health 2000; Kennedy 2001). Teams that include individuals from a range of professional backgrounds, it is argued, can tap into a range of disciplinary perspectives and are more likely to provide a comprehensive assessment of a patient's needs, and are thus better suited to help the patient decide upon the most appropriate course of action. As Fins and colleagues argue (2010), a pro-teamwork discourse is a defining feature of healthcare reform in the UK. This is perhaps best illustrated by the Department of Health's 2008 'next stage review': *A High Quality Workforce*, which states that achieving the NHS's goal of delivering "high quality care for patients and the public... requires an effective team of professionals across clinical, managerial and supporting roles" (Department of Health 2008: 8). Indeed, this pro-multidisciplinarity movement can be seen as an emerging socio-political trend in healthcare, a trend that has had a real influence on the provision of social services.

The trend has become encoded in legislation. In amongst this rhetoric are several policy initiatives which have prompted greater levels of interprofessional collaboration. Many of these pertain to the provision of primary, community-based care for those with psychiatric illnesses, chronic illness, people with disabilities, and the elderly (D'Amour et al. 2005). The 1990 NHS and Community Care Act, for example, stipulated that psychiatric nurses were required to assess a patient's needs for social care, leading to collaborations with psychologists, counsellors and occupational therapists (Leathard 2003: 14). Similarly, the Health Care Act 1999

created ‘pooled budgets’ for health and social services, enabling local authorities and health authorities to merge services. This enabled the formation of ‘rapid response teams’ that could provide emergency care for people at home, and ‘integrated home care teams’ to help people live more independently, both of which might consist of nurses, care workers, social workers, therapists and GP’s. Such policy initiatives created an environment where it was common for occupational therapists, for example, to liaise with social workers, physiotherapists, and doctors. Child Development Teams (CDT) are a good example of this form of collaboration. There are currently over 300 Child Development Teams in the UK, one for each district. The intention of these teams is to assess, diagnose and help manage children with developmental delays and disabilities in a community setting. Typically, these teams involve occupational therapists, physiotherapists, a paediatrician, a speech therapist, and a social worker, and most teams also have access to a child psychiatrist (McConachie et al 1999).

Generally teamwork within hospital settings has tended to involve a less diverse array of professionals. (Hospital medicine, as May and colleagues (2006) point out, has tended to be less interested in the ‘comprehensive’ approach to dealing with illness). Surgical teams are commonplace, and are orientated towards supporting the actions of the lead-surgeon. Critical care is also provided by multidisciplinary teams, generally made up of nurses and doctors with various clinical specialisms. And since the 1990s, multidisciplinary teams, also made up of doctors and nurses with various specialisms, have emerged as the predominate method of delivering oncology services (Department of Health 2010).

Various authors have highlighted the difficulties of establishing and working within interprofessional healthcare teams. As early as 1992 Hardy and colleagues identified five categories of barriers to joint working. These included: *structural* and *procedural* issues, such as differences in planning procedures and budgetary cycles that may prevent, for example, effective collaboration between health and social services; *financial factors* such as the cost of establishing and maintaining the appropriate administration and communication infrastructure (it was the structural, procedural and financial barriers to health and social services collaboration that the Health Care Act 1999 sought to remove); *status and legitimacy* issues that can exist between the different authorities responsible for providing services (such as NHS and appointed local authorities); and *professional issues*, such as the difficulty in

aligning diverse professional perspectives, expertise and skills, and the problems associated with professional self-interest.

This last of these, 'professional issues', has received considerable attention. Pietroni noted that the language and values that characterise disciplines can hinder the ability of inter-professional communication (Pietroni 1992). In effect, there can be a degree of incommensurability between different professions, each of which can be said to represent a distinct community characterised by particular expertise, language and tools (Fournier 2000). Other authors have noted that traditional hierarchies of professional authority can also impede the intended benefits of teamwork from being achieved. This has been noted particularly in hospital teams. In multidisciplinary critical care teams, for instance, doctors tend to have a far greater influence on clinical decision-making than the nurses (Coombs 2003; Coombs and Ersser 2004). During their ethnographic studies of several clinical sites, Coombs and Ersser (2004) noted that a patient's course of action was generally decided upon by doctors based on their biomedical understanding of the body. Nurses, who had often acquired a very detailed knowledge about the patient's family and the patient 'as a person' had very little input. This, Coombs and Ersser argues, constituted a 'medical-hegemony' in clinical decision-making (2004: 245).

There are, then, considerable challenges to multidisciplinary team-based health service provision. Such teams are an intersection of professional worlds, each characterised by distinct tools, understandings and practices. According to current policy discourse (or the current 'socio-political trend') this diversity is necessary for effective service provision, but in actual clinical practice, this diversity threatens to undermine the ability of such teams to function effectively. The existence of multidisciplinary teams, then, is dependent upon strategies that both preserve diversity and coordinate diverse activities towards the achievement of the aims of the team as a whole. In what follows, I will explore some of the strategies that bind the various members of the PMDS team together and coordinate their diverse activities towards the provision of a DBS service. Specifically I will explore several key 'binding' elements: the built environment of the hospital which was intentionally designed to foster multidisciplinary activities; the creation and circulation of a schedule which coordinates the activities of team members; and the weekly team meetings, which provide a forum for prompting individuals to align with team strategy and a structured space for multidisciplinary decision-making.

First, however, I will explore why the PMDS team was established as a multidisciplinary team in the first place. The socio-political trend towards multidisciplinary service provision is, in paediatric healthcare, underpinned by a particular model of ‘normal’ childhood development. The PMDS structure, along with the built environment of the hospital and the current NHS tariff structure all reflect a particular understanding of ‘normal’ childhood development and can be seen as manifestations of this socio-political trend.

4.2 The clinical justification for a multidisciplinary PMDS

The composition of the PMDS team reflects a particular understanding of motor system development. According to this understanding the new born child has a motor system that is largely unusable but semi-pluripotent. Through constant sensing of and interaction with the material environment, a child’s motor system becomes highly specialised and adapted, providing the child with a capacity to move their body and negotiate space (“fine” & “gross motor function”). Importantly, this involves and stimulates cognitive development: it involves, for example, the development of spatial awareness and the ability to anticipate the consequence of particular bodily actions. Generally a child’s progress is indicated by well-known developmental milestones: crawling, sitting upright, standing, learning to walk, and so on. If development is unimpeded the child will learn how to use their body and obtain the necessary cognitive skills to conduct a vast range of culturally mediated and meaningful activities: riding a bicycle, using a keyboard, brushing teeth (“occupational” tasks). Dystonia, like other childhood physical disabilities, is perceived to be problematic because it inhibits the child’s ability to engage in the sort of social and physical interactions and educational opportunities that are considered necessary for healthy development. In effect, it ‘locks’ the body, rendering it insensitive to the physical environment and unresponsive to the child’s will. Elements of the child’s motor system will fail to become honed and adapted, and this will consequently stunt some aspects of cognitive development. DBS promises to unlock the body and enables a child (supported by therapists) to engage in the interactions that are necessary for healthy development and meaningful living. As the Clinical Research Fellow states:

The way I see it is that the DBS unlocks dystonia so the therapists can get in and give you the functional recovery... it allows you to get some more intensive therapy. (Clinical research fellow, interview).

Accordingly, the PMDS was deliberately composed by Dr Martin to include a set of professionals with the skill-sets to identify how dystonia may be hindering various aspects of development, and how such hindrances might best be managed: a physiotherapist with the ability to examine the impact of dystonia on fine and gross motor function; an occupational therapist to examine the impact upon the child's ability to conduct "occupational" tasks; a psychologist to assess cognitive skills; and a speech and language therapist to examine talk and verbal communication, swallowing and feeding [interview].

Clinical exigencies dictated which other professions would be included in the PMDS. Neurologists were included within the team due to their knowledge of brain structures and medications: the former is drawn-upon to identify the DBS target and plan the implantation procedure, and the latter is necessary to advice on patients' medication regimes.

This understanding of childhood development and the corresponding belief that a multidisciplinary approach is the appropriate method of service provision for children with disabilities is prevalent within the UK. It has had a considerable impact on child health and social welfare policy which consequently have facilitated the establishment of the PMDS as a multidisciplinary team in several ways. Firstly, as stated above, multidisciplinary Childhood Development Teams are the common means of delivering health services to children with severe disabilities in community settings throughout the UK. Within these teams it has become commonplace for occupational therapists, physiotherapists, speech and language therapists and doctors to work together with clients (McConachie et al 1999). The PMDS physiotherapists and the occupational therapists had worked in such settings prior to joining the PMDS team, and were familiar each other's professions. Indeed, in this respect, the PMDS mimics a model of service provision that has been in existence for several decades, albeit in community setting.

Second, current NHS commissioning policy also reflects the notion that multidisciplinary is the preferable mode of service provision for children. Tariffs for an intervention are generally higher for a child than for an adult. For example, the base tariff for adult's first attendance to a neurology outpatient consultation is

£225; for a child, the same service has a tariff of £400. And, a hospital that delivers a specialist service intervention for a child will receive a 50% 'top-up' on the adult tariff (2012-13 Tariff Information Spreadsheet). This, according to the ex-Clinical Director of Children's Services, is based on the recognition that a child may need the support of a greater range of professionals (Interview). This commissioning policy has, then, reduced some of the financial hindrances to multidisciplinary service in paediatric service provision. It has enabled the PMDS to become a self-sufficient multidisciplinary service, and it has enabled them to employ their own administrator. (As we will see further on in this chapter, the administrator plays an important role in coordinating and ordering the activities of the team).

Third, this ideal of multidisciplinary paediatric service provision has also influenced the design and construction of clinical spaces. Specific hospitals used as the work place of the PMDS have been built in order to encourage multidisciplinary activities. In the following section, we will explore how the built environment of the PMDS team has been designed to encourage multidisciplinary, and we will explore how it actually influences their activities.

4.3 The children's hospital: materialised multidisciplinary

Various authors have explored the relationship between medical knowledge, hospital design, and biomedical practice (see Prior 1988, Keating and Cambrosio 2003, Adams, 2008). The gist of the matter is captured by Prior (1988). He argues that the spaces that constitute the built environment of a hospital should be seen as a social product: the physical form of a hospital, such as the layout of the beds and the location of amenities, embody particular understandings about the patient and disease (along with engineering considerations, aesthetics etc.). And importantly, Prior argues, such spaces are not merely an inert backdrop to human interaction. Rather, their symbolic and material dimensions guide, restrict and facilitate particular human interactions, and thus encourage particular forms of biomedical practice. Drawing on the work of Foucault (1978), Prior argues that hospital architecture therefore contributes to the production of particular forms of clinical work.

Using Prior's conceptualisation we can draw an interesting link between the architecture of the children's hospital where the PMDS is based and the multidisciplinary activities of the PMDS team. The design of the recently built

hospital reflects the belief that multidisciplinary service provision results in better health-outcomes for patients and consequently, the built environment of the hospital itself encourages (but does not cause) teamwork and multidisciplinary. Here, I will illustrate these points with extracts from interviews with several participants, one of whom was the Clinical Director of Children's Services and participated in the design of the hospital. Three aspects of the hospital will be explored: the open-plan office space, the ward design, and the greater hospital itself.

The office space

One aspect of the hospital that was specifically designed to encourage a team-based approach is the office space. The office space of 150 clinical and administrative staff are located on the same floor. Along one side are seven or eight enclosed offices, while the remaining space is open-plan. As the Clinical Director explains:

We were keen to try and bring teams together, because people had come from little boxy offices, all over the place, and often very isolated. What we did was to [have] areas for teams. So there's a neurology bay, a cardiology bay, a nephrology bay and so on. (Clinical Director, Interview)

When teams were moved into the office area they were allocated, they could then decide how they wanted to use it:

What some specialties did was put the secretarial staff, who are in their offices all day, in the closed offices, so they would have a bit more peace and quiet and get on with their audio typing and so on. Clinicians, who were coming and going all the time, were put in the open plan offices. Other specialties did it the other way round. They put the secretaries outside and the consultants took the closed offices. My own view is that it worked best when the clinical teams were in the open plan area, because they saw each other more, they could talk to each other more, they could provide support. (Clinical Director, Interview).

All members of the PMDS team including the administrator occupy roughly the same area of open plan office (figure 4.1, page 100). This is largely at the behest of the team leader, Dr Martin (Dr M), as illustrated by the following team meeting extract. Here team members are discussing relocation from one end of the office to the other:

Dr M: Can we begin by talking about the move? I really don't want us to be scattered around the place. We need to know where we are going.

Nurse: We need one of us to push [an administrator] for a common space

Sitting together enables team members to easily consult with one another about cases, and according to one member, it also helped to facilitate a positive social atmosphere:

It really does encourage people talking to each other and because you're more visible, it encourages ease of access. It breaks down the barriers of, 'Oh I've got to go to and knock on someone's door.' I think it does pull the team together... Socially it's lovely because we all get to chat with each other. It's not quite as productive as it could be, for that reason there. (Clinical research fellow, Interview)

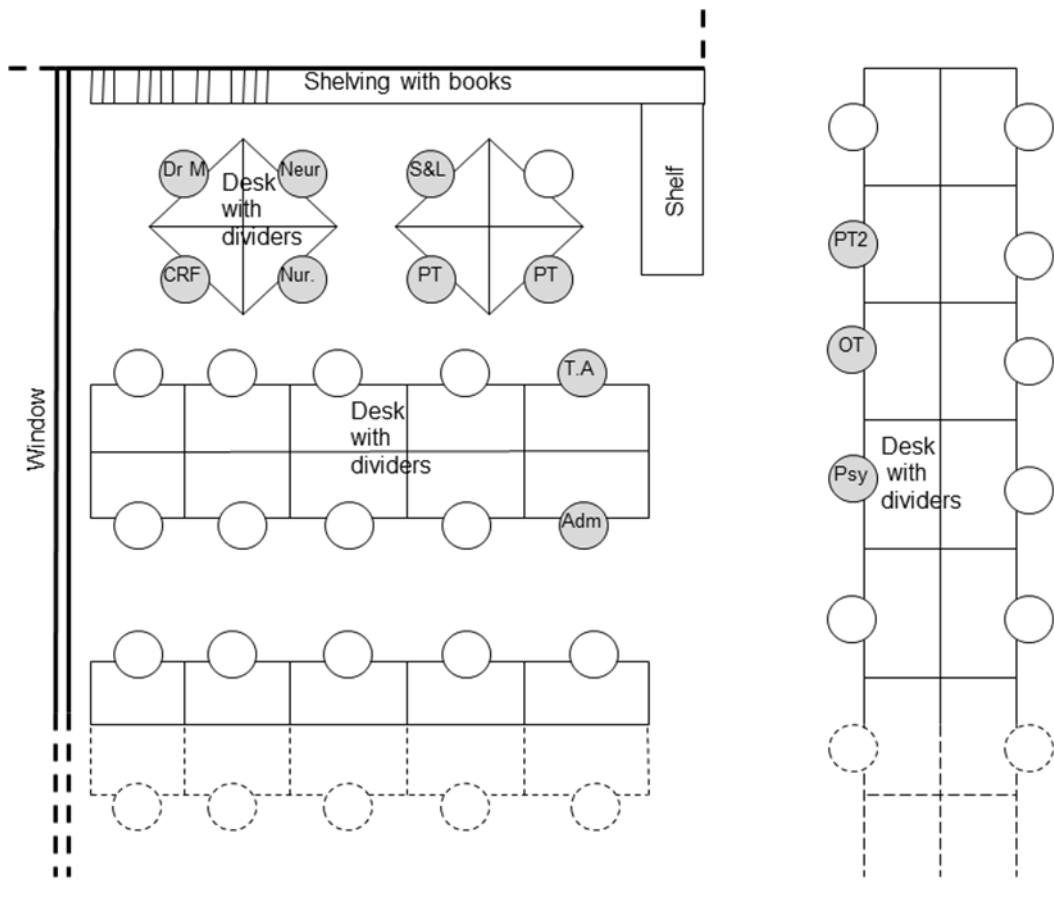
Indeed, one member of the team stated that she would prefer not to sit with the others as it resulted in constant interruption.

Importantly, sitting together in an open-plan space gives team members an opportunity to constantly check and coordinate their schedules. The administrator who, as I will illustrate further on, is responsible for producing a weekly team schedule, felt that it was particularly helpful for her work. Here she recounts a previous seating arrangement where team members were more scattered:

Some of us were in every single lobby scattered around. I think we work - I certainly work - a lot more efficiently [when] I can see all of them. If I had a quick question or someone's on the phone and I've got a quick query - I would have to [say], 'Oh let me write that down and when I can find that person then I'll call you back.' It's a lot easier if I just access my team, have them sitting around me. (Administrator, Interview).

Thus, we can see that one aspect of hospital's design that was intended to encourage and support a team-work based approach has been successful, at least for the PMDS team.

Figure 4.1: Open-plan office layout with common seating arrangement



Hospital wards

The wards in the hospital were also intentionally designed to facilitate multidisciplinary and a team-based approach to service provision. During the design of the hospital focus groups consisting of clinicians from a range of professions (nursing, physiotherapy, occupational therapy) were consulted on the ward layout (Clinical Director, Interview).

As a result the wards were designed to be flexible spaces where a range of varied services could be brought to the bedside of the child, rather than the child having to be transported around different departments of the hospital.

So that's thinking along a multidisciplinary route, you're acknowledging that the child actually may need to be seen by a number of different clinicians... And the way the building is designed, the services come to the child. Any bed should be able to support any type of service... wherever possible, the services should be taken to the child rather than the other way round (Clinical Director, interview)

As the Clinical Director states, creating this ‘child-centred’, flexible space require investing in a particular technical infrastructure.

So we invested a lot of money in portable equipment, portable ultrasound screens, portable x-rays and so on.... A German manufacturer that could provide these pendants where the power sockets are on columns that come down out of the ceiling, so that you can put the bed in the middle of the space and people can actually look after the child round all four sides of the bed (Clinical Director, Interview).

Flexibility, then, is enabled by a configuration of various technical and material elements. The tools of particular professions must be sufficiently mobile to move from one bed to another, and the ward itself must provide sufficient space for a team of clinicians to access the bed. Obviously, other medical and social considerations also influenced the design of the hospital. Limiting cross-infection and promoting interactions between children were two concerns that were explicitly mentioned by the clinical director:

And there are tensions pulling in both directions. You need to have [beds] sufficiently far apart that you minimise the risk of cross infection. But if they’re too far apart, actually the children may as well be in their own bays, because they can’t talk to the child next door.

After the DBS system has been surgically implanted a patient will spend seven days in the neurology ward receiving a course of antibiotics, but overall PMDS patients do not spend a great deal of time on the ward. Patients with DBS hardware-related infections and patients with status dystonicus will also be brought into the ward until their condition is under control. These patients require various medications and are managed predominantly by the ‘medical group’ within the PMDS team (the neurologists and nurse). Therapists will also individually visit these patients, perhaps to provide advice to family members and ward staff on how to physically handle the patient, or to conduct a quick assessment (the PT, for example, may need to screen for musculoskeletal contractures while the patient is heavily medicated). In this respect the configuration of the ward has indeed permitted a multidisciplinary space,

enabling members of the PMDS team to carry out necessary tasks at the bedside of the patient.

The greater hospital

Most of the PMDS activities with patients, however, take place in other parts of the hospital. Many of the pre- and post-surgical assessment activities that therapists conduct with patients require privacy or a large area of space with a specific set of resources.

The hospital was designed so that it contains a diversity of spaces and resources. Each ward contains a play area with toys and small desks and chairs for in-patients and their siblings to draw and interact with one another. Each ward also contains a kitchen area adjacent to the play area. Here, the families of in-patients can prepare food and hot drinks while watching children play. These areas of the wards mimic a generic domestic, open-plan kitchen-living area space. The hospital also contains a school with full-time teachers. This is located in a large mezzanine area of the hospital that overlooks a nearby park. It too resembles a 'generic' school environment: student artwork, alphabet and multiplication-table posters are littered across the walls, and it contains desks and chairs of various sizes. The clinical director explains that these features reflect a belief that the hospital is not treating individual children, it is 'dealing with families':

You always have to remember that a child is part of a family and anything that happens to the child has ramifications for siblings and parents...

The decisions we made when we were setting up the school is that actually if we're really going to help the children who are in hospital, we need to think holistically about the whole family and we need to think about the siblings who can sometimes almost be more traumatised by what's gone on than the child who's sick... The hospital school will take siblings as well as the children so they don't miss a week's schooling. They are doing something that's actually quite fun and keeping them absorbed and engaged. (Clinical Director, interview)

We can also see these features of the hospital as reflecting what could be called a 'clinical concern' for children's wider social context. Features of normal domestic and schooling scenes have been recreated within the hospital with the intention of minimising disruptions to the stable family unit.

Importantly for the PMDS team, these areas can be adapted without too much difficulty into the spaces required for conducting pre- and post-surgical assessments. For example, (as we will explore in greater depth in chapter 7), one assessment involves observing and quantifying the patient's ability to undertake tasks of daily living, such as brushing teeth, preparing cereal, or washing dishes. The kitchenettes – although not specifically designed as places of assessment – contain the appropriate arrangement of facilities for this assessment with patients who are less severely disabled. Other assessments require the child to attempt drawing and writing tasks. These can be conducted in the play areas or the school, both of which contain desks and chairs of appropriate sizes.

The hospital also contains a large gymnasium. This large room contains a variety of resources: inflatable balls, toys, adjustable desks and benches, padded floor mats of various sizes and plinths and hoists for moving severely disabled patients. The gym was designed to be an area for providing rehabilitative assistance to children and contains plenty of open space for gross-motor function activities (walking, running, jumping). For the PMDS, the gym also provides a suitable location for assessing gross motor function (as we will see in chapter 4), and for other assessments which require open space, such as the assessment of impairment. Here, plinths and hoists are essential for placing severely disabled patients into the body-positions required to conduct the assessments, and the available toys can be used to entice younger children to participate.

Thus, the recreation of domestic and educational settings and the provision of a gymnasium affords a variety of clinical activities: the various spaces that constitute the greater hospital are easily adapted into the spaces required by PMDS team members. To put it concisely, a diversity of spaces permits diversity of professional practice and consequently, many of the clinical practices that characterise each of the professions within the PMDS can take place under the same roof.

The greater hospital, along with the office and ward spaces, constitute what could be called a materialisation of a pro-multidisciplinary and pro-teamwork ideology. A particular socio-political trend in health service provision that encourages multidisciplinary team work (and which corresponds to a particular understanding of 'normal' childhood development) has been embodied within the physical structure of the hospital. Obviously this does not induce multidisciplinary

teamwork in a deterministic fashion, but it no doubt enables and prompts individuals to participate in multidisciplinary activities. As Prior argues, space is an active ingredient in producing and reproducing social practices (1988: 91), and the children's hospital, then, can be seen as actively configuring the multidisciplinary activities of the PMDS team. This hospital provides some material durability to multidisciplinaryity.

Disrupting multidisciplinaryity? Moving services to a new location

The importance of the specific built environment for the team's activities is illustrated when team members discuss moving some of the activities to a new location. A steady rise in the number of patients for the hospital as a whole is placing increasing pressure on available resources. In order to relieve some of this pressure, managers within the Trust are encouraging the PMDS to move many of their activities with patients to newly refurbished spaces within a new neurology centre located within the neighbouring adult hospital. (This corresponds to what Hardy and colleagues (1992) referred to as a financial constraint to interprofessionalism.) This move was the focus of much discussion during team meetings; the therapists in particular felt that it hindered their ability to work: For example:

OT: Okay, so the new neurology centre - I've taken a couple of kids there, the more functional ones, and both [the PT] and I are of the opinion that much more equipment is needed if we are able to work with these kids safely. I'm going to put forward a list with the minimal equipment we need. We need a plinth; we need a ceiling track hoist... We have been assigned rooms where other people don't want these things.

Dr M: Do they have computers?

OT: Yes but they don't work yet. They also don't have phones. Some of these things are just small things but we need them. There are no benches and I don't think one of the rooms is large enough.

As the above discussion illustrates, the OT perceives the rooms to be inadequately resourced to conduct her assessments with patients, particularly patients who are more severely disabled. Although the two hospitals are relatively close and

connected by a corridor, the distance from one to the other is also a considered to be a problem:

OT: I'm reluctant to send all patients there. For instance, Carl would take twenty minutes to walk there [because of his movement disorder], where as it would take you and me five minutes. And with Bridget, by the time we had gone back and forth between locations [to conduct assessments], it had taken us three hours to do what we could have done in one!

S&L: That is where transfer services should provide a wheelchair.

OT: But many patients like Carl refuse to use them!

Members of the team also worried that the move would threaten the effective administration of the team. Some duties currently undertaken by the PMDS administrator (which we explore in the next section) would need to be delegated to the new centre's administrator. This particular issue was discussed during the team's 'away day' (for which I did not take full field notes): team members stated that the new administrator would lack the knowledge of the team's 'idiosyncrasies' and their unique patient cohort; knowledge that is required to effectively coordinate room bookings with team members' schedules and a patient's clinical needs. Dr Martin replied that team members could inform the new administrator of the 'blocks of time' that they would need for a specific patient some time in advance. The therapists responded that this would not provide the flexibility that is required when dealing with such a variable cohort of patients: it is often very difficult to predict how long an assessment with a patient will take. This is an example of what Hardy and colleagues (1992) referred to as a procedural barrier to interprofessional practice; the planning and scheduling procedures of the new centre are mismatched with the workings of the team.

These discussions provide some insight into the types of pressures that can disrupt the activities of the team. Despite the suitability of the children's hospital for multidisciplinary teamwork, resource constraints and administrative complications threaten the PMDS' ability to fully utilise it.

4.4 Managing the PMDS diary: crafting a programme of actions

The second 'binding' strategy of the PMDS that we will explore is the team's use of a collective diary. Much like any diary it lists the times and locations of upcoming

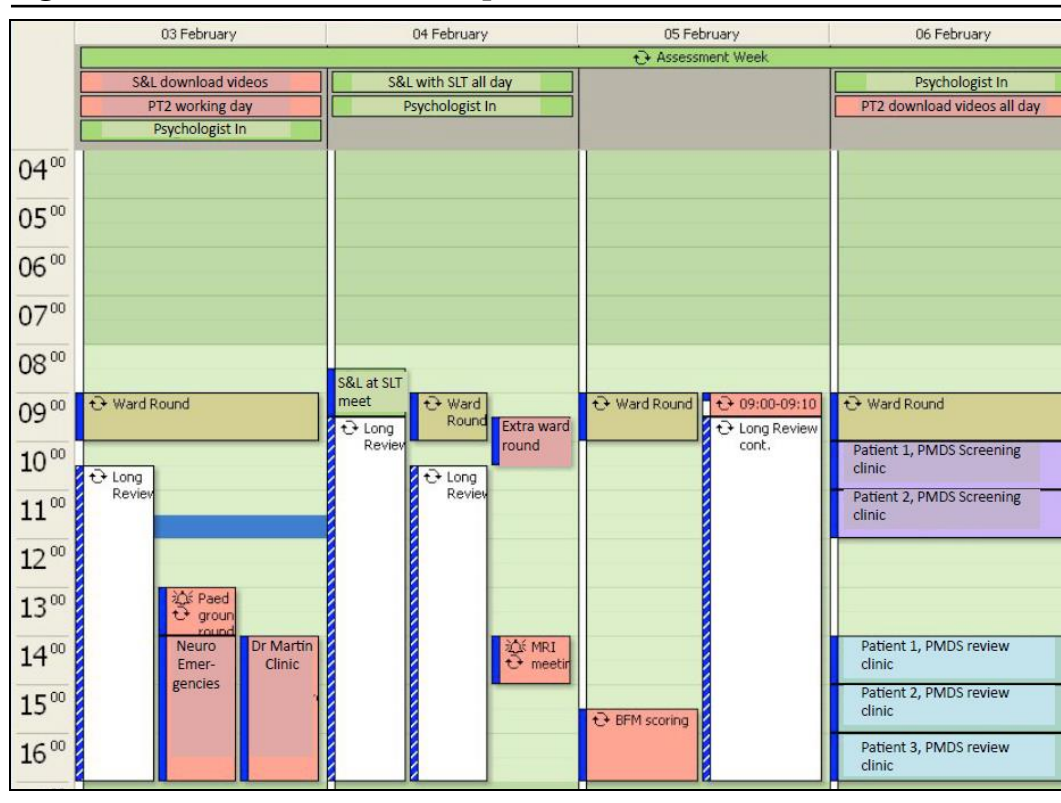
PMDS activities: the arrival and departure times of patients, the clinical activities of each team member, and the various locations where clinical activities will take place can all be represented on the diary. Any team member can consult the schedule and decipher which patient they are meeting, which other team members will be accompanying them, what activity will be taking place, and what room has been booked for them. During my fieldwork I noticed that it was often displayed during team meetings (via a projection system). It was consulted, debated and altered, and it was clear from these discussions that team members placed a great deal of importance on the diary. Indeed, it was a constant point of reference for members of the team who planned their own schedules to align with it.

The diary can be seen as what Actor-Network theorists have referred to as a *programme of actions* (Akrich and Latour 1992; Latour 1992). This is an entity that functions as a set of instructions or a script, detailing how other entities (human and non-human) should act and inter-act at specific times and locations so that an overall specific output can be achieved. Software programmes, for instance, stipulate how the diverse components of a machine should interact so that a particular task, or set of tasks, can be completed. A successful programme of actions, then, enables the various unique capacities of a range of diverse entities to be coordinated and orientated towards the achievement of a set of collective goals. This is the intention of the PMDS diary: it stipulates the actions and interactions required from a heterogonous group of professionals so that each new referral can be adequately screened, and so that each DBS patient can be suitably assessed and managed. By doing this, the diary provides a degree of structure and routine to PMDS activities. As team members consult the diary week after week, a diverse group of professionals, patients and their family members are enrolled in and perform the institutional routines that characterise the PMDS, while (ideally) achieving the aims of the team as a whole. An example of a common week of PMDS events from the diary is illustrated in figure 4.2, page 107.

Creating and updating the diary, then, is obviously an important task. It is an 'ordering' process, where a diverse array of elements must somehow be coordinated into a single programme of actions. In this section we will explore this ordering process. It is undertaken by the team's administrator and the nurse together, usually several times a month, during what they refer to as a 'scheduling session'. It is a challenging task. As the administrator stated during an interview, it is

her ‘biggest challenge’: patients with very different requirements must be booked in to see health professionals who have different tasks to perform, some of which require several hours to complete. Patients cannot simply be booked in to pre-defined 30 minute time slots, for instance. Using interview extracts and notes from an observation of one of these sessions I will illustrate some of the complexities that must be anticipated, coordinated and ordered by the nurse and administrator in order to create a coherent diary. I will also argue that the ordered diary emerges from what Carmel (2013) has referred to as *craft work*. Craft work, according to Carmel, is characterised by two features: the application of different knowledges, and practical reflexive interaction with the object being crafted.

Figure 4.2: Section of the near-complete PMDS schedule



Institutional factors that influence the PMDS schedule

Scheduling sessions usually take place at the nurse’s desk in the middle of the PMDS team seating area of the open plan office. The task is carried out on a computer so that the nurse and administrator can easily access and move between several patient databases and the Microsoft Outlook software programme with the ‘Calendar’ feature that contains the diary.

At the beginning of my observation of a scheduling session I noted that they do not begin with a blank schedule: before any additional data has been added to it, it already displays a great deal of information. Firstly, the schedule contains a particular format that reflects, to some degree, the institutional routines of the greater hospital. Working days and working hours are clearly delineated: Monday to Friday, 8am until 6pm. All PMDS activities must be allotted into this conventional and institutionally defined temporal structure. Secondly, various activities have already been entered within this pre-defined temporal structure, each indicated by a coloured 'block'. These are the standard clinical activities that take place every week, largely regardless of 'contingencies'. These also reflect various institutional pressures. For example, as consultants employed by the NHS Trust, both neurologists are obliged to conduct a daily round of the neurology ward (9am to 10am), and Dr Martin is obliged to run a neurology screening clinic on Monday afternoons. Other routine weekly activities include the PMDS screening clinics on Thursday and Friday mornings and the neurosurgeon's visit on Friday afternoon.

Importantly, these blocks of activity have been colour-coded using a system devised by the administrator and nurse. The colour of the block indicates the impact it will have on the scheduling of additional activities, and thus, by implication, it indicates the importance of the individual involved. During an interview the administrator explained the colour codes:

Red is important meetings or activity that is not flexible, that is important for the whole team to take into consideration when scheduling patients. Dr Martin's [screening] clinic on a Monday afternoon means that he will not be available to see PMDS patients at that time... Green means that that particular member of staff is not available for that period of time but they're not like a doctor. These are [things] that don't necessarily affect the timetabling of patients but are useful for others to know. (Administrator, interview)

At the beginning of the scheduling session the diary is already loaded with meaning: it reflects particular institutional patterns and it contains colour codes that indicate the importance and availability of various team members. Thus, while the MO Calender spreadsheet provides affordances (empty spaces) for scheduling additional clinical activities, these meaningful elements also present a degree of obduracy; they influence when and where additional clinical activities can be allotted. Creating a

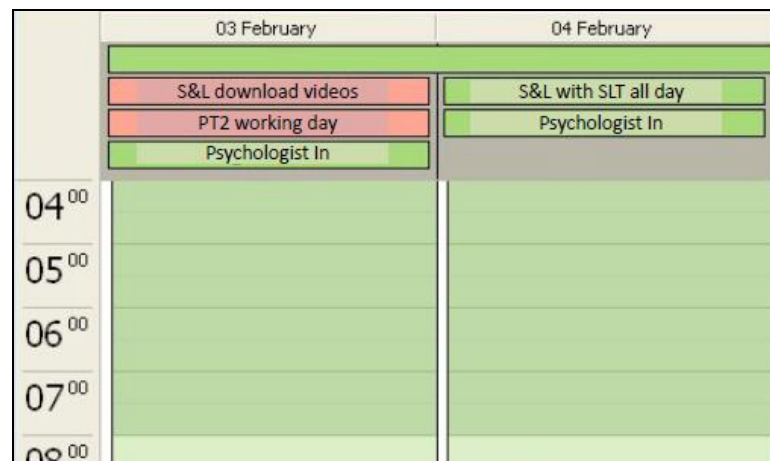
workable programme of actions for the PMDS, then, requires that the nurse and administrator carefully respond to these meaningful elements while they add additional layers of meaningful elements. It could, in other words, be described as a process of “crafting”, where the nurse and administrator mindfully respond to the medium they are working with, as it evolves and responds to their actions (Carmel 2013).

Knowledge of team members’ capacities

The first information that the nurse and administrator add to Calendar spreadsheet pertains to the availability of team members. Crafting a workable programme of actions requires knowledge of the capacities of each of the agents that will perform it (Akrich And Latour 1992). In regards to the scheduling process, the nurse and administrator require an understanding of the professional role of each team member, and importantly, an awareness of their availability to carry out PMDS activities. As the administrator states, each member of the team has their own individual commitments that need to be considered before patients can be scheduled:

The biggest challenge for me, with it being a multidisciplinary team, is diary scheduling. You’ve got eight professionals who take leave, go to conferences, have their own research and other things that they do... (Administrator, interview).

Once the nurse and administrator are aware of the availability of team members (which they can often check by simply asking team members seated nearby), they carefully note these details on the diary for each week. Along the top of the diary the administrator uses a series of coloured bars and text to note the availability of professionals for that day (figure 4.3, page 110). Again, the colour of reflects the importance of the team member: red for more important team members whose absence will likely affect the PMDS activities that can be scheduled for that day, and green for less important detail that is still useful for team members to know.

Figure 4.3: Section of schedule indicating team member availability

Financial considerations and knowledge of families

Once these details have been added, the nurse and administrator can then ‘book in’ patients for that week. The first set of patients to be booked in is the new referrals. These will be booked into the routine weekly PMDS screening clinics on Thursdays and Fridays. Screening clinics are used to identify new DBS candidates from the many referrals received by the team and thus ensure that the team generates sufficient revenue. Indeed, revenue generation determines how many patients and clinicians will be ‘allotted’ into these clinics, as illustrated by the following team meeting abstract:

PT: For it to be financially viable [with that tariff], we need to see two new patients in a slot. We won’t be making any money [from that specific screening clinic], but it enables us to weed out some of the patients and initiate needed actions.

The tariff for this activity is £511. This must cover the cost of: A neurologist, who is required to assess, among other things, the patient’s medicine regime; and a therapist (either an occupational therapist or physiotherapist), who is required to assess the patient’s functional concerns. Consequently, when ‘booking in’ new referrals the administrator and nurse ensure that:

Adm: Dr Martin sees two new patients every Thursday morning and [Neurologist 2] sees two new patients on Friday mornings. One therapist is also present (Observation notes).

Two new referrals will be allotted into these clinics on each day along with a neurologist and one of the available therapists. These details are entered into the diary and the clinic is coded 'purple'. Additionally, only new referrals that have a 'letter of guarantee' from their PCT that states a willingness to fund the DBS service will be booked in to these clinics. As the extract from the scheduling session illustrates:

Adm: This patient here, heaps of information has been sent to us but no letter of guarantee yet. We can't book them in until we get one (Observation notes).

Next, the nurse and administrator must book-in patients requiring pre and post-surgical assessments. Because these assessments can take a great deal of time and require many team members they can be difficult to align with the other elements on the schedule:

Trying to fit a child in for a review [post-surgical assessment] at a time when all of the required people are available within a set timeframe, and when you've got several hundred kids on our service now, many of whom are now being reviewed – it can be a struggle. But that's something that we just have to come to terms with. It's not going to get any easier (Administrator, interview).

The nurse and administrator consult the PMDS DBS database which contains all patients and indicates the date of their last visit to the PMDS. From this the nurse and administrator can identify those that are due for an assessment. These names can then be 'cut & pasted' into the schedule, if an appropriate space with the necessary time and staff members can be found. However as the following excerpt from the scheduling session indicates, the nurse and administrator must also take into account other concerns:

Adm: Friday's are [the patient's] day off college, so that works well for him. They come in from [county] so mid-morning onwards would be ideal. It is a three-hour round trip.

Nurse: It will have to be 11am.

Adm: That will do. It is not too early for them.

When finding an appropriate time in the schedule the nurse and administrator consider various details about the family and the patient, such as schooling commitments and their living location. Those families that have to travel some distance will be booked into Trust-provided accommodation, the availability of which will also affect the scheduling of patients. Obviously, then, the scheduling process requires the nurse and administrator to know such details about families. Both, in their wider roles within the PMDS, do acquire this personal knowledge of families and they are able to draw on this during the goal setting session. Indeed, knowing the families quite well is “the nature of the service”. The administrator, for instance, states:

I’m the first point of contact for the patients... some of them end up talking to me quite a lot if they make contact with the team quite a lot.... I do my best to go down and meet as many of the patients as I can because obviously that is the nature of the service. (Administrator, interview).

Drawing on clinical knowledge

Clinical knowledge is also needed when crafting a workable programme of actions, and it for this reason that the nurse is involved in the process. Before pre- and post- surgical assessments can be placed within the schedule the nurse needs to ensure that the clinical needs of the patient can be met by the available staff. As she explains:

Our administrator, she doesn’t understand all the illnesses, whereas I know their clinical details, what they’re coming in for, what clinical need they have. [That’s why] I need to help arrange the whole diary and everyone’s life within the service. (Nurse, interview).

This extract provides an example:

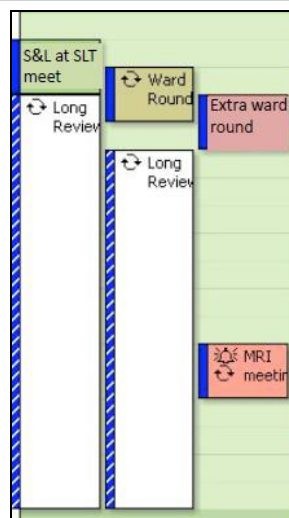
Adm: They cancelled their previous appointment because it was his brother’s first day at school.

Nurse: It is a three-year review so [the physiotherapist] will want to see him.

The assessment will be ‘booked’ once a time period within the schedule has been found that is manageable for families and corresponds with the availability of the

staff members required. Here, then, the nurse and administrator take note of the red and green coloured ‘blocks’ within the schedule to determine which staff members are available. The assessments are coloured white on the schedule to indicate that many of the staff members will be involved (text is added to note which specific staff are involved). The sessions are also given a blue and white ‘hashed’ border to indicate that the booking details have not yet been sent to the family, (These are changed to a blue-only boarder once the administrator sends these details: figure 4.4)

Figure 4.4: Schedule section with group assessment (‘long review’ in white)



By this stage the diary is almost full. The remaining free time can be used by members of the team to complete paper work, but often emergency bookings will occupy these times. Emergency bookings might be made for patients with infections, status dystonicus, or with suspected hardware failures, or for patients who have inexplicably deteriorated.

Interestingly, aspects of the built environment facilitate the scheduling session and the process of ‘ordering’. Throughout the scheduling session the open-plan arrangement of the office enables the nurse and administrator to check details with some other members of the team. Here is an example from the session I observed:

Nurse: [Physiotherapist!] You have a very busy day! [Patient] needs to come in for an injection.

PT1: Sedation is going to take 30 minutes. Can you book her in for 3:30? I don't finish until six so it doesn't matter if it runs past five.

By examining the diary crafting process we can see how the itinerary of activities of the PMDS is shaped by a broad range of concerns, not just the clinical needs of the patient. Creating the diary requires the administrator and nurse to draw on their knowledge of the capacities and availability of each team member, personal knowledge of families, and a clinical understanding of the patient's requirements. These 'complexities' must be coordinated with an institutionally-defined timeframe, institutional obligations and funding pressures. It is via this process of crafting that the administrator and nurse create a PMDS programme of actions: a diary that describes and prescribes the actions required from each team member so that the overall goals of the PMDS team can be achieved. We can say that, as team members adhere to and enact the schedule, the PMDS as a multidisciplinary service is 'performed into being'.

Of course, it would be naive to suggest that the product of the scheduling session is a 'completed' diary which is diligently adhered to by all members of the team. The diary is constantly subject to alteration as families cancel meetings and emergencies arise, and team members inevitably engage in what Akrich and Latour (1992) refer to as antiprogrammes¹¹ such as taking sick leave, and sometimes the nurse and administrator have simply not been able to anticipate what a particular patient requires from the PMDS. As the administrator explains:

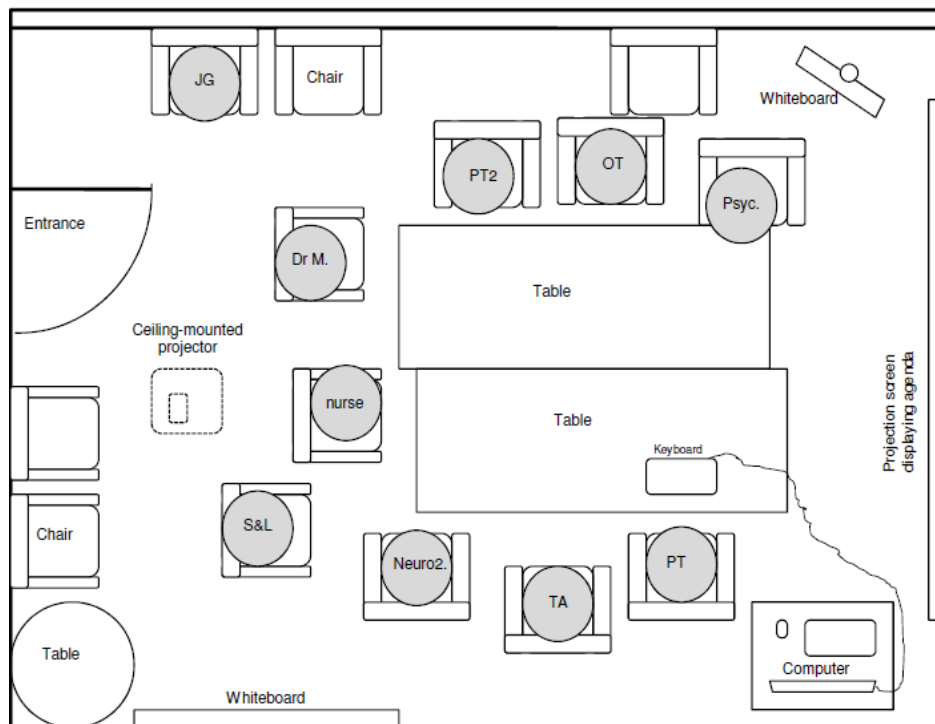
Sometimes we make the right decisions and sometimes we don't. And [team members] email us to say, 'Why have you put this patient in here? I need to see them at that review and I'm on annual leave.' If you've just spent three hours going through the diary, making all these changes, and then you get an email saying, 'Well that's not going to work, that's not going to work,' it can be a bit, you know, it makes you feel a bit deflated sometimes, because then we have to go back and do it again. But it's, it's just all par for the course really. (Administrator, interview).

¹¹ *Individual actions that do not correspond to those of the collective.*

4.5 The team meeting: A forum for group decision making

The third 'binding' feature of the PMDS that we will explore is the weekly team meetings. These are scheduled for every Monday between 9:30am and 10:30am, although during the time I was conducting fieldwork it was common for meetings to be postponed or cancelled, and those that did take place were seldom completed within the hour. Indeed, it was not unusual for a meeting to take two hours long (to the obvious frustration of team members). The team meeting had several purposes. It provided a forum to: discuss current clinical cases and decide upon an appropriate course of action for each case; to assess which new referrals should be allocated a slot in the PMDS screening clinic; and to address any concerns that individual team members may have about the service as a whole. In effect, the team meetings represented a regular, structured time for multidisciplinary decision making - a feature that commentators have argued is vital for effective multidisciplinary service provision (West and Slater 1996; Housley 2003). And, the team meeting also provided a structured time to talk about and resolve any tensions that threaten to upset the functioning of the team as a whole. In this section, we will draw on extracts of my observation notes from various team meetings to explore both these features.

The meeting room where PMDS meetings took place was one of the few enclosed rooms in the open-plan office space. Team members sat around two tables that had been pushed together in the centre of the room. The exact seating arrangement differed from meeting to meeting, although Dr Martin would sit in one of the chairs closer to the door (he often arrived several minutes after everyone else). A large projection screen was attached to one wall of the room, at the head of the tables, which was used to display various documents and images via the computer and projector nearby. A common arrangement is illustrated in Figure 4.5.

Figure 4.5: A common team meeting seating arrangement

The meetings were informal: there was no chairperson and the meetings initially seemed to me to be rather disorderly. The meetings did follow a structure, however. An agenda was projected on the screen where it could be seen by all team members. The agenda was a Microsoft Word document, and as team members worked their way through the various agenda items and various clinical cases, one member of the team would add comments and actions to each point on the document. Thus, the agenda was converted into the meeting minutes as the meeting progressed and each member of the team could observe and scrutinize the actions as they were inscribed in the document. Several different team members undertook the minute taking role throughout the fieldwork period: the administrator, the more senior physiotherapist, the psychologist and the speech and language therapist (notably, neither of the neurologists ever did this task). In the absence of a chairperson, no one individual kept the team moving through the agenda points or coordinated the utterances of the other members, and it was not uncommon for several team members to be talking at the same time or for discussions to jump back and forth from one action point to another.

A direct, upfront style of communication was a common characteristic of team meetings and several members of the team, particularly the occupational therapist, and the senior physiotherapist, appeared to be unafraid to express their

opinions. This no doubt reflected what several team members later described to me as the “strong personalities” within the team. As an outsider, it seemed to me that this created rather tense exchanges within the meetings. I was explicitly told during the course of my fieldwork, however, that: “team members get on very well, even if it does not always seem so” (Therapy assistant, interview). Indeed, in addition to the seemingly terse exchanges, there was often a great deal of humour in team meetings. In amongst clinical discussions it was not unusual for team members to share comical stories from their work. In one meeting, for example, the nurse told the team that one of their older, more functional inpatients had managed to sneak his girlfriend into the neurology ward for the night, much to the chagrin of the ward nurses. Stories such as this were often a source of amusement for the team and no doubt managed to diffuse some of the tension.

The authority of Dr Martin during team meetings

The lack of a chairperson and the informality of the meetings are not indicative of an absence of authority, however. Dr Martin’s authority as team leader was expressed in other ways. He would often put forward utterances that reasserted his position as team leader; utterances which also had the effect of, at least discursively, ‘unifying’ the team. In the following extract Dr Martin responds to the frustrations voiced by several team members over the limited time available to conduct research. Dr Martin states that research is part of their obligation to conduct clinical audits:

Dr M: We need to be very clear about what research means. Research is about audits. Everybody has to participate in audits. It is mandatory within the NHS. We have to put in audit time each week, and this can then help us to reflect on the business of delivering this service. When we collect data, we are doing an audit and that provides information that enables us to make changes in how we manage patients in the future.

In this utterance Dr Martin’s use of the pronouns “we” and “us” discursively unites individual team members in order to remind them that their individual research activities are part of the collective work of delivering “this service”.

Dr Martin would sometimes step in to quell tensions during the meeting. In the following extract the speech and language therapist is visibly frustrated with the long duration of the team meeting:

- S&L: Why are we going through these [patients] again? We went through them at the last meeting!
- PT1: We are doing them again because no one can remember where we left off! Okay we need to go through and find where we left off last time.
- Dr M: Just calm down! Relax! I have to leave soon, and before I go I want some alterations to be made to the agenda. You need to add these details to Rebecca....

During meetings it was common for team members to express frustration at decisions made by hospital management. The decision to move some of the PMDS activities to the Neurology Centre in the adjacent hospital was often discussed: as we saw earlier, team members felt that the new centre was inadequately resourced for PMDS activities. In these discussions Dr Martin would often play a diplomatic role: he would articulate the perspective of ‘management’ and suggest a compromise. In the following extract Dr Martin responds to the other team members concerns that the new centre is poorly resourced:

- Dr M: We want to give the new centre the opportunity to step up... From a management perspective, everybody agrees that we should be actively involved in the new centre. Usually, when these sorts of shifts occurs, it is necessary to slow the work down a little while people become accustomed to the new location... We need to adopt a pragmatic approach to this. We need to try an invest time in the centre and push for them to provide the equipment we need. They will be willing to set up the environment so it is safe and useful.

Again Dr Martin constantly employs the use of “we” to discursively unite individual members of the team and direct them towards a particular, collective strategy for dealing with the dilemma. It is in this way, by attempting to ease tensions and orientating team members towards collective strategies, that Dr Martin displayed authority during team meetings. We can also see that these actions are an attempt to manage some of the challenges of delivering a multidisciplinary service.

Coordinating team documents

The meeting also provides an opportunity for members to discuss the management of team documents. Team documents contain information that is relevant to most members of the team, and may require profession-specific inputs from several team members. They are, in a sense, ‘multidisciplinary’ documents: information from a range of professions is pooled-together within one portable document under the heading “Paediatric Motor Disorder Service”. Two examples include the ‘PMDS Parent Questionnaire’, which is sent to all new referrals and contains a range of questions about the patient’s medication regime, communication skills, mobility and so on, and the ‘Multidisciplinary Team (MDT) Report’ that is completed for each patient and which involves a summary and set of recommendations from each PMDS clinician. The MDT report is sent to the child’s local community services. The circulation and completion of these documents is an important aspect of the effective functioning of the team: they are part of what Law has referred to as the network of heterogeneous entities that constitute an organization (Law 1992).

The importance of these documents is revealed by discussions that took place during team meetings. Generally such discussions were negative in tone. For example, team members complained that questionnaires were not being sent to all new referrals or were not be adequately completed by parents. This threatened their ability to make effective use of clinical time with patients:

OT: I have quite a few things to put on the agenda... Firstly, questionnaires. It seems that they are not being sent out regularly. We had a patient here and the family said they had not received the questionnaire. Personally, I have decided that I’m not going to see a patient unless they have filled it in: it takes too much time – it is a waste of clinical time – if I have to cover those issues and ask those questions with them while they are here. I spend so much time with that patient when it should have taken much less time.

Psyc: Yes, we really need to make sure that all families receive the questionnaire!

The slow rate at which patients MDT reports were being completed was also lamented by members of the team. In several meetings the more senior physiotherapist chided other team members for failing to complete their sections of the reports, resulting in a backlog of semi-finished reports (outstanding reports are listed at the end of the agenda). Here is an example:

- PT1: Look; I know this is a contentious issue but we need to discuss this. Some reports are getting on for five months. Jane's for instance.
- Nurse: That was delayed because we were waiting on some information from the family.
- PT1: No! She just needs the neuro exam added.
- Dr M: Can I just say that the chances of me doing those [outstanding] reports today is negligible.
- PT1: I know, but they have been on the agenda for months.
- Neuro: [Directed at Dr M.] Well, just do Jane's report today then.

In most cases these frustrations were directed at the 'medical' members of the team, specifically the neurologists. In one meeting the physiotherapist suggested sending out various components of the report separately to local community services. Another team member replied that fragmenting the reports in this way might be counterproductive, as there is not necessarily a clear distinction 'medical' and 'therapy' elements within the PMDS service:

- PT1: I think we are going to need to send out separate reports, given that it is taking so long for the medical notes to be added to them.
- Nurse: But where would you put the pain report?
- PT1: Well, if you can complete it in a month or two, they can be sent out with the therapy reports.
- Nurse: That would be difficult: the medical stuff and the therapy stuff often overlap. Recommendations often need to go together.
- PT1: I know, but some of my recommendations need to be read by people quickly. They can't be sitting there, unread for months.

These discussions illustrate that getting all team members to actively contribute to the production and circulation of PMDS team documents was challenging. And as the above extracts illustrate, the team meeting provided a forum where the importance of such multidisciplinary documents could be reaffirmed and where team members could be reminded of their obligations to complete and circulate such documents.

A space for group decision making

Of course the main activity that takes place during team meetings is the discussion of clinical cases and clinical decision making. As Centellas and colleagues have argued (in press), team meetings can provide an opportunity for multidisciplinary teams to engage in an “interactive process that facilitates interdisciplinary collaboration by aligning different disciplinary identities” around a particular case “without necessarily blurring or softening disciplinary identities or local meanings” (In press). In this section we will use extracts of these discussions to illustrate how multidisciplinary is enacted within team meetings. We will see how the team meeting provides a forum in which different types of specialist knowledge and expertise are articulated and filtered into the decision-making process. As this happens, disciplinary boundaries are demarcated, and a ‘composite’ account of the patient produced.

During discussions various team members articulate a knowledge of clinical cases that reflects their particular area of expertise. In the following extract several members of the team discuss Emma, who has a complex and severe movement disorder and had a DBS system implanted several years ago. The physiotherapist’s appraisal of the case is presented in terms of her ‘movement control’ and her ‘functional’ ability – both of which reflect the physiotherapist’s focus on gross motor function:

PT1: She has been deteriorating. Her selective movement control is certainly getting worse.

Dr M: Has she grown? Because there is a mechanical disadvantage that can arise when you grow but the muscle can’t compensate with the new mass...

PT1: I was getting her to lie on her tummy and lift her leg – it seems to me that the signal is just not getting through. It is not simply about weakness. Qualitatively, her dystonia is getting worse and functionally she is deteriorating.

Neuro: We had to adjust her stimulation parameters. She wasn’t responding well to higher stimulation doses.

Dr M: Yes, with higher stimulation there is the possibility of inducing Parkinsonian symptoms.

We also see from this extract that the neurologists (which includes Dr Martin) employ a different lexicon when proffering an understanding of Emma; terms like ‘stimulation’, ‘stimulation parameters’ and ‘voltage’ were often used by the neurologists when discussing cases, indicating that managing the implanted DBS system was part of their role within the PMDS. Typically the neurologists would also provide reports on patients’ medications regimes, brain imaging results, and provide a summary of surgical procedures – all of which align with a biomedical understanding of the patient. The following extract is an example of this. Here a teenage patient named Chris appears to have had a DBS system malfunction and will require surgery:

Dr M: There is a problem with the [DBS] connection. His left arm became very dystonic and I have admitted him and I’m glad that I did that because he went into status dystonicus. [The neurosurgeon] came over and we went over the images and it seems the extension wire and the electrode connection has become adrift. When I changed the stimulation parameters I managed to get him out of his status dystonicus, and I have put him on a tiny bit of [medication]. His status dystonicus – it was frightening for the ward team, but at least they got to see the DBS at work when I managed to pull him out of it.

Not surprisingly the psychologist’s contribution to discussions tended to include utterances pertaining to mood or cognition. In the following extract we can see her employ specific terminology (such as suicidal ideation) that reflect her disciplinary expertise. Here the team discusses Jimmy a potential DBS candidate who is uncertain about whether or not to proceed with DBS.

Psyc: Well, he is an interesting one really. He has personality and behavioural issues. I think he is lonely and he has poor self-esteem. He has never had suicidal ideation but he definitely wishes he wasn’t alive, which is not the same as ideation. His family says that what happened to him was an accident, but it may have been an extreme move to seek attention... He and his family are very unsure about DBS.

Similarly, the contributions of other team members reflected their particular area of specialty. For example the speech and language therapist: “When I last saw her I

noted that she speaks very quickly. Once she gets speaking she has trouble stopping”, and: “She has some freezing when eating, but there is no danger with her swallowing...” The nurse’s contributions were similar to those of the neurologists and tended to refer to DBS hardware, medications and surgical procedures (she would also refer to patients’ pain).

During meetings, team members draw upon their distinct disciplinary commitments to bear upon their understanding of the patients being discussed. As Centellas and colleagues have argued (in press), this has the effect of demarcating the professional identity of each team member. Importantly, as clinical cases are discussed and team members make their particular contributions, a composite picture of the patient emerges: a patient that is understood in terms of their gross motor function, stimulation parameters, mood and self-esteem, feeding capacity, and functional ability. Together, team members enact a patient that is more than just a biomedical entity.

In addition to contributing their own discipline-specific understandings to discussions, team members would also draw upon an awareness of patients’ families and wider social circumstances. All members of the team appeared to display and contribute such awareness. No doubt this reflected a familiarity with families that developed during the considerable amount of time they spend with the PMDS (particularly during pre- and post-surgical assessments). In some discussions, for instance, team members vocalised the opinions or worries of a family or family member. In the following extract the team is discussing how to move forward with Jimmy, the patient described above by the psychologist:

Psyc: ...he and his family are very unsure about DBS.

PT: Clinically, you want to offer him DBS. He is the sort of case that responds well.

Dr M: I have met him! I think he would make a great candidate for DBS.

OT: His family is reluctant because we can’t tell them exactly how he will respond.

Psyc: I think we should put him in touch with another family [that have had DBS]. They still won’t be able to get the sort of certainty they want though.

Neuro: Let’s put them in touch with Colin. That will give them a broad range of what to expect.

As the extract demonstrates the team members would like Jimmy to precede with DBS, but in consideration of the family's perspective they decide to put him in touch with the family of one of their other patients.

In some discussions team members will draw upon their understanding of a patient's relationship with siblings and parents. The following extract pertains to Ioannis, a patient around five years of age who has been displaying a great deal of agitation. There has been some uncertainty as to what is causing the agitation:

Dr M: We need [the psychologist] to have a discussion with the family. The family is in distress – let me tell you what has been going on. Ioannis has been waking up early in the morning, screaming and soiling himself, and then in the evenings they are having trouble getting him into the bath. I think there is a large behavioural component to what is going on: I think he is intensely jealous of his [slightly] younger brother who is running around, playing... It is difficult for the family but I told them we can't use medications inappropriately. We will bring him into the ward for four or five days, and if he doesn't kick up such a fuss here in front of strangers then we know it is a behavioural issue. I witnessed his interactions with his family. It is clear that it is one of those classic situations where he is spoiled on the one hand but there is a huge emotional entanglement on the other.

It was not uncommon for the wellbeing of a family to be taken into account when deciding upon a course of action for a patient. In the example presented below the team decides to keep a patient (Arivinder) in the ward to provide some relief to the family, at least until the family can access some support services:

Dr M: I have been talking to his dad. Dad doesn't want to take him home only for him to have another episode and for everyone to be completely demoralised.

PT1: Is he dischargeable?

Dr M: He is on par with others who have been discharged, so yes.

OT: But he fluctuates every day.

Neuro: His family seem a little bit happier in hospital.

PT1: When Arivinder is bad, his dad holds him while the nurse gives him some medication. At home his dad has to do it all by himself.

Dr M: It is better, then, to wait and not discharge him now until he has access to [support group].

PT1: In terms of actions this week?

Dr M: Just waiting and watching. Lets see if he goes to school. We can fill in a sleep chart and monitor his dystonia and sleep patterns.

PT2: I will contact home services [community support group].

Indeed it was not uncommon for team members to refer to a patient's access to community services, or to decide upon a course of action that involved contacting support services. Schooling, a patient's performance at school, and relations with peers were also talked about. In the following extract team members discuss the possible causes of William's changes in mood:

Dr M: [The dystonia in] his legs are much better. I put him on double [stimulation] contacts and I reduced the right lead voltage to avoid dyskinesia in his face.

S&L: His speech was good.

Psyc: And he seemed cheerful when he was here.

Dr M: On that point, it would be interesting to see whether his mood problems are because now, even though his dystonia has improved with DBS, he still can't keep up with his peers at school. This could be making him frustrated and stressed. Prior to DBS, he could always attribute his inability to keep up with dystonia. Perhaps now that he has DBS, he and others are placing too much expectation on him. This is in contrast to the changes in mood resulting directly from stimulation itself.

Psyc: His dad certainly does not think it is directly a result of the stimulation... you would think the school would be understanding and make allowances for him.

Thus, schooling, family dynamics and the availability of community services were often discussed. References to these elements are used to help 'understand' the patient and thus inform decision making. Within team meetings, then, patients were enacted not just in terms of gross motor function, pain, medication regimes, stimulation parameters, functional abilities and so on, but also as individuals within a wider network that includes families, schooling and peers, and community services. Unsurprisingly, discussions and decision-making that involved these

frames of reference tended to draw on prevalent social norms. For example, team members make judgements on whether a patient has an ‘overly dependent’ relationship with a parent leading to ‘emotional entanglement’ (as with the case of Ioanis above). Schooling and interaction with peers are talked-about as things that should be encouraged, and it was common for team members to make assessments and recommendations based on their perceptions of age-appropriate behaviour. A good example of this is the case of Carl, a 16 year old patient who is about to have the DBS system implanted:

PT: I really think Carl should have a non-rechargeable battery. I was really glad when [the psychologist] agreed with me! Dr Martin has been pushing for him to have a rechargeable battery. A non-rechargeable battery would be much better for Carl – he is at that age where he will want to go out and do things. He can’t be expected to routinely be at home to recharge his battery.

Psyc: Let’s contact his family and let them know [that that’s what we advise]. They should know that they don’t have yet another big decision to make on their own.

Thus, in addition to providing a regular structured time for addressing tensions that could threaten the functioning of the team, team meetings provide a forum for multidisciplinary decision making. They provide team members with a space to articulate their particular understanding of the patient; understandings which reflect their disciplinary expertise and their familiarity with the patient’s social and family circumstances. As various team members contribute to a discussion, a clinical case is rendered intelligible in terms of a wide variety of elements, from brain imaging and stimulation parameters to relationships with parents and performance in school. Inevitably, in PMDS team meetings these ‘patient-centred’ discussions involved drawing on particular understandings of ‘normal’ childhood and teenage development.

4.6 Discussion: The broad remit of the PMDS clinical gaze

In *The Birth of the Clinic* (1963/2003) Foucault describes the emergence of what he referred to as the medical gaze of modern medicine. This gaze, he argued sought to delineate and define the body in terms of its concrete shape and form, and its

emergence signalled the birth of the biomedical model of disease and the body in which a patient's social circumstances are largely elided or considered irrelevant to clinical decision-making (Fox 2012: 143).

Within the PMDS team meetings something quite different to Foucault's medical gaze is in operation. Biomedical considerations are certainly mentioned within team meetings and without a doubt such considerations influence a great deal of PMDS clinical decision-making, but social considerations are also foregrounded. In addition to talk about brain images, medication regimes and surgical considerations, PMDS team members devote considerable discussion to non-biomedical considerations: schooling, relations with peers, family dynamics, a patient's mood, and so on. Indeed, we could say that the PMDS casts a broad clinical gaze over their patients; a gaze that extends from the inner concrete shapes and forms of the brain, to the subjective thoughts and emotions of their patients, and to the internal dynamics of domestic life.¹² Like the medical gaze described by Foucault, there are normative consequences for those subjected to the broad clinical gaze of the PMDS. Patients are, in effect, subject to a broad surveillance where they are inevitably compared to various norms and where clinical action is undertaken with the intention of upholding such norms – the decision to implant a non-rechargeable neurostimulator in Carl so that he can “go out and do things” like a normal teenager is an example of this.

We can see here, then, how the PMDS engages in what could a ‘comprehensive’, ‘patient-centred approach’ to service provision that has been promoted by proponents of interprofessionalism and multidisciplinary. Bourret (2005) has argued that particular forms of clinical work emerge from various collaborative arrangements. He illustrated how the development of new forms of molecular clinical practices in breast cancer genetics was predicated upon the emergence of multidisciplinary teams involving biologists and particular clinical specialists. These novel clinical practices (which constitute what could be called a clinical molecular gaze) emerged from the pooling of the heterogeneous resources from these disciplines and the subsequent blurring of disciplinary boundaries

¹² This is in notable contrast to the multidisciplinary oncology teams explored by Coombs and Ersser (2004), where nurses' understandings of patient ‘as a person’ were very much ignored in favour of doctors' biomedical knowledge.

(Bourret 2005: 57). Similarly, we can see here how a particular ‘comprehensive’ clinical gaze has emerged from a specific form of multidisciplinary collaboration.

What I have attempted to illustrate is that this type of collaboration is an achievement: it requires a great deal of work. Teams such as the PMDS (or indeed any organisation) do not simply exist in the ‘order of things’; rather, they are brought into being and are maintained through various practices of socio-technical organising (Alcadipani and Hazzard 2010). I have explored several of these practices such as the careful arrangement of the built environment which was purposefully designed to encourage multidisciplinary, the diary scheduling session which is used to enrol each individual team members into an collective itinerary of actions, and the team meetings itself, which provides a forum for reminding individuals to contribute to and circulate the various team documents that are necessary for effective functioning of the team. There are, of course, numerous other practices that have the effect of maintaining and unifying the multidisciplinary PMDS team. For example, team members regularly socialise together at a pub, which no doubt reinforces a sense of group friendship and trust. The team also maintains a webpage as part of their NHS Trust website which delineates the team and presents it to the public as a “comprehensive service”. (This can be seen as an example of what Gieryn refers to as boundary work (1983): a rhetorical effort to assert the remit of the team and distinguish it from other services). And importantly, tools and protocols used within the PMDS can have a ‘unifying’ influence: some assessments, for example, can be carried out by several members of the team, and some may require several team members to work together (the goal setting session which we will explore in chapter 6 is a good example of this): such activities tend to blur disciplinary boundaries during clinical practice (Carmel 2006). The PMDS can be seen as the on-going consequence of these everyday practices of ordering and unifying, and it is upon these types of practices that the broad, ‘patient-centred’ and ‘comprehensive’ clinical gaze is predicated.

Foucault argued that the modern medical gaze was encoded in, and thus perpetuated by, various institutional arrangements: It was not simply a mode of perception and reasoning that existed solely in the minds and practices of observers and doctors (1963/2003: 109). Similarly, Bourret argues that that the emergence of collaborative clinical teams (and thus a specific form of clinical work) in breast cancer diagnosis reflects various governmental and professional stipulations that

explicitly encourage multidisciplinary (2005: 58). In this chapter I have indicated that the barriers to multidisciplinary for the PMDS team are perhaps not as imposing as those encountered in other areas of health and social service provision. There is, it seems, a prevalent pro-multidisciplinary socio-political trend promoting multidisciplinary teamwork, particularly in paediatric settings. This trend is reflected in a favourable tariff structure which has reduced the financial boundaries for teams such as the PMDS, and of course the structure of the hospital itself, which permits particular forms of multidisciplinary by providing diverse spaces for diverse clinical activities as well as spaces that encourage collaboration. Such arrangements provide ‘institutional weight’ and durability to the PMDS team and their comprehensive, ‘patient-centred’ clinical gaze. Indeed, we can assume that the successful emergence and stabilisation of teams such as the PMDS is shaped by, and depends upon, their ability to resonate with such institutional arrangements.

In the discussion of this thesis I will situate these observations on the multidisciplinary work of the PMDS within a discussion of medical innovation more generally. In the meantime we will explore how the PMDS manages three specific challenges associated with the introduction of deep brain stimulation technology into paediatric neurology. These challenges, as I stated in the methodology, were often discussed by team members during team meetings, particularly during the academic team meetings that took place on Fridays. As we explore each challenge, we will see other instances of this patient-centred clinical approach; indeed, while exploring how the team manages the expectations of patients and families (Chapter 6) and how they measure clinical outcomes (Chapter 7), we will see that it is encoded within specific clinical tools.

5 Body work and diagnosing dystonia

5.1 Introduction: The challenge of diagnosing dystonia

Well over half the patients who attend the PMDS for deep brain stimulation have secondary dystonia. In these patients, many of whom have cerebral palsy, dystonic movements often co-exist with spasticity, muscle weakness, and contractures, as well as cognitive and communicative difficulties. Of these various manifestations of neurological pathology, it is only dystonia that can be directly managed with deep brain stimulation. In its ‘pure’ form, the spasms and shaky movement that characterise dystonia easily distinguish it from other motor signs. Spasticity, for example, appears as stiffness and rigidity, the consequence of the excessive contraction of a muscle or muscle group. Yet the clinical presentation of many PMDS patients, some of whom are the most severe cases in the UK, is complex. In these patients it is not unusual for both dystonia and spasticity to occur in the same regions of the body (‘mixed hypertonia’) and distinguishing the two becomes clinically difficult (Lebiedowska et al. 2004). Consequently, it is often unclear which motor sign is causing the patient the greatest discomfort or has the greatest impact on motor function. This is further complicated by the presence of permanent muscular-skeletal abnormalities, or contractures, which can also restrict a patient’s movement and produce painful posturing.

This presents a challenge for the team. In order to determine if DBS will be of any benefit to a patient, they must be able to distinguish dystonia from other manifestations of neurological pathology, and they must be able to determine to what degree dystonic movements are detrimentally affecting the patient. If, for example, a patient has both spasticity and dystonia but it is predominately spasticity that is creating difficulties for the patient, then DBS will be of little use. There are no technological solutions to this challenge. MRI and PET may render neurological abnormalities visible, but the images they generate cannot be used to distinguish the various effects of these abnormalities. Current clinical measurement tools are also of limited use as they lack the sensitivity necessary to identify and capture subtle differences (Gordon et al. 2006).

The PMDS’ solution to this problem is to rely on the embodied knowledge and tactile skills of the two physiotherapists. During an initial interview with patients and during the subsequent regime of pre-surgical baseline assessments, the

physiotherapists conduct an examination of gross motor function and a musculoskeletal screening, both of which are used to identify the various manifestations of neurological pathology and to assess the degree to which dystonia affects the motor functioning of the patient. In order to conduct these examinations the physiotherapists must use their own bodies to extract sought-after clinical information from the bodies of patients. In this chapter we will explore how the physiotherapists use a set of corporeal skills to produce useful clinical information. We will see that they use their bodies to encourage patients to comply with the examination, and we will see that they rely on a carefully honed sense of touch to differentiate dystonia from spasticity. Extracts from field notes taken during my observations of both a gross motor function examination and a musculoskeletal screening will be used as examples. I will identify and describe two modes of what several authors have referred to as body work (Brown et al. 2011; Maseide 2011): *communicative body work*, and what Moreira refers to as *sensorial reflexivity* (2004). As we will see, these modes of body work contribute to the production of clinical knowledge that enables the team to identify suitable candidates for DBS and to predict how these patients may actually benefit from the therapy. Within the PMDS team the successful adoption of DBS into paediatric neurology requires the body work of physiotherapists. This chapter will illustrate, then, that body work is a vital component of knowledge production within clinical contexts, and is an important and much overlooked component of medical innovation.

5.2 Perspectives on the role of body in knowledge production

Within the broad and diverse field of philosophy there have been several schools of thought that have emphasized the absolute centrality of the body in processes of knowledge production. What these diverse schools have in common is a rejection of Cartesian dualism, which, in various manifestations, has tended to underlie a great deal of western thought, particularly the school of analytical philosophy, and to some extent, traditional sociology. Descartes argued that the body and bodily senses were a fallible and untrustworthy source of knowledge. Knowledge and beliefs (or at least those worth having and acting-upon) are, rather, the domain of the mind: they are explicitly present in consciousness and they are the product of reflective, sceptical and reasonable deliberations (Shusterman 2012). The effect of Cartesian dualism is that the role of the body and bodily-sensations has been largely

elided from accounts of knowledge production, scientific endeavour and medical progress. Knowledge, in other words, is portrayed as disembodied.

Various forms of ‘non-Cartesian’ philosophy have sought to affirm the centrality of the body. In general terms these schools of thought argue that we experience the world within and through our bodies. Our bodily sensations shape our perceptions, feelings and thoughts, and it is from these that useful knowledge emerges. The pragmatism of William James and John Dewey is an example of this line of thinking. For Dewey and James, a great deal of productive and useful mental activity takes place below an individual’s conscious awareness - implicit, non-discursive and vague, and guided by incorporated habit (Shusterman 2012). Such activity informs beliefs and enables useful, pragmatic bodily action. In a similar vein, the phenomenological perspective has emphasized the centrality of corporeal sensation to informing action and beliefs. Merleau-Ponty for example argued that our perception of the world, how we come to understand it and thus act within it, derives from our embodied dispositions (Crossley 2012). We *learn* how to sense the world via our bodies; how to see, hear, feel, smell the world, and it only via these sensations that that we can act within, and form knowledge of, the world. Merleau-Ponty (1962) referred to these acquired ways of sensing-and-acting as habits. They are collectively shared and transmitted and importantly they become sedimented or ingrained in the body as embodied dispositions. According to this line of thinking, then, different cultures or different professional groups can be characterised by their particular (perhaps idiosyncratic) embodied dispositions (or habits of sensing-and-acting) that generate specific forms of knowledge. According to both pragmatism and phenomenology the notion that a disembodied mind can occupy some sort of Archimedean point, from which various truths about the world can be deciphered, is a myth.

Similarly, various scholars within STS have illustrated the role of the body and embodiment in the production of scientific knowledge. This work (and indeed the field of science and technology studies more generally) has offered an alternative explanation of scientific progress to that put forward by positivist and rationalist philosophers of science (c.f. Reichenbach 1938; Popper 1959; Hempel 1966) that has tended to portray scientific knowledge as “abstract, universal and placeless” (Henke and Gieryn: 2008: 343), (and, of course, body-less). In contrast, various STS scholars have sought to highlight the artisanal, craft-work nature of scientific activity

and knowledge production, a key component of which is the tacit and embodied knowledge of scientists (Knorr-Cetena 1981; Lynch 1982; 1985; Collins 1987). Generally, tacit knowledge has been defined as unwritten knowledge and skills that circulate within scientific communities, a sort of ‘feel for the game’, that enables individuals to utilize technical apparatuses together with more formal forms of scientific knowledge to generate meaningful scientific statements. Such knowledge, according to Polanyi’s (1962) influential description, cannot be directly communicated or codified. For Lynch, tacit knowledge is incorporated into the specific practices of scientists and “plays a central role in the evaluation of experiments and experimental results” (Cambrosio and Keating 1988: 245). Collins’s definition of tacit knowledge includes manual and perceptual skills, such as “the ability to make a throat swab and see relevant shapes under the microscope” (1987: 336). These various theorists emphasize the importance of tacit knowledge, or acquired habits of ‘sensing-and-acting’ in transforming local specificities (laboratory apparatuses and materials) and formal rules (such as scientific protocols) into novel and explicit scientific statements about the world. According to the translation model of science put forward by Latour and Woolgar (1986; Latour 1987), tacit and embodied skills are a vital component of the chain of transformations between various forms of matter (reagents, raw materials), inscriptions (diagrams, marks, tables and curves), and explicit propositions (Callon 1995). Indeed, according to this model embodied and tacit knowledge enables the generation of meaningful semiotic elements (utterances and texts), from material elements. The production of knowledge, then, is dependent upon, and shaped by, the embodied ‘sensing-and-acting’ skills of scientists.

In this chapter I will argue that the embodied ‘sensing-and-acting’ capacities of the physiotherapists are essential to the work of the PMDS team. Importantly, the physiotherapists use these embodied sensing-and-acting skills to translate what I will call *momentary affects* into meaningful semiotics elements: they use their own acquired perceptual skills to decipher various, temporarily-induced bodily movements within their patients, which they then verbally articulate and/or inscribe in particular texts. The meaningful utterances and texts subsequently enable the team to confirm whether or not the patient is a good candidate DBS, and to help predict how that patient will respond to the therapy. Here, then, I will be adopting a model of clinical work that is similar to the translational model of scientific

knowledge production put forward by Latour and Woolgar (1986). Useful medical documents or clinically-useful propositions about the patient emerge from a chain of interactions (or an assemblage of heterogeneous elements) involving the embodied skills and knowledge of the physiotherapists, the body of the patient, a carefully arranged material environment, and the application of formal protocols

5.3 The clinician's body in medical sociology

Scholars within medical sociology and the sociology of health and illness have tended to focus on the bodies of patients and those subjected to clinical discourses and practices, rather than the bodies of those working within the health practices. In this regard, drawing on a flourishing of work within sociology more generally, scholars have analysed the body as a malleable marker of identity, a vehicle for particular types of lived experiences, a sexed and sexualized object used to oppress women or non-heterosexuals, and as the focus of various disciplinary practices aimed at creating governable subjects (Shilling 2007). It has been explored as a site of contestation between 'objective', technology-derived representations and the 'subjective' experiences of patients (Rhodes et al 1999), and as a patched-together assortment of various enactments (Mol 2002). Yet, there has been comparatively little work exploring the role of the clinician's body in clinical practice.

The exceptions can be roughly divided into two groups, each illustrating a different aspect of what has been called *body work*,¹³ or the corporeal work, conducted by health professionals. First, there are studies that have explored the *communicative body* of those working in health care. Here scholars have explored the way in which health professionals use their body to help encourage the compliance of patients within clinical interactions. Brown and colleagues (2011), for example, have explored how clinicians use their bodies to convey information to patients, usually as a complement to verbal language, within the context of gynae-oncology. For many of the patients included in the study, whether or not they trusted a clinician depended a great deal on the clinician's bodily actions and gestures. Particular forms of body movement and presentation inspired trust and confidence in patients, thus facilitating clinical practice. In a similar vein, Måseide (2011) noted

¹³ Generally the term 'body work' refers to work done to the body of others (Twigg et al 2011). Yet several authors (Brown et al 2011; Måseide 2011) have used the term to refer to the corporeal work conducted by health professionals. It is in this sense that I will use the term.

how clinicians used their own bodies to help instruct patients how to use and move their bodies during examinations. Respiratory physiological examinations, for example, require patients to physically interact with technical equipment in a precise (and challenging) fashion. In order to encourage patients to do this, clinicians would often use bodily gestures in addition to verbal instruction, and if this were done successfully, the interaction would generate a textual artefact that could subsequently be used to inform further clinical action. Måseide illustrated that communicative body work, therefore, was essential to ensuring the success of the examination, and suggests that clinical examinations can be seen as “mutually constituting processes between various agents, bodies and body modes” (2011: 297).

These studies suggest that the body is an important instrument for communicating with patients and thus enabling clinical interactions to produce a desired output. The second aspect of the body work explored by several scholars is what Moreira (2004) has referred to as *sensory reflexivity*. Sensory reflexivity refers to the sensing-and-acting habits acquired by health professionals via training and clinical experience; the learned perceptual skills and embodied dispositions that are often difficult to verbally articulate and communicate, but are nevertheless a vital component of clinical practice. Drawing on Merleau-Ponty’s work, Harris (2011) illustrates that conducting even the most routine, mundane clinical activities such as inserting a cannula requires a tactile competency that can only be acquired through bodily practice, and can easily be disrupted if, say, a new type of cannula is introduced. Perhaps the most thorough examination of this embodied sensing-and-acting within a clinical interaction is Moreira’s exploration of neurosurgical practice (2004). The neurosurgeons in Moreira’s study had, via training and clinical experience, carefully attuned their tactile and visual senses to particular phenomena within the fleshy bodies of their patients. Only by learning how to sensorially register these particularities within the patient could they then act upon them and thus conduct the surgery. Importantly, Moreira illustrates that these sensing-and-acting abilities of surgeons are *dependent upon a wider array of carefully arranged material and semiotic elements*. First, the patient had to be carefully prepared before surgery: medicated, shaved and physically positioned so as to expose specific body regions. And secondly, elements within the operating theatre, such as surgical tools, texts, lighting, and other theatre staff, were precisely arranged, thus creating a layered

space that, Moreira argues, enabled, channelled and constrained the actions of the surgeon. The carefully arranged material and semiotic elements enabled and endorsed particular actions; or to put this in another way, they created particular sensory affordances for the surgeon to act upon. Moreira points out, then, that both the surgeon and the patient are the *subject* of this wider surgical assemblage: the patient's body is configured to present particular sensory affordances, while simultaneously the surgeon is configured as a particular sensing-and-acting surgeon-body.

As these authors have demonstrated, clinical work is not something that is simply done to, or done with, a subjectified patient body, it is also something that is *done via*, or *done through* the bodies of those working within health care. Communicative body work and sensory reflexivity are elements of what could be called the craft work of clinical practice: the local and often ad-hoc work which brings together patients, various technological apparatuses and more formal or codified forms of knowledge (such as clinical protocols) in such a way that a diagnosis or assessment can be achieved, or a therapeutic intervention can be conducted. As we will see in this chapter the process of deciphering dystonia within the PMDS requires the physiotherapists to engage in both communicative body work and to utilize their particular, carefully honed sensing-and-acting capacities (or sensorial reflexivity). In order to conduct the Gross Motor Function Measure (GMFM) and the musculoskeletal screen, the physiotherapists use their own bodies to instruct and guide the patient on how to position and move their body in such a way that it presents particular opportunities to examine specific parts of the patient's motor system. In order to take advantage of these opportunities, the physiotherapists employ their tactile sensibility to 'feel' and thus identify spasticity, muscle weakness, contractures and dystonia. Importantly, as Moreira (2004) argues, this body work is enabled by a carefully constructed material and semiotic space.

5.4 Using the body to diagnose dystonia

A brief overview of the GMFM and muscular-skeletal screen

The physiotherapists use two assessment tools to identify dystonia and to attain some idea of its impact upon the posture and motor function of the patient. These are a manual musculoskeletal screening and a specific means of examining gross motor function called the 'Gross Motor Function Measure' (GMFM). Parts of both

of these assessments may be conducted during the initial interview with potential new patients, in which case they are used to help select appropriate DBS candidates. During subsequent pre-surgical baseline assessments, both the musculoskeletal screening and the GMFM will be conducted in full and the information they produce will be used to confirm that a patient is indeed an appropriate DBS candidate, and to help predict how that patient may respond to DBS.

Musculoskeletal screening can involve any number of standard examinations of muscle strength, joint movement, muscle bulk and reflexes. The intention of the screening is to evaluate a patient's motor system and locate abnormalities that are causing motor dysfunction. Various regions of a patient's body can be explored one-by-one and specific sets of examinations can enable the clinicians to decipher if an abnormality is located in a particular part of the peripheral motor system apparatus (such as muscles and neuro-muscular junctions) or the central motor system apparatus (pyramidal system, the basal ganglia, or the cerebellum) (Reeves and Swanson, 2008). Conducting many of the examinations requires the physiotherapist to engage in a great deal of physical work with the patient. They may be required to manually move a joint or place their body weight upon parts of the patient's body, and in many cases they must be able to 'feel' particular phenomena within the body of the patient. Particular manifestations of neurological pathology, for example, have a signature 'feel', but this is perceptible only if the patient's body is manipulated in a specific fashion. Within the PMDS the physiotherapists use neuromuscular screening to physically detect and locate spasticity, muscle weakness, contractures and dystonia. As we will see further on, conducting an effective musculoskeletal screening requires the physiotherapist to possess a carefully honed tactile sensibility.

The GMFM was developed in the 1980s specifically to assess children and young people with cerebral palsy (Russell et al. 1989). According to the authors it can be used to obtain detailed information on a child's motor skills, to measure motor skill changes over time, and as a means of assessing the impact of posture aides and braces. In order to conduct the examination the client must attempt a range of 'gross motor' movements, which include lying, rolling, sitting, crawling, kneeling, running and jumping, as prescribed by a GMFM manual (Russell et al. 2002). Specifically, the client must attempt 88 separate tasks, ranging from the very easy such as turning their head while laying their back, to the more difficult such as

jumping forward 30cm with both feet simultaneously. As this is done, the physiotherapists provide a score for each task using a four-point scale, where zero is 'does not initiate' and three is 'completes'. From these individual task scores an overall score is calculated. This reflects the client's motor function capability (what they can do), rather than their performance (what the child does do) in everyday settings. Importantly, in addition to quantifying a client's motor function, physiotherapists can use the tool for guiding clinical decision-making and intervention planning (Tiemann et al. 2005). As the assessment is carried out it can provide physiotherapists with an opportunity to interpret the possible causes of gross motor function impairment and this can then be used to decide upon an intervention.

It is in this respect as a guide for intervention planning that the GMFM is particularly useful for the PMDS. The therapists use it as a means of assessing and quantifying their patients' gross motor function, and along with the musculoskeletal screen, as a means of identifying the possible cause of patients' motor function impairment. As one of the physiotherapists explains, this is not a function of the tool itself; rather, it is a matter of the physiotherapist's interpretation:

The GMFM actually only gives you a number. It doesn't tell you why somebody can't do something. And that's what the professional who's doing it brings to the interpretation. I would be disappointed if somebody did a whole GMFM and couldn't tell me why they thought the child was having some difficulties. The professional carrying out the GMFM interprets as they go about it, from analyzing the quality of movement, and then linking that to the [muscle screening] - if I know a child has weakness around the hips, it wouldn't surprise me that they'd have trouble standing on one leg. (Physiotherapist 1, interview).

Together the musculoskeletal screen and the GMFM enable the PMDS physiotherapists to 'decipher' dystonia from other manifestations of neurological pathology, and to produce an overall picture of how each manifestation is impacting upon a patient's gross motor function. As one physiotherapist indicates, this information enables the team to assess the suitability of DBS for that patient:

And it will give us an idea of what they're able to do, what they're not able to do and how the dystonia is preventing them doing something, or whether it's actually weakness, because we need to decipher if they're unable [for example] to stand up,

is it the dystonia that's impacting that? Or is it more weakness? And then obviously from our clinical experience, we know that DBS isn't going to directly influence weakness. So it's just kind of deciphering. (Physiotherapist 2, interview)

In order to successfully conduct both the musculoskeletal screen and the GMFM, the physiotherapists use a range of tools and props. As the following section will illustrate, these tools and props constitute part of a material terrain that configures particular interactions between the bodies of the physiotherapists and the patient, enabling the generation of sought-after clinical information. In order to explore this in some detail, we will follow a specific case: Carl, a 16 year old patient with secondary dystonia. Carl is accompanied by his mother, and the assessments are conducted by both PMDS therapists.

The importance of spatial organization: Constructing a material terrain

The musculoskeletal screen and the GMFM take place in the hospital gymnasium. Importantly for the physiotherapists, the gymnasium is large enough with sufficient open space for the patient to perform various GMFM tasks (one task, for example, requires the patient to run ten metres in a straight line). The gymnasium also contains adjustable couches and benches, height-adjustable desks, mats, several inflated balls of various sizes and an area that has been delineated with a pattern of floor markings (see figure 5.1, page 140).

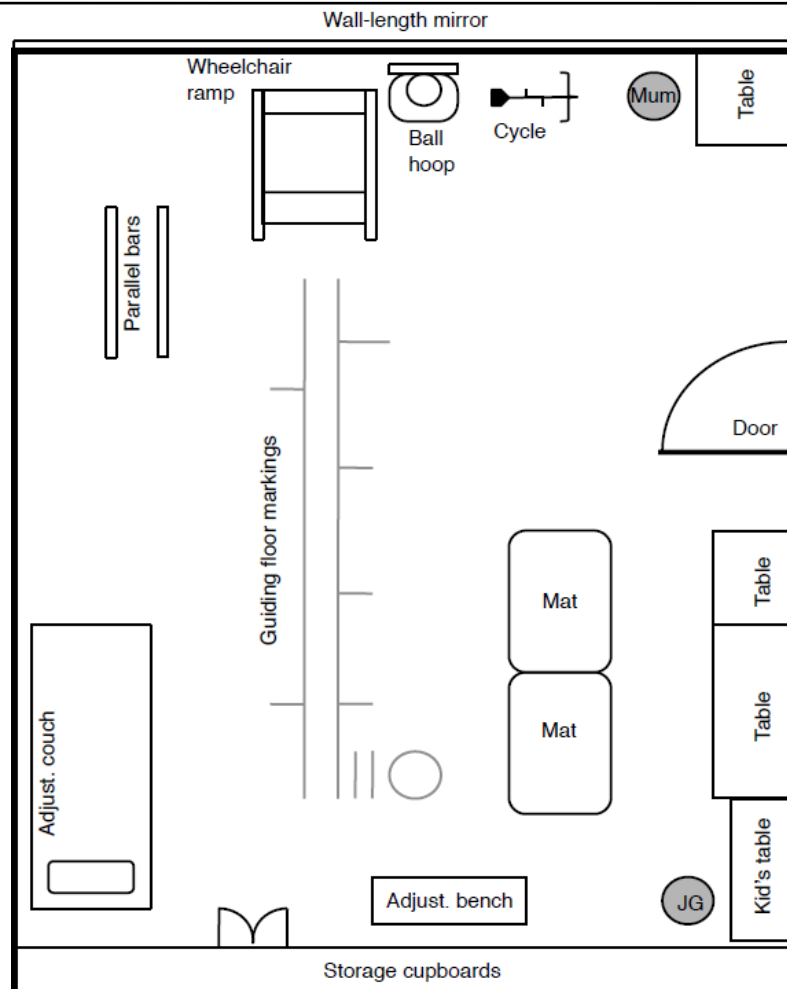
Before Carl's assessment begins, the physiotherapists set about adjusting and arranging many of the objects within the gymnasium, creating a material spatial configuration in which the musculoskeletal examination and GMFM can be conducted. Aspects of this resulting distribution of material objects are prescribed by the GMFM manual are therefore (ideally) uniform across all GMFM assessments. As the physiotherapist states:

The GMFM is quite defined about having something at waist height and defines what there is. Various height adjustable benches and tabletops and all those kinds of things [are required] (Physiotherapist 1, interview)

Thus, just prior to beginning Carl's assessment, one of the physiotherapists asks him to stand next to the couch which she then adjusts so that it is at his waist height. The bench is also adjusted so that as Carl sits on it his feet will be placed squarely

on the ground. Meanwhile the other physiotherapist pulls two floor mats together and places them nearby, thus providing several metres of padded floor space.

Figure 5.1: Gymnasium containing objects used during the GMFM and musculoskeletal screen (The ‘material terrain’).



Some elements within the gymnasium have been permanently arranged in accordance with the GMFM manual. The most obvious example of this is the set of guiding floor markings, a series of lines of various lengths and a circle which have been painted on the floor in the middle of the gym. These can be used to help guide the patient perform various GMFM tasks such as walk in a straight line or jump a specific distance. Rather than having to mark out lines and distances during each examination, the physiotherapist arranged for a set of guiding markings to be painted permanently on the floor of the gym. During an examination, then, a

patient can simply be instructed to ‘jump from inside the circle to the line’. As the physiotherapist states:

The GMF are the main lines that are down there... I mean the idea [of the markings is] that there’s quite set criteria in the test that the patient has to adhere to. For instance, if they walk along the line, they have to have their foot on the line, they can’t step off. So having the facility set up ready to go. And also having them predetermined, it means we’re all using the same marks each time. Before we had the lines painted on, we often had to push two mats together and measure it every time and get children to walk between the mats... But you can imagine there is an error that would potentially affect the child’s score. So it’s obviously its faster for us and more professional looking, but it also means all the professionals are using exactly the same test criteria to score the children on. So that’s the advantage of those. (Physiotherapist 1, interview).

These guiding floor markings, along with the adjusted bench and couch and the padded floor mats, create part of a material terrain, a spatial organization of objects which enables the GMFM and musculoskeletal screen to take place. As we will see this terrain permits particular forms of body work as it constrains, prompts, guides and channels the actions and interactions of the physiotherapists and the patient. Specifically, we will see that this material terrain participates in the production of *momentary affects* which are subsequently translated by the physiotherapists into utterances and texts.

Communicative body work: from text and words to corporeal movement

Carl’s assessment begins with the GMFM. From the very start it is apparent that the examination takes place in a terrain that is both material *and semiotic*: as well as the material objects noted above, there is considerable verbal communication, various texts are read out aloud and other texts are created. For the GMFM to precede and generate sought-after clinical information, Carl must perform each of the 88 tasks in the manner instructed by the GMFM manual. It is the role of the physiotherapists to translate the events as described within the text of the manual into actual events within the gymnasium. Much of this is done via verbal instruction, but these instructions are not word-for-word those of the manual; rather, they are the physiotherapists’ interpretation, translated into language that is more appropriate for a 16 year old patient. Words such as ‘prone’ and ‘supine’, for

example, are translated as ‘lie flat on your belly’ or ‘lie flat on your back’. At one point the manual stipulates that it is imperative that the child attempt as well as they can to complete each task. The physiotherapist explains this to Carl as ‘getting points:’

Carl: What if I can’t do [a task]?

PT1: It is okay. We are just screening. We are just trying to find out what you can and can’t do...It’s about getting as many points as you can.

The physiotherapists do not rely on verbal instructions alone, however. In order to ensure that the events within the gymnasium proceed as stipulated by the GMFM they use their own bodies to communicate the instructions within the manual to Carl. Indeed for many of the tasks they use both verbal and corporeal communication to instruct Carl how to position and move his body, often in reference to the objects that constitute the material terrain. Below is an example where the more junior of the two physiotherapists (PT2) uses her body to instruct Carl on how to perform ‘Task 41’, which requires moving from ‘prone’ to ‘4-point, weight on hands and knees’. (The other physiotherapist watches and provides a score for Carl’s attempt):

PT2: I want you to lie down on your front, flat on the mat facing me and then get up on all fours. Like this [She lies face down on the floor flat (prone), and then picks herself up so that she is resting on her knees and hands (4-point)]

Carl: *[Repeats the task without noticeable difficulty]*

Similarly, ‘Task 63’ requires the patient to move from standing position to a squatting position without using their arms. Again the physiotherapist uses her body and her own verbal translation of the text to instruct Carl:

PT2: Now you have to do a squat. Let me show you – you have to get your bottom lower than your knee. *[From an upright position, she slowly bends her knees, with her arms extended out in front of her for balance until she is in a squatting position]*.

Carl: Does it matter if your bottom touches the ground?

PT2: No, just as long as you don't fall back on it.

Carl: *[Completes the task with noticeable difficulty]*.

Here the physiotherapist uses her body to demonstrate how the task should be performed. In effect she embodies a small part of the GMFM text; she enacts it with the intention that Carl will mimic her and do the same. Throughout the assessment the physiotherapists use their bodies in this way; as a means of corporeal communication that will, ideally, enable the descriptions within GMFM text to be enacted by the corporeal movements of the patient.

Generally throughout the assessment this corporeal communication and verbal communication are used together as a means of complementing one another. In the process, both bodily movements and words can acquire specific meaning within the assessment. Indeed, verbal utterances are indexical to the physiotherapist's body movements and the other material and discursive elements that constitute the diagnostic space. Examples of this are the physiotherapist's instructions on how to perform 'Task 45', which requires the patient to 'crawl reciprocally forward for 1.8m':

PT2: The first thing we are going to do is the commando crawl. Get down on that mat for me. You need to pull yourself along and keep your body very low, to the end of the second mat [which is approximately a distance of 1.8m].

Carl: *[Looks puzzled]*.

PT2: Okay, this is what I mean. [She then gets down on the floor so that she is resting on her stomach and elbows. She then uses her elbows and knees to propel herself forward.] Remember to keep low.

Carl: *[Carl, without speaking, gets down on the floor and does this same with some difficulty]*

PT 2: Remember to keep low!

As she does this her utterances acquired specific meaning for Carl. The 'commando crawl' and 'keeping low', descriptions that initially caused confusion, are equated with specific corporal form and movement; they acquire specific referents within the assessment. By using her body to complement verbal instructions, she is, in effect, participating in the production a meaningful semiotic world. Performing each task involves a series of translations from semiotic elements to corporeal-material

elements within gymnasium. Parts of the GMFM text are articulated as verbal utterances or bodily movements by the physiotherapist, and if the patient is compliant, he will position and move his own body as best he can in accordance with these verbal and bodily articulations of the text.

The result of this chain of transmutations, then, is that the patient will adopt a series of GMFM prescribed body postures and movements. Importantly these postures and movements are prescribed in relation to other material elements of the assessment; the patient is channelled into a series of specific relations with other objects or the guiding lines on the floor. Task 47 requires the patient to climb on hands and knees up four steps, and tasks 26 and 27 require the patient, seated on the mat, to reach for a toy placed 45 degrees behind their left and right sides. These resulting *body-object ensembles* configure the patient's body in such a way that enables the physiotherapists to extract useful clinical information: The patient's body is coaxed into specific positions that enable either one of the physiotherapists to scrutinize particular aspects of the patient's motor function.

To put this in another way, the ensemble produces particular *momentary affects*: temporary corporeal phenomena that are registered by (and thus 'affect') the observant physiotherapists. Examples of momentary affects include Carl's inability to move his body to perform a set task, or as we will see further on, specific bodily movements that are registered via the carefully honed tactile skills of the physiotherapists. These momentary affects are generated by a collective of elements: it involves the careful arrangement of material objects, the compliant patient, and the active and attentive physiotherapists.¹⁴

Importantly, these momentary affects will be captured and translated into more durable modes of representation such as a text. As the following examples show, while the junior physiotherapist (PT2) instructs Carl, the other physiotherapist (PT1) watches carefully and provides a score for his performance on the GMFM score sheet. The first example, Task 72, requires the patient to walk forward ten steps carrying a large object with two hands.

¹⁴ Or to use material semiotics terminology, we could say that momentary affects are particular capacities for interaction which are enacted by the carefully arranged assemblage involving bodies and objects within the gymnasium.

PT2: Okay, now I want you to walk holding this ball. Do you remember these [inflatable balls]? I was an 80s child and they were common in my time. Now, let's use these lines on the floor. Walk between them all the way to the end.

Carl: *[Picks up the large, inflatable pink ball which has two small handles on either side and walks to the end of the guiding lines. Despite appearing a little unsteady he does this without any obvious difficulty]*

PT1: Easy peazy! No problems there *[She scribbles a 3 on the GMFM score sheet.]*

Here we see the translation of corporeal movement and semiotic elements within the assessment. In this case Carl's bodily movements, movements that entail negotiating other material elements within the gymnasium, are translated by the physiotherapist into a number (3) that is subsequently inscribed on the score sheet adjacent to the specific task number (72). This process creates a text with a specific meaning that derives from the relationship between the assigned scores and the task numbers. In this way the momentary affects generated within the ensembles are translated into a more durable, textual representation of the patient's motor capabilities.

Task 56 requires the patient to stand upright and still for three seconds. Tasks 55 and 54 require the patient to stand upright, holding on to a bench with one hand and lift the right foot off the ground, and then the left foot of the ground. Again, PT2 provides instructions while PT1 makes a note of the score:

PT2: Now, stand next to the couch. Just stand there for 20 seconds, as still as you can.

Carl: *[Stands next to the couch, but his shaking body makes it difficult for him to keep balance. Several times he has to adjust his feet to keep himself from falling].*

PT1: How much effort does it require to stand still?

Carl: It is hard to stand still. I can't stand still at all.

PT2: Now, put your hand on the couch, and try and see if you can lift the alternate foot.

Carl: *[Does this with the left foot with some effort]...*

PT2: One, two, three, well done.

Carl: *[Tries with the right foot, but keeps having to place his second hand on the bench to stop himself from falling].*

- PT1: Carl, would you mind taking off your t-shirt? I want to see what is happening with your spine.
- PT2 *[According to the GMFM manual] you get three goes on each foot. Try standing on it. One, two, three, four, five...*
- Carl: This is the problem, when I try and stand on this [right] foot.
- PT2: Your left foot moves [flails] around and throws you off balance, doesn't it.
- Carl: Yes.

This particular ensemble has enabled the physiotherapists to capture useful clinical information in addition to a numerical GMFM score. The shape of the couch enables Carl to attempt to stand upright, first on one leg and then on the other as instructed by the physiotherapists, and this has led to the generation of two notable momentary affects: his twitching spine and flailing left foot. The physiotherapists provide a brief description of these in Carl's notes – again, momentary affects are translated into a more durable form. At a later time these notes will help inform the team's prediction of how Carl will respond to DBS.

Sensing and acting: from corporeal movement to text and words

Once the GMFM is completed, Carl and the physiotherapists have a short break before beginning the musculoskeletal screen. By this stage the physiotherapists have an idea of which particular areas of the motor system are causing difficulties for Carl, and this information is used to decide which areas of his musculoskeletal system will be screened. Carl's shoulders, pelvis hips, knees and ankles will be screened for range of movement, muscle weakness, spasticity, and contractures, and this will, ideally, enable the physiotherapists to decipher the presence of dystonic movements.

The screen takes place on the adjustable couch. As it progresses Carl is instructed to adopt a number of body-positions, each enabling a particular aspect of the musculoskeletal system to be screened. Much like the body-object ensembles of the GMFM, in each one of these positions the material form of the couch participates in moulding and supporting the patient's body in such a way that it can be scrutinized: the adjusted couch participates in configuring the patient's body so that it will generate momentary affects for the physiotherapists. However, unlike the GMFM, the physiotherapists themselves become corporeally involved in the

ensemble. Indeed, the musculoskeletal screen constitutes a *body–body–object ensemble*. Here is an example of one such ensemble during which the physiotherapist is examining the range of movement of the hip joints:

PT2: I will see if there is any asymmetry... [Directed at PT1]. Now, Carl, lie in your tummy on the couch.

Carl: *[Does as is instructed]*

PT2: *[Stands at the base of the couch and holds both of Carl's ankles, one in each hand. She then splays his legs apart in one steady movement, before bringing them back together until they are slightly crossed over].*

Within these ensembles the physiotherapist's body serves two purposes. The first is as a means of physically manipulating Carl's body, as illustrated above, in such a way that it will divulge particular information. When testing for range of movement or smoothness of movement (which can be used to detect spasticity) the patient is instructed to remain passive and the physiotherapist will support and move a part of the patient's body in a specific fashion. The physiotherapist is actively using her own physical body, then, to prompt the patient's body to divulge useful clinical information. Standard techniques of musculoskeletal screening, outlined in various user manuals and learned by physiotherapists as part of their training, describe how the physiotherapist should use their body in this way. For example, many examinations require the physiotherapist to apply 'overpressure' to a particular joint, which involves gently flexing or extending a joint beyond its usual range. While doing this the physiotherapist is instructed to "be in a comfortable position", use their "body weight or the upper trunk to produce the force, rather than the intrinsic muscles of the hand, which can be uncomfortable for the patient", and in order to accurately direct this force, ensure that their "forearm is positioned in line with the direction of the force". All force should be "applied slowly and smoothly to the end of the available range" (Ryder 2011: 9).

In some cases the patient will take a more active role: when testing for muscle weakness, for example, a patient will be instructed to attempt to move a limb while the physiotherapist uses her own body weight to create resistance. Here is a specific example from Carl's assessment. Carl is seated upright on the couch with his legs dangling off one end. The physiotherapist is exploring his muscle strength in his quadriceps:

PT2: Carl, I'm going to try and hold your feet down and I want you to try as hard as you can to extend your leg. *[She moves to the end of the couch and holds both his feet, one in each hand].*

Carl: *[Slowly extends his legs, with noticeable effort, while the PT exerts pressure]*

PT2: *[Talking to PT1]* There is a bit of loss at inner range – I think it was the jerkiness.

PT1: That fits with the movement disorder.

This example also illustrates the second purpose of the physiotherapist's body within the ensemble: to physically register particular momentary affects generated by the moulding and manipulating of Carl's body. As various physical manipulations take place the physiotherapist uses a carefully honed tactile sensibility to assess muscle strength, smoothness of movement, and movement range, and thus help identify motor system abnormalities. Here then, the body-body-object ensembles are enacting motor system abnormalities as particular bodily sensations. During an interview the junior physiotherapist described how particular abnormalities 'feel' when she is conducting a screen with a patient.

If you take a knee, to see if a child or a young person has spasticity, you bend the knee very quickly you'll suddenly get like a bony block, it will feel like a bony block but it's not a bony block, but it's like a catch. And then it will release and you will be able to bend it a bit further. Now that is spasticity. Whereas if you have the leg that's straight and you're about to bend it and you struggle to bend it throughout range, but you don't get one of these fast bends where you get a stop, then that's high tone... Sometimes you might get a leg and bend it and you're feeling any resistance but it's really floppy, so you would call that as low tone. And then other times you'll try and bend a knee and you can't flipping bend it because the quadriceps are kicking in, which is dystonia, it's literally kicking in and stopping you bending [their knee]. It's completely rigid and you can't bend it
(Physiotherapist 2, interview)

Indeed as the physiotherapist points out, various motor system abnormalities have their own 'signature' feel. This "bony block that is not a bony block" sensation of spasticity, which can only be detected when the muscles are passively moved at high

velocity, is often described as the ‘clasp-knife’ response (due to the similarity with the rapid increase of, and then rapid decrease of, resistance when closing a folding pocket knife) (Burke et al. 1970). Similarly, the difficulty in bending a knee through its range of movement due to high tone (or hypertonia) is been referred to as ‘lead-pipe rigidity’. These are, of course, descriptions of specific, collectively generated momentary affects.

During Carl’s assessment the physiotherapists are drawing upon a sensorial understanding of the motor system and its abnormalities. This tactile capability has been acquired during their professional training and has no doubt been honed in clinical practice. In effect, they have acquired a body that is tuned to particular sensorial affordances, just as the neurosurgeons described by Moreira (2004) become sensitive to numerous visual and tactile sensorial differences within an operating theatre. To borrow Latour’s parlance, they possess a body that has learnt to be affected by and moved by a set of contrasts that many other bodies would fail to register (Latour 2004). And importantly, as we have seen above it is only within specific body-body-object ensembles that this sensorial capability is realized: the body of the physiotherapist is, in effect, configured as a clinical information-gathering apparatus by the specific corporal-material elements that constitute the ensemble. Of course it may not always be clear to the physiotherapist what it is that they are sensing, in which case they may ask the patient for some clarification. At one stage during Carl’s assessment, for example, the physiotherapist asks Carl “are you ticklish or is this the involuntary movement?”, to which Carl replied that it was the former. And, at another point when Carl is pushing up on his toes while leaning against the couch, he is asked to which of his lower legs feel weak, to which Carl replies “both”.

Indeed verbal communication, whether it be instructions or questions directed at Carl, are necessary for the screening process to proceed smoothly. But throughout the screening there is also a great deal of talk between the physiotherapists. The more junior physiotherapist who is leading the screening vocally articulates her tactile sensations to the other physiotherapist. For example, during an exam of the hip region:

PT2: I’m getting intermittent pulling, twitching at the abduction.

And again, during another examination of the hip which requires Carl to lie on his back, holding and his knee in a flexed position while the physiotherapist splays his legs:

PT2: I got some resistance there, and the abductor switched on.

PT1: I think it is those intermittent jerks.

And during an examination of the range of motion of his left knee:

PT2: Ahh – there is a catch here.

Here, then, the physiotherapists are again adding a meaningful layer of semiotic elements to the assessment activities. Groups of words are used to articulate particular sensations (or momentary affects) that as a result acquire a discursive existence as ‘intermittent jerks’, a ‘catch’, or ‘some resistance’. Specific collectively generated momentary affects are therefore translated into utterances. These utterances are then inscribed in text: both physiotherapists jot down some of these utterances along with their interpretations (‘muscle weakness’ ‘spasticity’ and so on) in handwritten notes, so that by the end of the screening they have produced a document that provides a textual picture of various aspects of the Carl’s motor systems and its abnormalities. There has been, therefore, a series of transmutations from physical phenomenon to utterance to text, in which the embodied knowledge of the physiotherapist, her ability to physically mould and manipulate the patient and her honed tactile sensibility have been essential.

At the end of Carl’s screening the physiotherapists explain their findings to both him and his mother. He does indeed have dystonic movement that affect the gross motor function in parts of his upper body, and in his left leg, and he has dystonic posturing in his feet. But, the main problem for Carl, the physiotherapists inform him, is muscle weakness around the pelvis.

PT1: Carl, the hip abductors and hip extensors are an issue. The main issues are around your pelvis, it is due to muscle weakness. Maybe we could teach you to do some exercise that could help you there.

5.5 Discussion: the body as an inscription device

If we are to avoid reifying a Cartesian-like division where the patient body is the subject of a disembodied medical discourse, it is necessary to explore how health professionals use their own bodies in everyday clinical practice. As the example presented here illustrates, the body of the patient is entwined in clinical practices that that are done with, or done via, the body of the clinician. Indeed, the physiotherapists demonstrate what could be called an embodied knowledge of the motor system and motor disorders: a somatic memory and awareness of how to corporeally engage with patients, and how aspects of a motor disorder or a ‘normal’ motor system should feel, or visually appear, when the patient’s body is placed in particular positions or made to move in a particular way. Many elements of the physiotherapists’ somatic awareness of the motor system may be expressible in language (the ‘clasp-knife’ description of the tactile sensation of spasticity is an example of this) but this is not a knowledge that resides entirely within a cognitive domain and it is not, then, wholly and fundamentally shaped by the reflective deliberations of the mind. Merleau-Ponty’s notion of *corporeal schema*, as articulated by Crossley (2001), is useful here. Crossley describes the corporeal schema as learned embodied ‘know-how’. It is a pre-reflective understanding of how to move the body and register the surrounding world: a “perspectival grasp upon the world from the ‘point of view’ of the body” (2001: 102) that is inseparable from practical action and enables reflective thought. Within the PMDS the corporeal schema of the physiotherapists, their ability to use their own bodies to manipulate the body of the patient so that they can then register and differentiate the various manifestations of neurological pathology, is vital for identifying DBS candidates and helping to predict how individual patients may respond to DBS therapy. For the PMDS, therefore, the physiotherapists’ embodied knowledge and corporal skills are an important component in the process of creating and operating a DBS service.

Merleau-Ponty’s notion of corporeal schema is intended to counter the Cartesian model of knowledge production. The example presented here suggests that cognitive deliberations are just one component in the production of clinically useful knowledge regarding a patient (and thus just one component of the processes that constitute ‘innovation’). Indeed, it is perhaps more useful to describe such clinical knowledge as an emergent product. It emerges from a series of coordinated interactions involving various heterogeneous elements and cannot be attributed to

the activities of any one of these elements (such as the sceptical and reasonable deliberations of mind of the clinician). In Carl's case the final GMFM score and the physiotherapists' written notes, which together contain useful clinical information about Carl's motor system, are an example of this. Their production required a careful arrangement of material objects and technical apparatuses (such as the adjustable couch and the guiding floor markings), the afflicted body of the patient, the embodied knowledge of clinicians, and the application of formal protocols (such as the GMFM). These ensembles produced the enactments from which more durable clinical information could be obtained. The resulting clinical knowledge about Carl's motor system cannot be attributed to any one of the elements within these interactions: rather, it is the consequence of all the various elements as they jostle, shape, constrain and enable one another.¹⁵

Latour (1987) has argued that the production of scientific knowledge within the laboratory involves a series of transformations between various states of physical matter, and between physical matter and textual inscriptions. He has termed those apparatuses that transform physical matter into the textual inscriptions (graphs, lines, and tables) that subsequently become the basis of scientific propositions as inscription devices. (1987: 68). We have seen that the assessment of gross motor function involves a similar series of translations between material and semiotic elements, the product of which is a text; a set of inscriptions and interpretations that together form a durable and circulate-able representation of the patient's motor system. This process of inscription, however, is not conducted by a technological device as in Latour's conception of the laboratory. Rather, it is the trained and highly configured body of the physiotherapist that enables this

¹⁵ In this chapter we have focused exclusively on the body work of the physiotherapists. Of course, other members of the PMDS team also have their particular corporal schema, or an embodied knowledge of how to use their bodies within clinical contexts, that reflects their own professional trajectories. The neurologists, for example, have no doubt acquired a perceptual skill that enables them to interpret the various shades of grey within an MRI image, and the speech and language therapist may utilize an aural sensibility that is not possessed by other member of the team. While various elements of embodied knowledge and some corporeal skills will be shared by all members of the team, it is reasonable to suggest that the PMDS is characterized by multiple clinician bodies, each with their own acquired habits of sensing-and-acting, and each capable of engaging in particular forms of body work with patients.

translation to occur, and in this regard, it is appropriate to say that by using their bodies in this way, *the physiotherapists are acting as an inscription device*. Indeed, this inscription work cannot be delegated to a non-human technological apparatus, because no technology is capable of distinguishing dystonia from other manifestations of neurological pathology.

In the following chapter we will see how the clinical knowledge produced during the GMFM and muscular screen are, along with other knowledge and considerations, utilised during a goal setting session with Carl. The representation of his motor system as inscribed in the physiotherapists' notes is used as a means of predicting how Carl will respond to DBS, and thus as means of informing him and his mother of what they can expect after the DBS system has been implanted and activated. Interestingly, we will see how this knowledge helps them to manage a challenge that results from a particular socio-political trend: the emergence of shared-decision making in healthcare.

6 Managing the expectations of patients & families

We're dealing with people's hopes and expectations. They often come to us with very raised hopes that we are the team that can offer something new and life changing, and then obviously in some of our cases, we are actually breaking the news to them that the outcomes we expect are not what they were hoping for. It means that they feel a loss all over again (Physiotherapist, interview).

6.1 Introduction: the challenge of managing expectations

Families arriving at the PMDS for the first time have varying degrees of knowledge about deep brain stimulation. Many families have made use of the Internet to access information and arrive at the hospital with “reams of paper and are very knowledgeable about [DBS],” while other families arrive with “absolutely no knowledge whatsoever” (Clinical research fellow, interview). Because of the novelty of DBS, however, the information available to patients (and indeed health professionals) concerning the effectiveness of DBS as a means of managing dystonia is limited. Many of those families that do undertake research into DBS have obtained information from the popular media which has tended to focus almost exclusively on those clinical cases that have done very well (particularly cases where a wheelchair bound child has regained an ability to walk unaided) thus giving an over-optimistic portrayal of DBS therapy (Racine, et al. 2007). This creates a challenge for the team:

There's often misperceptions, the problem is the press reports the case studies that do well, so there can be perception that DBS will get my child to walk. Because actually that's what you read about in the press... We had one child who six weeks after his surgery, was in the press, starting to walk again. And that's a very worrying thing for us... Managing the expectations - that can become very difficult. (Clinical research fellow, interview).

It is not uncommon, then for families to arrive at the PMDS with unrealistic expectations about the effectiveness of DBS in managing the symptoms of dystonia. No doubt this ‘false hope’ is exacerbated by the vulnerability and desperation of some of the severely affected patients and their families (Marks et al. 2009). Generally by the time families are being considered for DBS, they have already tried

a range of other treatment options without meaningful success, and DBS represents something of a last hope for improving the child's quality of life.

The challenge is complicated by the lack of a comprehensive body of medical literature that can be used to predict how individual patients will respond to the therapy. A nascent body of literature does provide some indication of the efficacy of using DBS to manage dystonia. Reports of small clinical studies involving mixed cohorts of adults and children with generalized primary dystonia state that, on average, subjects will experience a 50% improvement in motor symptoms, and that one third will experience at least an 75% improvement (Vidailhet et al. 2005). Improvements in patients with secondary dystonia appear less dramatic, averaging 24%, with a great deal of variation between individual patients (from 0% to 71%) (McClelland et al. 2011). The PMDS team does use these figures to provide some guidance to families who are considering DBS: during a "DBS information session" the specialist nurse will present families with these percentages ("everyone wants to know the percentages!") but she also emphasizes to families that children will fall outside these ranges. Generally, however, the literature is considered of minimal use in predicting the outcomes of individual patients and thus in guiding the expectations of specific families. As we will see in the following chapter there is scepticism among the team and other DBS centres about the specific scales used to measure clinical improvement and generate these official percentages (Gimeno et al. 2012; Marks et al. 2009), and most of the PMDS patients have secondary dystonia, thus falling within the group for which the improvement figures are highly variable and therefore almost meaningless.

This presents a major challenge for the team: how can the expectations of desperate families be managed when the literature provides so little guidance on predicting how an individual patient is likely to respond? Solving this dilemma and ensuring that families have realistic expectations about the benefits of DBS is important for several reasons. Firstly, it helps protect the reputation of the team by reducing the chances that they will be accused of failing to deliver an (unrealistic) clinical result. As Dr Martin puts it: "If you paint the most optimistic picture, you are setting yourself up for certain failure." (Team meeting). Secondly, in order for families to make an informed decision about whether or not to proceed with the highly invasive procedure, it is necessary for them to comprehend the likely consequences of DBS therapy. In an era when facilitating patients' autonomy and

enabling patients' capacity for decision making are heralded as fundamental to ethical medical practice, managing the expectations of patients can be seen as *an ethical challenge*. Indeed, the ethicists Bell and colleagues (2009) have argued that conveying the risks and benefits to vulnerable patients in order to ensure that informed consent can be obtained is one of the key ethical challenges associated with all deep brain stimulation therapies. In this chapter we will see how the team attempts to manage this particular ethical challenge of managing the expectations of patients, and thus obtain their informed consent. The chapter will illustrate how members of the PMDS team, specifically the occupational therapist and one of the physiotherapists, use a tool known as the Canadian Occupational Performance Measure (COPM) to convey the potential benefits of DBS to families. This tool has been adopted from occupational therapy; it was designed to facilitate a patient-centred approach to healthcare, and its introduction into paediatric neurology and the specialty of deep brain stimulation by the PMDS team is novel. It therefore represents an innovative attempt to manage one of the challenges associated with the introduction of new medical therapies: managing patient expectations in the absence of a useful body of literature. As we will see, the COPM facilitates a particular mode of patient decision making. Before we explore this tool and how it is employed by the team, it is necessary to provide some context on a socio-political trend within healthcare that promotes patient involvement in decision-making and patient autonomy in medical practice. This context will enable us to see the historical circumstances that have brought about the need for such tools, and it will also enable us to see why the consequences of implementing this tool in clinical practice are of interest to sociology.

6.2 Decision making and patient autonomy in healthcare

Over the last one hundred years or so there has been a transformation in the decision-making role of patients within medical contexts. In the early part of the 20th century, an era dominated by what commentators often refer to as the 'paternalistic' approach, it was health professionals (or more specifically, male doctors and surgeons) who decided what course of action was most appropriate for their patients (Coulter et al. 1998). This approach assumed that both the health professional and the patient had the same goals but that only the doctor was sufficiently informed to decide how to achieve these goals. In effect, the views and

preferences of these patients were considered largely irrelevant. Over the course of the century, however, new approaches to decision making have emerged accompanied by much-banded notions of ‘patient choice’ and ‘patient autonomy’. According to this socio-political trend, the role of the health professional is to communicate their clinical knowledge and their professional opinion effectively to the patient, so that the latter can be sufficiently informed to decide. Decision-making is the prerogative of the patient, and the health professional is expected to ensure that the patient’s expectations are not unrealistic.

There is still considerable variation in the level of patient-involvement in decision-making in actual contemporary clinical practice.¹⁶ Generally, however, policy makers and bioethicists are endorsing those that entail a greater level of patient involvement. NHS policy, for example, stipulates that patients should be given choice of hospitals, should be encouraged to participate as ‘partners’ in treatment decisions, and should also be seen as users who can meaningfully contribute to the development of health services (*NHS England commitment to shared decision making 2013*)

Various arguments have been put forward to explain the movement away from paternalistic decision making approaches and the subsequent embracing of a discourse of consumer choice. For example, Annandale (2002) suggests that it is useful to frame the emergence of patient choice discourse as a manifestation of what Beck has referred to ‘reflexive modernity’, where new parameters of risk and uncertainty permeate everyday life. In such conditions individuals become more aware of the fallibility of authority and ‘established’ knowledge, and thus become more critical. (In medical contexts, this awareness has no doubt been facilitated by media coverage of various medical scandals that have indicated that the goals of the medical professionals did not always align with those of their patients.)

¹⁶ Commentators have defined three models of patient involvement in decision making in clinical contexts (Morgan 2008). The first, ‘*professional choice*’, is very much synonymous with the paternalistic approach of previous times, where decisions are made by solely by health professionals. The second, ‘*shared decision making*’, refers to the sharing of information between health professionals and the patient, and both parties then decide upon a course of decision making together. And the third, ‘*consumer choice*’, is where health professionals dispense information to autonomous patient-consumers, who then decide on a course of action according to their own goals and values. As Morgan (2008) points out, all three of these approaches to decision making occur in a contemporary clinical practice, but seldom in a pure form.

Empowerment of the individual is at the heart of this reflexive modernity, and the language of consumerism fits in with this (Annandale 2002). Accordingly, individuals are encouraged to assess benefits and risks and reflexively choose a course of action that aligns with their own goals and values, whether they be at the supermarket or in a clinical context. In a world characterized by risk and fallibility, the patient has been framed as an active consumer, capable of appraising and deciding upon the course of action that will best achieve his or her aims.

This has no doubt been facilitated by the emergence and increasing authority of the field of bioethics which has emphasised the importance of patient autonomy. Bioethics as a distinct intellectual pursuit had its birth in the US during the 1970s. In light of a series of public medical controversies, early proponents of the field wanted to provide some guidance to health professionals working in ethically problematic situations. Philosophers (bioethicists at that time were predominately philosophers or theologians) attempted to systematize bioethics by developing a set of principles that could be applied in any such situation by health professionals without training in ethics or philosophy. Beauchamp and Childress's *Principles of Biomedical Ethics* (1977) is by far the most influential product of this. The four 'principles' outlined by Beauchamp and Childress (respect for autonomy, nonmaleficence, beneficence and justice) have become the standard toolkit when engaging with ethical issues in medicine and biomedical science in both the UK and US. (Wolpe 1998). Although the authors have emphasized that no one principle should be considered a priori more important than any others, in the process of being incorporated into actual health care practices the principle of autonomy has become the most dominant. Wolpe (1998) argues that it has become the default principle; the principle that is appealed to when two or more principles may come into conflict (such as autonomy and justice).

The principle of respect for autonomy stipulates that patients can decide upon a course of action with an understanding of what that action would entail and without undue controlling influences that might dictate their decision. This necessitates, they argue, that health professionals disclose information in a way that is accessible to patients while checking that patients comprehend what is being said to them (Beauchamp and Childress 2001). These are the elements of informed consent, and the informed consent process is the means by which the autonomy of the patient can upheld in clinical practice.

Wolpe (1998) provides several reasons for the emerging dominance of autonomy over other principles. First, it resonates with the atmosphere of liberal individualism that has been so dominant, particularly in the US, for the last fifty years. Patient autonomy aligns with notions of self-governance, liberty, individual choice and freedom, often heralded as the foundational values of the US. Secondly, autonomy is relatively easy to codify and implement within institutional settings via the process of informed consent. In contemporary clinical settings, which are inevitably large and bureaucratic and where patients and health professionals are often strangers to one another, the informed consent process has been institutionalised as the means of establishing some sort of trust. Wolpe argues that in an era where structural impediments prevent more informal bonds between health professionals and patients, informed consent, much like any contractual arrangement, aims to ensure that both parties satisfy their obligations to one another: health professionals will disclose the risks and benefits of a course of action and refrain from placing undue pressure or presenting misleading information, and patients will assess these risks and benefits and decide according to their goals and values. The regulatory guarantor that this interaction will take place has become the participant information leaflet and the informed consent form (Wolpe 1998). By stipulating that such forms are read and signed by patients and health professionals prior to an intervention, institutions such as the NHS can demonstrate that they are respecting patient autonomy and are thus engaging in ethical conduct, in a way that would not be possible with the principles of, say, justice or beneficence.

The movement towards patient involvement in decision making has also had an impact on the rights of children and young people. The United Nations Convention on the Rights of the Child (1989) stipulations that children and young people have the right to express their opinions freely, and that these opinions should be given due weight (according to their age and maturity) when making decisions that directly affect them. Additionally, the Convention also respects the rights and duties of caregivers to “provide direction to the child... in a manner consistent with the evolving capacities of the child” (UNCRC Article 14 and 15). These UN stipulations have had considerable impact on government policy around the world - at least according to official government reports (Alderson and Morrow 2011). In contemporary health contexts in many Western Countries (including the

US and UK), this balance between children's right to express their opinions and caregivers' rights to provide direction to their child is captured in an informed consent arrangement whereby permission is obtained from caregivers and assent is obtained from the child (Ross 2006). This arrangement assumes that children under the ages of 16 (or 18 in some contexts) are unable to provide consent as they lack the capacity to make an informed, autonomous decision. Thus, overall permission is obtained from caregivers, and children are provided with an opportunity to either comply or disagree with a decision. Current NHS policy, for instance, states that permission for an intervention must be obtained from a caregiver for all children and young people under the age of 16. In some circumstances a caregiver can give also give consent for a treatment if the child has refused, but this would likely be decided "in the courts" (NHS Choices 2012).

The field of bioethics and its principles approach to ethics, therefore, has facilitated the socio-political trend towards greater patient involvement in medical decision-making. The emergence of this 'patient choice' and 'patient autonomy' approach has placed new pressures on health professionals. They now have a responsibility to ensure that information, particularly the risks and benefits of a course of action, is disclosed to patients in accessible language (Morgan 2008). They have a responsibility to ensure, then, the expectations of patients regarding the effects of a course of treatment are realistic; a task that is particularly tricky when the treatment being offered is relatively new.

6.3 Criticisms of the dominance of autonomy

The framing of patients as 'consumers,' or rational, autonomous actors has also resulted in challenges. Indeed principlism approach to ethics (and particularly the emerging dominance of 'autonomy') have received considerable criticism from the social sciences. Generally such criticisms point out that rather than simply enabling patients to act, principlism imposes a set of decontextualised norms upon patients. Principlism (particularly the principle of autonomy) and the corresponding emergence of a discourse of 'consumer choice' within medicine assume that individuals are, and should act as, independent rational agents regardless of their context. This 'atomistic' conception ignores the fact that individuals are socially embedded. As Fox and Swazey stated some time ago:

In the prevailing ethos... the value of individualism is defined in such a way and emphasized to such a degree, that is virtually severed from social and religious values concerning relationships between individuals; their responsibilities, commitments, and emotional bonds to one another; the significance of the groups of the social communities to which they belong; and the deep inward as well as outward influence that these have on the individual and his or her sense of moral. (1984: 358)

As various clinical institutions are configured to respect the autonomy of these independent and rational agents, patients find that they have little choice but to engage in this type of decision making. This can cause additional distress for patients. Rothman (1986), for instance, interviewed mothers who were presented with the decision to undergo amniocentesis after speaking with a genetic counsellor. The focus on individual 'autonomous' decision making within this context had the effect of isolating women at a time when building connections with a support system and her child was very important (Rothman 1986). Similarly Morrison, who also studied how autonomy is enacted within the context of genetic counselling, noted that the strategies employed by genetic counsellors tended to place the burden of decision making on the individual mother, while the mother's wider social relationships with others, relationships that could have provided support and guidance, were largely elided (Morrison, 2008).

In a similar vein, Mol has criticized the 'logic of choice' that underlies the patient-consumer discourse, noting that it fails to account for the absolute dependency of the patient and their body (particularly the afflicted body) on a plethora of other social and material entities (personal relations, medicines, etc). The patient is bound by such dependency, and cannot simply choose with the freedom of a consumer in a supermarket (Mol, 2008).

The notion that children and young people are unable to provide consent has been criticised by some commentators, most notably Alderson and Morrow (2011). Alderson and Morrow's make two key points. First, Alderson and Morrow argue that even young children are capable of a sufficient level understanding that permits them to make 'informed decisions', as long as information is provided to them in an accessible form and that they have guidance and support from parents or caregivers. Second, relying on support and guidance from family members should not be equated with an inability to provide consent. Alderson and Morrow highlight

the myth of the autonomous, independent decision maker that seems to underlie the notion of informed consent. Adults, they argue, often rely on the guidance and direction from others, particularly family members, when making difficult decisions about treatment, and this does not mean that they are any less capable of giving consent.

In short, social scientists have criticized the emerging dominance of autonomy and consumer choice as an imposition of liberal individualism within the realm of health care. Such criticisms aim to illustrate that there is no such thing as an objective, value-free panacea to ethical dilemmas in medicine (c.f. Corrigan 2003). Accordingly, we should remain open to other approaches to decision making and other strategies for managing difficult ethical challenges in clinical practice, particularly those that are attentive to, and foster, the socially embedded nature of patients.

This is where empirical social science can provide some useful insights into the debate. In the contemporary clinical contexts within the UK and US, health professionals are expected to disclose particular information and ensure that patients have realistic expectations about the effects of the treatment, and patients are expected to become involved in decisions about their treatment. It is important to explore how these responsibilities are enacted (or not enacted) within various clinical settings for two reasons. Firstly, it can enable us to see whether the emerging dominance of the principle of autonomy does, inevitably, lead to the imposition of a particular mode of patient involvement in decision-making within actual clinical practice. Are patients provided with little choice but to act as rational, autonomous agents, abstracted from their social context, as Rothman (1986) and Morrison (2008) illustrated? And has the informed consent process really replaced more informal bonds between health professionals and patients, as suggested by Wolpe (1998)? And secondly, empirical research can draw attention to the emergence of novel ways of managing these dilemmas. Clinical practice is inevitably messy and often unpredictable (particularly in new areas of medicine such as deep brain stimulation), and health professionals and patients may have to engage in ad-hoc solutions to immediate challenges. Such circumstances are a source of innovation.

I have undertaken such an empirical investigation and in this chapter we will see how the PMDS team has created a novel way of disclosing information to patients regarding the likely effects of deep brain stimulation therapy. The Canadian

Occupational Performance Measure (COPM) is used as a means of managing the expectations of families so that they can make an ‘informed’ decision about whether or not to proceed. Interestingly, as we will see, as PMDS team members and families use the COPM, the socially-embedded nature of the patient is scrutinized and brought to the forefront: The potential effects of DBS therapy are discussed in terms of a patient’s dependency on a wider array of social and material entities, and it is this dependency that is used as the basis of deciding whether or not to go ahead with the therapy. Ultimately, patients and their families are still expected to appraise the risks and benefits and decide whether or not to proceed based on their own goals and values, but this involves enacting, rather than eliding, the patient’s social embedded-ness. As we will see, however, for the COPM to work as intended, team members must engage in a great deal of ad-hoc work.

6.4 Informing families on the effects of DBS

Patients who have been identified as potential candidates for deep brain stimulation will spend a considerable amount of time with the PMDS service. It is not unusual for candidates to undergo the equivalent of three days of pre-surgical assessments, thus providing families and team members with an opportunity to become familiar with one another. According to members of the team, the process of informing families about the effects of DBS, and thus re-adjusting the unrealistic initial expectations of families, takes place throughout this pre-surgical assessment period. There are, however, specific sessions dedicated to the management of expectations and the disclosure of information to families.

The first of these, the ‘DBS information session’, is not unlike standard information sessions provided to patients for many medical interventions, and I will only briefly outline it here. The DBS information session is conducted by the specialist nurse and includes the patient and their supporting family members. This usually takes place near the beginning of a family’s time with the PMDS, shortly after the patient has been designated as a candidate, and it is not unusual for the same family to undergo the information session more than once as there is quite a bit of information to convey. During the session the nurse will communicate a body of information that has been agreed upon by PMDS team members. This includes detail of the DBS device, the surgical procedure, how to take care of surgical wounds, how to recharge the device, how the scars on the scalp and the torso will

appear, and how quickly the patient's hair will grow back after the procedure ("lots of kids always ask about their hair" Nurse, interview). The session is also used to explain and illustrate the efficacy of DBS (as a percentage defined by the literature), and the rates of adverse reactions, including cerebral haemorrhage and infection, and what each adverse reaction would actually entail for the patient (in the case of infection, for example, the DBS system will have to be removed). A PowerPoint presentation with some text and plenty of pictures (many of previous patients who have undergone DBS) is used to illustrate these various details, and families are given an opportunity to play around with dummy DBS equipment.

The information session is used for illustrating to families what the surgical procedure and post-surgical recovery entails, and for demonstrating the rates and consequences of adverse effects, but it is not used to explain how DBS will affect the specific motor symptoms of individual patients. Families, then, will leave the information session with little knowledge about how DBS therapy will specifically benefit their particular child. Indeed, despite the nurse emphasising that DBS is not a cure, families may still hold unrealistic expectations about how DBS can help their child. The team attempts to deal with this particular challenge in the second type of session dedicated to managing patient expectations: the goal setting session. The goal setting session is novel; it is the team's unique response to the challenge of gaining informed consent for a new and uncertain medical therapy, and for this reason, it forms the basis for the rest of this chapter.

6.4.1 *The goal setting session*

The goal setting session is a semi-structured interview involving the patient, their supporting family members, and two or three members of the PMDS team (usually the occupational therapist and the physiotherapist). The aim of the session is to communicate to families how DBS is likely to benefit the patient and to quantitatively measure a family's perceptions of the patient's abilities. Usually, the session is held in one of the larger consultation rooms that are also used to carry out some of the pre-surgical assessments and which have sufficient space for the people involved. Generally the goal setting session takes around an hour.

The goal setting session takes place soon after the patient has undergone the required pre-surgical assessments (which include the GMFM muscular-skeletal screen we explored in the previous chapter), and usually several months before the

scheduled surgery to have the DBS system implanted. As we will see this timing is important as it enables team members to form (during the pre-surgical assessments) their own expectations about how DBS will benefit a particular patient. The session is structured around the use of the COPM, a tool that has been adopted from occupational therapy.

The Canadian Occupational Performance Measure (COPM)

The COPM is a standardized, semi-structured interview that was developed by a team of Canadian occupational therapists led by Mary Law in the 1980s. Originally it was designed as a tool for therapists to measure and quantify changes in a patient's functional abilities over time, such as before and after a therapeutic intervention. During the interview patients and their families are asked to identify at least five key tasks of daily living (such as washing the dishes, brushing teeth) that the patient would like to improve. For each task they are then asked to rate, on a scale from one to ten, the importance of the task to them, their ability to perform that task, and their satisfaction with their ability. From these set of numbers an overall average is calculated. In order to help maintain consistency (and ensure that scores can be compared), users of the COPM are provided with a manual containing a set of instructions and a standardized score sheet.

The COPM, then, measures the patient's self-perception of their abilities. According to the authors the logic behind this focus on self-perception is that the clinically important aspects of an affliction are how it impacts on the actual, day-to-day life of the patient. It is this impact that should be measured (and ideally reduced), and not those aspects deemed important by health professionals who may have very little understanding of the experience of living with the affliction (Law et al. 2005). We can see here how a particular normative orientation has been incorporated into the tool; an orientation that attaches a heavy weighting to broader "functionings" of a patient. Accordingly, both 'disease' and the treatment of disease should be understood and assessed according to their impact on those aspects of a patient's life that the patient feels are important. The tool embodies what occupational therapists refer to as the patient-centred approach of their discipline.

Use of the tool in occupational therapy is widespread: the authors state that it is now used in over 35 countries (Law et al 2005). The PMDS, however, is the only DBS service that utilizes the tool as part of their routine clinical practice. It was

introduced around 18 months after the establishment of the team largely due to the initiative of the OT: it was, she states “embedded in my training” (OT, interview) and she used it in the community prior to joining the PMDS. While the team uses the COPM as a means of measuring changes in patients’ abilities (along with several other outcome measures), the primary reason for introducing the tool was to help set realistic goals for patients. The introduction of the tool was a pragmatic response to a specific clinical challenge

In the process of being adopted into the PMDS it has undergone a degree of modification. As Berg argues in relation to clinical protocols, its introduction has altered local clinical practices, but the tool itself has also been altered by local factors: it is both transformative and transformed (Berg 1998). First, within the PMDS patients and families are asked to identify the five or more daily living tasks that are important to them prior to the goal setting session. Indeed, they are usually asked to identify these tasks very early on during their time with the PMDS, so that they can then attempt to perform these tasks as part of their pre-surgical assessments. And second, the COPM in its original form was intended to involve one therapist and one patient. In the team’s version, the patient and their supporting family members will be involved (usually both parents), and two or three team members will conduct the session together. Usually this includes the occupational therapist (OT) and physiotherapists (PTs), who by the time of the session have an idea of how the individual patient may actually respond to DBS, and sometimes the psychologist, particularly if the patient has experienced depression. In this way the COPM has been modified to suit the aims and the environment of PMDS.

As we will see below, the COPM *provides a script* that coordinates the activities of the individuals involved. In order to ensure that the COPM functions as intended, team members must engage in ad-hoc work in order to *enrol patients and families* in the script. This may involve using props, and often involves the use of humour. Importantly, the COPM script *encodes a set of power relations* and designates positions of authority to those involved in the goal setting session. By ascribing a spokesperson’s role to patients and families, it encourages their active involvement - although this is highly configured by team members. Consequently, I will argue, the ‘patient-centred’ logic of the COPM prompts a particular mode of communication that can be seen as ethically favourable, and it enacts the patient as a *socially-embedded* entity.

The COPM as a script

Despite its flexibility, particular aspects of the COPM must remain constant across contexts if it is to function as intended. While the COPM is partially transformed in the process of being adapted, it also introduces a set of fixed roles into the PMDS working environment. Thus, like all protocols, it is transformative as well as being transformed (Berg, 1998). Protocols embody a script that delegates roles to various heterogeneous elements (human and non-human), prescribing a particular arrangement of elements and particular actions in space and time. Berg states that protocols provide staff members with a set of mandated instructions to which they can refer, and thus orientate themselves and act accordingly; staff delegate the role of coordination to the protocol, and in turn, the protocol delegates particular roles to staff members (Berg, 1998). This enables staff to carry out what can be highly complex and variable tasks with some consistency. Indeed for the PMDS the COPM provides a script that enables them to carry out the highly complex and potentially variable task of managing patient expectations.

Each goal setting session follows the same semi-structured interview format. First, in the PMDS' rendition of the COPM, the occupational therapist and the physiotherapist are designated as the 'leaders' of the goal setting session. It is their role to ensure that the session follows the COPM format and that the patient and family members adhere to their prescribed roles. At the first interview that takes place with family members prior to the patient's pre-surgical assessments, this role entails prompting patients and family members to identify the five daily living tasks that they would like to improve. As the COPM manual states:

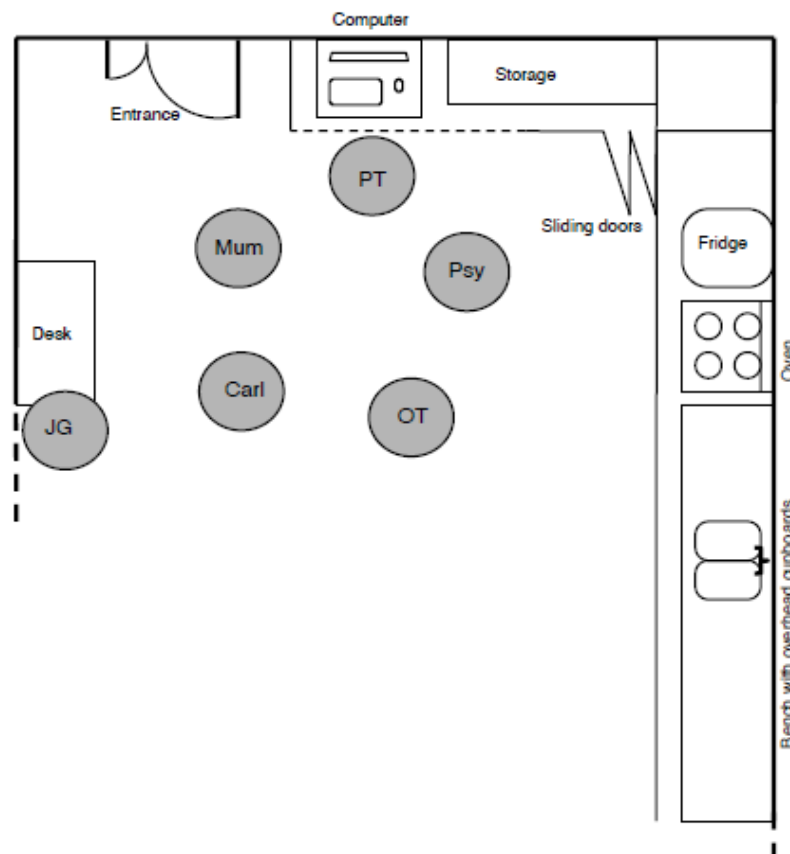
It is important that clients identify occupations that they want to do in daily life...

The therapist should encourage clients to think about a typical day and describe the occupations that they typically do..." (Law et al. 2005: 13)

This involves guiding patients through a portion of the COPM score sheet which lists a number of possible areas of concern: personal care; functional mobility; community management; household management (cleaning and cooking); play/school; recreations; and socialization (Law et al. 2005). These 'areas of concern' are used by the session leaders to prompt the family to think about the impact of the patient's motor disorder on their day-to-day life, and for each area,

families and patients are asked to identify specific tasks they would like the patient to improve (such as dressing, hygiene, visiting friends, preparing food). The family is then asked to identify from these which five are the most important. It is these five tasks that the patient will attempt to perform as part of the pre-surgical assessments, and it is these five tasks that the team will later use as the basis for managing expectations during the goal setting session.¹⁷

Figure 6.1: Floor plan of seating arrangement during goal setting session



As 'leaders' during the goal setting session, the two therapists have several tasks. If adequately performed, the therapists will guide the patient and their family towards the creation of five 'realistic' goals for DBS, each corresponding to one of the five tasks that family has identified as problematic. To illustrate how this occurs we will again use an interaction with Carl as an example. The interaction involves Carl, his

¹⁷ It is not unusual for more than five tasks to be chosen. This may occur if patients identify different priorities to those of their parents. Rather than have to choose between them, both sets may be chosen. Differences between patient and family members goals are discussed further on.

mother (Mm), the occupational therapist (OT), physiotherapist (PT) and the psychologist (Psy).

The first role of the leaders is to arrange the meeting space so that it is informal and not intimidating in order facilitate honest and open communication (as recommended by the COPM manual). Generally this involves arranging the seats so that all those involved are sitting in a circle facing one another, and so that one of the leaders can easily access a computer. The floor plan in figure 6.1 (page 168) shows an example of such a seating arrangement.

Second, the therapists begin the session by restating the daily living tasks that had been identified by the patient and their family prior to the pre-surgical assessments. (These are accessed via the computer – the details of the earlier interview are kept electronically). This is followed by prompting the patient and/or their supporting family members to clarify the specific problem they are having with the task:

OT: Now, when I met you last time, we talked about the things that you wanted to improve. You identified a number of things... These were handwriting, shaving, self-feeding, drinking, and using public transport.

PT: So with your handwriting, what aspects are you not happy with? Speed? accuracy?

Carl: Both... I get hand cramps. I would like to be able to handwrite on a clear page without making a mark all over the page.

PT: Okay, what about drinking?

OT: I've noticed that when you drink from a bottle, you bring it to your mouth and tip your whole head back. Is that to make sure your arm doesn't flick it away and spill it?

Carl: Yeah.

For each one of the five tasks the patient and their family members are encouraged to be as specific as possible; to specifically and explicitly outline what it is that the patient is having problems with. (The COPM manual states, "it is essential that therapists use their skills in interviewing, probing for full responses" (Law et al. 2005)). As Carl and his mother are prompted to add more and more detail, each particular problem becomes more intelligible: each is actively delineated. In effect, the resulting 'five tasks' are the product of an interaction between the therapists, the

patient, their supporting family members, as scripted by the COPM. This interaction may also involve the identification and delineation of a new task. Here is another example from Carl's goal setting session:

- OT: And another thing is you wanted to use public transport. Is this a problem because are you worried that you will attract attention or is it because you cannot physically manage?
- Mm: Last time we went out in public, a man laughed at him. The man made such a big deal of pointing Carl out. He hasn't really gone out since. And if he gets one of his tics, it can be very difficult on the bus. They throw him off his feet.
- OT: Okay, we should keep the two things: confidence in public and being able to use public transport.

Here we can see that as a result of the clarification process, one of the difficulties identified by Carl and his mother (confidence in public spaces) has been re-delineated as two (confidence in public places, and physically being able to use public transport).

While the five tasks are being clarified and rendered intelligible, the role of the therapists is to offer their predictions on how the patient's ability to carry out these tasks will be affected by DBS. These predictions are, of course, based on their observations from the pre-surgical assessments and their experience of previous DBS outcomes within the PMDS. If dystonia ("involuntary movement") is deemed to be the cause of the problem, then the therapists will tentatively predict that there will be some improvement:

- KT: Carl, tell me about shaving. Why does mum do it for you?
- Carl: It pulls on my hair, it is really sore.
- OT: His arm pulls away and the hair gets caught in the shaver. It is definitely the involuntary movements that are making it difficult to shave... Carl – if DBS does reduce your voluntary movements, you will find it easier to shave.

And if a difficulty is perceived by the therapists to be caused by muscle weakness, contractures or spasticity, then they will predict that no improvement will occur. Additionally, the therapists may also draw on their knowledge of previous PMDS

patients. Here is the occupational therapist's prediction about how DBS will affect Carl's handwriting:

OT: I think your computer is your best option. DBS may help a bit, but you won't be able to rely on your handwriting. We have noticed some very minor improvements in patients, but that is after four or five years.

Once the patient and their family have been prompted to clarify the tasks they would like to improve and the therapists have offered their prediction, the COPM 'script' requires that therapists guide the family towards a set of goals for each task. This involves negotiation, and it is during these negotiations that particular goals will be delineated as 'realistic' and others 'unrealistic'. Here is an example of the physiotherapist negotiating with Carl. Note that she draws on some of the clinical information that she and the other physiotherapist produced during the GMFM and musculoskeletal screen that we explored in the previous chapter:

PT: About this problem with stability on public transport. We noticed during your [GMFM and muscular-skeletal screen] that you have muscle weakness around your pelvis that DBS won't improve. You could probably improve it with a lot of hard work and exercise in the gym, but we shouldn't set a goal that you are not prepared to put in the effort for in the first place.

Carl: I'm not motivated, but that is because it takes me so much energy to do things!

PT: Can we agree that we don't put this as an initial goal? You could tackle it when you have some more motivation, but I don't think we should put it down as a goal for DBS. We should aim for other goals.

As result of this negotiation, one potential goal pertaining to the patient's wish to use public transport has been discarded as unobtainable with DBS, and thus 'unrealistic'.

Below is another example of negotiation, this time involving psychologist and Carl. (Team members felt that Carl might be depressed, and thus requested that the psychologist participate in the session).

Psy: Carl, about your wish to have more confidence in public. We need to clarify: What would it take to improve your confidence? Would it be not falling at all? Or falling less?

Carl: Just less falls and less jerky movements.

Psy: So, would just a little bit of improvement, then, help with your confidence, do you think?

Carl: Yes.

Psy: Because some people might not be happy if they still had some visible signs of the movement disorder. It is good that you think that a little improvement will help.

Here the psychologist has implied that it is unrealistic to expect DBS to remove all visible signs of the movement disorder, and has suggested to Carl that “a little improvement” is a more suitable goal.

The product of these types of negotiations, then, is a set of at least five goals, and what exactly counts as ‘realistic’ or ‘unrealistic’ are delineated in the process. The resulting five goals, like the ‘five tasks’ that form the basis of the goals, are a product of the COPM-scripted interactions between participants. If all goes to plan and all participants adhere to the script, the resulting five ‘realistic’ goals for DBS will reflect the family’s wishes for meaningful improvement in the patient’s day-to-day functioning, and they will reflect the therapists’ educated (but tentative) predictions. In short, the five goals will be important to families, and according to the therapists they will be achievable with DBS.

It is in this way that the COPM is used to manage the expectations of patients. The COPM instructs therapists to prompt families to be explicit about their difficulties and hopes, and that therapists then communicate the effects of DBS in terms that are comprehensible and meaningful to families. Indeed the potential benefits of DBS are explained in terms of the patient’s day-to-day activities: as an improved ability to shave with less difficulty, or hold a glass, or prepare a bowl of cereal. The effects of DBS are conveyed in specific terms using examples familiar to the family. According to team members, this is the advantage of the COPM-scripted goal setting session:

This is the idea of doing these setting sessions, where you’re really critically defining a target, you know, there’s no - we’re not nebulously talking about things getting

better, we're talking about you being able to dress that right arm better. (Clinical research fellow, interview).

A 'well-informed' family, then, is the ideal product of an interaction that has been carefully coordinated according to the COPM.

Quantification

As discussed above, in addition to managing the expectations of patients, the PMDS team also uses the COPM as an outcome measure (as originally intended by its authors). This involves a process of quantification, where the family's perceptions of the patient's abilities are converted into a set of numbers. If the COPM is carried out again, perhaps after a DBS system has been implanted, these numbers provide an 'objective' point of comparison and thus a means of measuring the effect of DBS.

Once the realistic goals have been negotiated, families are asked by the therapists (who are guided by the COPM manual) to provide three scores for each of the five daily living tasks which have become the basis of goal setting. Firstly, for each task, the patient and their supporting family members are asked to identify how *important* it is to them, on a scale from zero (not important) to ten (very important). Second, they are asked to rate their *performance* of that task; how good they perceive the patient to be at undertaking it. And third, they are asked to rate how *satisfied* they are with their performance. The COPM manual recommends that therapists spend time with patients to ensure they understand the rating system, "using concrete examples such as the judging of figure skating" if necessary (Law et al. 2005: 18). Consequently three numbers are produced for each task. Here is an example of this quantification from Carl's goal setting session:

PT: Okay. Let's go on and score these [daily living] tasks... So firstly, confidence to go out in public places. On a scale from zero to ten, how important is that to you, ten being the most important?

Carl: Eight.

PT: And how good are you at this?

C: Zero.

PT: And how satisfied are you with that?

C: Two.

During the interaction the therapist notes each number on the (standardized) COPM score sheet. Once all tasks have been rated an overall average is calculated for performance and satisfaction. It is these two numbers that will provide a point of comparison when the COPM is repeated at a later date.

Just as the process of goal setting involved negotiation and guidance from the therapists, so too does the process of quantification. Part of the therapist's role (as instructed by the COPM) is to interrogate patients on the numbers they have chosen, particularly if the rating appears to conflict with earlier discussions.¹⁸ Below is an example of such a negotiation from Carl's goal setting session. Mum has been asked to provide ratings for Carl's ability to drink:

- OT: Okay, now it's Mum's turn... Drinking. [Importance]?
- Mm: Nine.
- OT: Performance?
- Mm: Eight.
- OT: Really? You hold his cup for him! It is really hard to improve from an eight!
- Mm: Oh, okay. Well, I was thinking if him using a bottle. But, I suppose, a two.

Quantification, then, is the result of local negotiations between therapists, patients and family members: Therapists prompt and guide patients and their families toward a set of numbers that are perceived to be appropriate by both parties. As we will now see, this, and the process of negotiating realistic goals, often requires a great deal of work from the therapists.

Enrolling patients and family members in the COPM script

Ensuring that the goal setting session function as both a means to manage expectations and as an outcome measure requires that all participants adhere to their COPM-scripted roles. As 'leaders' of the session the therapists are responsible for ensuring that patients and family members adhere to their particular roles as

¹⁸ The COPM manual instructs: "It is suggested that you question if they clients have understood the rating scale... further discussion may serve to clarify whether these are truly goals they wish to pursue" (Law et al. 2005: 21).

prescribed by the COPM. The process of prompting and negotiating with patients is part of this ‘enrolling’ process, as is the informal seating arrangement (which encourages families to communicate honestly). Generally, however, the task of applying the standard COPM protocol to what is often a highly variable group of people is a challenging task

The COPM protocol permits some forms of variation, so not all variation is necessarily problematic. There is large variation in the age of PMDS patients, for example, and this can influence the types of goals they hope to achieve with DBS:

[Young children] might be less valuing at that particular age of getting dressed, because it doesn’t matter so much that at six, ‘My mum is still dressing me.’ But at sixteen, the dressing may take a different priority. (Physiotherapist, interview).

And as we will see further on it is not unusual for patients to have different goals from their supporting family members. Importantly, however the COPM allows for this type of variation. It was designed with the belief that different patients would have different goals and areas of importance, and that each patient should be entitled to identify those goals that were important to them. For the therapists, variation among patients and between patients and their families regarding the areas of their life that they would like to improve does not create a major challenge (We will see further on how the team deals with situations where patients and their supporting family members have different goals).

Other differences do threaten to derail the COPM session. Different levels of competency between families, for example, present a challenge.

And then there are just different styles of communicating and different levels of understanding [Sometimes] you’re kind of dealing with expert parents. And then you have the opposite extreme of somebody that doesn’t understand their child’s functional difficulties at any level and therefore can’t be realistic about them either. (Physiotherapist, interview)

Team members state that cultural beliefs, particularly those around the duties of mothers, can present a challenge. In the following interview extract the physiotherapist is providing an example where a mother’s sense of duty influences her responses during the quantification process.

JG: Have you noticed any cultural differences in how families rate their child's abilities?

PT: Very much so. I can think of a one girl where... so the performance scores [provided by her mother] are really appropriately scored for – it's a nightmare to dress her, it's a nightmare to transfer her, she's in pain all of the time, she doesn't sleep. All of these things. But satisfaction scores were high because [the mother felt] 'she's my daughter, and that's what my role is, it's to care for her and I will never be dissatisfied about doing so.'
(Physiotherapist, interview)

Another problem is that, due to the severity of their affliction, some patients have great difficulty communicating. This can make the task of identifying their perspectives and goals challenging. Many patients will have access to some sort of electronic communication aid but those who lack the sufficient dexterity to operate such a device may rely on bodily gestures to communicate. The potential for families and patients to become upset can also threaten ability of the goal setting session to produce realistic goals. The requirement for direct and honest communication means that families may have to reflect on terribly upsetting issues or consider a bleak, challenge-ridden future.

Like all human actors, then, patients and their family members are potentially 'unruly' and their compliance with the COPM script cannot be guaranteed. During the course of goal setting sessions, therapists must engage in a great deal of ad-hoc work in order to encourage patients and family members to 'follow the script'. In some cases this may involve the use of objects or props. For example, team members have devised a vision board that can be used to communicate with patients who are unable to access an electronic aid. Depending on the age of the patient, the vision board will have a series of numbers, the words 'yes' and 'no', happy and sad faces.

So yes we have a vision board, where we put our numbers from one to ten for the importance of a certain goal. Or we have 'yes' and 'no', smiley face and sad face, in terms of the goals... Depends on how able they are. We have had cases when they just look at the yes and no answer... we have children who can easily move the upper limb and point. (Therapy assistant, interview)

Such tools enable the team to explore, at least partially, the patient's perspectives, as prescribed by the COPM. The therapists will also use humour to guide patients and families and prevent them from straying from the script. (Indeed, several team members felt that being able to laugh with each other and with families was a vital skill of the PMDS). Humour may be used throughout a session to help keep the situation feeling informal and quell tensions that could potentially disrupt the session. The following extract from Carl's session is an example of this. Toward the end of the session, Carl is visibly tired and his mother is beginning to answer on his behalf. In order to get Carl to provide a rating without being influenced by this mother, she receives the following instruction:

OT: Mum! Don't influence him! Hide your face and cover your ears, we need to hear from Carl!

The instruction was given at high volume but with obvious jest: the OT was smiling as she said it, and Carl along with the physiotherapist and psychologist responded with a giggle. The instruction had the intended effect: Mum, also chuckling, turned her chair so that she was not facing Carl and covered her ears with her hands, enabling Carl to respond.

These are examples, then, of the techniques that the therapists use in order to encourage families and patients to follow the COPM script. It is this type of work that is required to ensure that diverse and variable patients and families will act in a sufficiently uniform and stable manner so the goal setting session will generate the desired outcomes. It is, as Berg states, part of the work necessary to transform heterogeneous elements into the predictable and disciplined entities required for a protocol to work as it is intended (Berg 1998). As the example of humour demonstrates, much of this work requires a tacit social sensibility; an ability to appeal to the emotive capacity of individual patients and family members in order to enrol them in the script.

Such techniques do not always work and inevitably some goal setting sessions will fail. Below the OT recounts a case where the parents were too upset to proceed. Their child's dystonia was one symptom of a particularly nasty progressive metabolic condition, and the future outlook was grim.

We were just talking to them, you know, the psychologist and I. Because they knew what was going to happen [to their child]... [we] made the parents cry. They said ‘I don’t want to think about it. I know what’s going to happen, I just can’t get my head around it’ (Occupational therapist, interview).

Encoding Power

Like all protocols the COPM encodes particular power relations. As elements are arranged and coordinated according to a script, some are accorded with more authority than others. Specifically, scripts and protocols assign *spokespersonship* and decision making roles to particular elements within the local context. Spokespersons (or ‘spokes-things’) are those elements that are designated with the authority to ‘speak on behalf of’ or delineate and define some entity or state of affairs (Latour 2005: 31), and elements designated as ‘decision makers’ are those that are granted the capacity to direct the course of events during the implementation of the protocol. Berg states that these roles are designated to those elements that exhibit the “most predictable or unequivocal behaviour”, thus enabling the protocol to function as intended by its authors (Berg 1998: 240). Berg adds that with clinical protocols, which seek to reduce ‘capricious variation in clinical decision making’, such authority is often granted to laboratory tests and machines.¹⁹ Similarly, in an attempt to tame or silence potential sources of contingency, such protocols tend to provide little space for a patient’s voice.

The power relations encoded within the COPM reflect the ‘patient-centred’ philosophy of its original authors. For Law and her colleagues, it is the impact of an affliction on patients’ daily living that is clinically relevant, and the COPM has distributed decision-making and spokespersonship roles accordingly. Clearly, the COPM endows the therapists with considerable authority, and in this respect it reifies a pre-existing hierarchy between the clinician or health professional and the patient. The therapists, as we have seen, are instructed to guide and direct patients and their family members throughout the interaction, prompting them to offer the type of responses that are mandated by the COPM script. Indeed, during the goal setting and quantification processes it is the therapists who are endowed with a

¹⁹ The results of a machine-derived white blood cell count, for example, will determine a patient’s course of treatment. This is rather than, say, the clinical judgment of the clinician or the viewpoint of the patient.

decision-making capacity during the interaction: as we saw in the example of Carl's goal setting session, if they perceive the responses to be imprecise, insincere or unrealistic, then they can decide to engage in further prompting and negotiation.

In the process of being instructed, guided and prompted, however, patients and their family members are being called-upon to act as spokespersons. They are designated to speak 'with authority' on the impact of the movement disorder and to delineate which specific aspects of this impact are important and thus should be addressed with an intervention such as DBS. As we saw with Carl's example, he and his mother were encouraged to delineate what they felt were the more pressing effects of the dystonia: his confidence in public; his difficulty with shaving and with drinking, for instance. The COPM, then, provides space for the voice of families and patients; indeed, it requires their active input to function as a patient-centred outcome measure. This is not to say that patients and families can say as they please: they are constantly directed towards the particular modes of expression required for the COPM to function (a good example of this being the expression of 'satisfaction' with a numerical value during the quantification process). The COPM script then, configures a particular a 'patient voice', or a particular mode of expression.

In PMDS goal setting sessions the therapists will attempt to ensure that both the patient and their supporting family members are accorded this spokesperson role. It is not uncommon for a patient and their supporting family members to have different goals and expectations. For younger patients, for example, these revolve around being able to interact with friends, whilst parents are often more concerned about long-term care issues:

The family might have a lot of care type issues and then the kid will be like, 'Well I don't care about that, I want to access my computer, I want to be able to play with my friends' And I think we need to be able to capture that, because the goals are different and that's fine. We might be able to achieve both the goals.

(Occupational therapist, interview)

Provided both the patient and family members are willing to negotiate a set of 'realistic' goals, such differences are not considered problematic by the therapists. Indeed, in order to engage the patient as much as possible (as stipulated by the COPM) it is common for the therapists to negotiate a set of goals with a patient and then a separate set of goals with supporting family members. In order to encourage

patients to answer honestly and ensure they are not ‘spoken for’ by their family, part of the goal setting session may be carried out with the patient alone. More often, though, this will simply involve instructing family members to wait their turn or ‘hide their faces’ during the interaction (as we saw with Carl and his mother).

The therapists, then, will attempt to manage the interaction so that patients, as well as their family members are accorded this spokesperson role. In some cases, however, the severity of the child’s affliction may prevent this and their family members will speak on their behalf (although some attempt will be made to include the child):

If we’re unable to have a whole sentence from the child or get an idea what they will want to achieve, then the parents set the goals and we have a yes/no conversation with the child. (Therapy assistant, interview).

Thus, like all protocols, the COPM encodes a set of power relations and attributes authority to particular elements. By delegating decision-making capacity to the therapists it reifies pre-established hierarchy, but by designating patients and family members as spokespersons it also encourages active patient and family involvement in the goal setting interaction. Patients and family members are provided with a space for expression, albeit a highly configured space shaped by the therapists in adherence with the COPM.

Enacting a socially-embedded patient

The COPM script provides no space for MRI images, CAT scans, references to defective basal ganglia or nervous-system malfunction. It provides no space for talking about DBS electrode replacement, surgical procedure, or stimulation parameters. Indeed, talk about the brain and the aetiology of movement disorders is largely absent from the goal setting session. The patient-centred logic of the COPM, manifested in the way that it distributes authority among the therapists, patients and family, precludes talking about dystonia in this way.

Instead patients and their families are encouraged to give their account of living with the disorder. As we have seen, they are prompted to explain how the disorder impacts upon their day-to-day life in very specific terms, and then identify which aspects of this impact they would most like to improve. They are encouraged to talk about the mundane, everyday life of the patient: feeding and drinking,

hygiene, sleep, pain, playing with friends, writing and using computers, using public spaces. As a result, during the course of the goal setting interaction, the movement disorder may be understood as an inability to use the bus, having to rely on mum to help with shaving or drink from a cup, a fear of being laughed at in public by strangers, or an inability to write more than a few sentences before getting cramps. It is according to such details that the movement disorder is rendered intelligible within the goal setting session. It is, in other words, enacted as social affliction; as a hindrance to engaging and acting in the world of people and things that is beyond goal setting session and outside of the hospital.

Consequently, the patient is enacted as a social being, immersed within a network of relations involving other people (family members, friends, strangers), and objects (computers, pens, cups, buses). It is these relations, and the patient's capacity to act within this network of people and things, which are closely examined within the goal setting session. Via the guiding and prompting of the therapists these relations are brought to the forefront of the interaction, and then through a process of negotiation they become the basis of the patient's five goals. As we saw with the example of Carl's goal setting session, the therapists will also refer to these social relations as they articulate the likely effects of DBS therapy. In this way, the potential effects of DBS are, ideally, rendered comprehensible to patients and families: potential benefits are communicated as an improvement in a particular aspect of the patient's day-to-day functioning. Using the COPM to manage expectations of patients and families, therefore, entails that the socially-embedded nature of the patient will be brought to the forefront.

This socially-embedded rendering of the patient is, of course, a temporary product of the goal setting session. It is actively produced by the therapist, the patient and family members as they attempt to adhere to the COPM script, and as Mol (2002) has illustrated, such temporary enactments may be elided by enactments or renderings generated in other interactions at other sites within the hospital. At the end of the goal setting session, however, part of this 'socially-embedded' rendering of the patient is granted some durability. The standardized COPM score sheet that contains the negotiated goals, the results of the quantification process, and a few additional notes, is added to the patient's records. These are then used a point of reference when the patient returns for review after the DBS system has

been implanted, thus enabling team members and families to assess its impact on the patient's day-to-day life.

6.5 Discussion: An innovative strategy for managing expectations

The socio-political trend promoting 'patient autonomy' and increased involvement of patients in their decision making has put particular pressures on health professionals. They have a responsibility to communicate the risks and benefits of treatment options to patients, and they have a responsibility to ensure that patients understand this information before the intervention takes place. In short, health professionals are expected to ensure that patients have realistic expectations before they obtain informed consent.

For the PMDS team this can be particularly challenging. The team's response to this is to innovate: to adopt a tool from occupational therapy, an outcome measure, and modify it to suit the local context of the PMDS. Consequently the COPM has become the basis of the goal setting session and the therapists' means of attempting to manage the expectations of patients and their families. The team's inclusion and modification of the COPM can be seen as an example of *learning-in-practice*; it is an example of health professionals developing, implementing and modifying a new procedure, while working with patients, in order to manage the challenges presented by the introduction of a new technology.

As we saw, the therapists must engage in a fair amount of ad-hoc work to ensure that patients and families adhere to the script. Families are required to communicate honestly and in specific terms and to negotiate reasonably. This requires a rapport and degree of trust between the therapists and families. According to the therapists, it is often during the earlier pre-surgical assessments that they have had a chance to form informal bonds with families and patients, and so by the time of the goal setting session, patients and families are more willing to speak openly. In this particular setting, then, trust and informal bonds are considered an important requirement for managing expectations and thus enabling patients and families to make an 'informed' decision. The informed consent process, then, has not necessarily replaced the more informal, trusting relations between health professionals and patients that, according to Wolpe characterized clinical contexts in previous times (Wolpe 1998). For the PMDS team, a trusting relationship with patients is a crucial part of the disclosure process. Additionally,

much of the work required of therapists in order to keep patients and families to the COPM script could be described as *emotional work*.²⁰ In order to encourage patients and families to communicate honestly and in order to prevent them from becoming distressed and upset in the process, therapists must carefully manage emotions during the goal setting session. The use of humour is an example of this, and without this type of work the COPM would fail to work as intended. Indeed, emotional work can be seen as an important component of the innovation process.

I have argued that during the COPM the patient's movement disorder is enacted as a social condition: it is understood in terms of its impact on the day-to-day life of the patient. The patient, then, is enacted as a socially embedded entity. This is another example of the 'broad clinical gaze' that was enacted during the team meetings. In this case it is a result of the normative stance that has been encoded with the COPM: the 'patient-centred mantra' that underpins occupational therapy. Consequently, this COPM-scripted goal setting session is in noticeable contrast to the genetic counselling sessions explored by Morrison (2008), where counsellors' emphasis on patient autonomy tended to obscure mothers' wider social relations, relations that could have provided much needed support and guidance. This difference is perhaps no surprise. The COPM-scripted goal setting session is another product of the socio-political trend within the UK that is promoting multidisciplinary service provision, particularly to in paediatric settings: It has been created by a team whose multidisciplinary activities are supported by, for example, the NHS tariff structure and the built environment of the hospital within which they work.

The PMDS goal setting session also illustrates the role of non-human elements in ethical work. The COPM script requires therapists to draw on their own professional and emotional capacities; it requires the use of additional tools, such as communication aids; and it requires an informal, comfortably arranged working space. Together, these various elements ensure that the script and its patient-centred normative orientation are enacted in actual clinical practice, and they are all, therefore, implicated in the ethical work of managing expectations and enabling informed decision making.

²⁰ Emotional work is the labour undertaken by individuals in order to manage their own and other's emotions so that some institutional aim can be achieved (Bolton 2001).

Of course the goal setting session is just a small part of a family's time with the PMDS service, and in other interactions different renderings of the movement disorder and different enactments of the patient are produced. Indeed the COPM goal setting session is one component of the informed consent process. The information session is another component. Once families have participated in both these sessions they are given at least several months to make the very difficult decision about whether or not to go ahead with DBS. Often team members will put them in touch with other families that have gone through with DBS. If a family does decide to go ahead, they will be asked read a participant information sheet and sign a consent form on the day of surgery.

As we have seen, the COPM goal setting session involves quantifying patients' self-perception of their abilities. In effect the COPM translates the specific hopes and frustrations of individual patients into a series of numbers. For each patient the COPM will be repeated after the DBS system has been implanted and the resulting numbers will be compared to those from their pre-surgical goal-setting session. This is part of many data-gathering activities conducted within the PMDS aimed at creating an objective body of evidence regarding the efficacy of DBS. These activities, we shall see in the following chapter, reflect the socio-political trend within healthcare towards evidence-based medicine, and they also constitute an attempt to manage the final problem that we will explore: measuring clinical outcomes.

7 Measuring clinical outcomes

If the scale is insufficient then many patients are going to be unfairly excluded from a therapy that can offer them much needed relief. We don't want people to be excluded because an inadequate tool has selectively produced the relevant data, thus giving the impression that only a select few will benefit. (Dr Martin, team meeting)

7.1 Introduction: the challenge of measuring outcomes

In chapter 3 we explored the conjunction of historical circumstances that enable teams such as the PMDS to exist. In addition to producing novel opportunities for managing neurological illnesses, this conjunction of circumstances has also created series of constraints that influence how such opportunities can be exploited. The PMDS team operates in a climate of medical device regulation and evidence-based medicine, and they are expected to generate appropriate 'objective' evidence that deep brain stimulation is an effective tool for managing dystonia in children. We also saw that this climate necessitated the development of standardized clinical assessment tools that could be used to create such evidence. In regards to dystonia, there is a precedent for how this evidence should be generated: using the Burke-Fahn-Marsden Dystonia Rating Scale clinical assessment tool (BFMDRS, or BFM for short). It was this tool that was utilized in the multi-centre Medtronic-sponsored trials that were used to obtain regulatory approval for DBS as a treatment of dystonia in both the US and the European Union, and it has become the standard clinical assessment tool for determining the effectiveness of the therapy. Because of this, the clinical outcome data reported in the existing body of literature on DBS and dystonia has been generated using the BFM.

Not surprisingly the BFM is used by the PMDS. If the team wishes to compare their outcomes to those in the literature, or if they wish to demonstrate to external funders and regulatory agencies or the wider neurological community that their therapy is effective, then it is necessary for them to use this standard tool. This, however, is problematic for the team. The BFM tool was developed for use for adult patients with primary dystonia. Most PMDS patients have secondary

dystonia, and consequently the BFM is of limited use.²¹ Specifically PMDS team members argue that the tool fails to capture improvements in many of their patients with secondary dystonia; improvements that are relevant and important to patients and families. In this chapter we will see how the team has attempted to ameliorate this problem by using another clinical assessment tool which they have adopted from occupational therapy called the Assessment of Motor and Process Skills (AMPS). PMDS team members argue that it is capable of detecting relevant and meaningful changes in patients with secondary dystonia. In effect, the team is attempting to redefine ‘what counts as data’ in such a way that it will support their activities. Although the team’s use of this tool is unique in tertiary paediatric neurology, it can be seen as part of a wider trend towards using clinical assessment tools that involve active patient participation.

Here we will explore why team members felt that the introduction of this AMPS was necessary, and we will see how the tool is actually used in clinical practice. Conducting the AMPS requires the occupational therapist to construct an assessment space that resembles a typical domestic space within the home, such as a kitchen. The patient is then instructed to perform a domestic task, or an Activity of Daily Living (ADL). As this is done, the therapist carefully scrutinizes the patient’s ability to use their body as an efficient implement, noting how they navigate and interact with other objects within the domestic space. First, however, I will give a description of clinical assessment tools and state why they are interesting from a sociological perspective.

7.2 Conceptualising clinical assessment tools

Here I will suggest that there are two interrelated reasons why clinical assessment tools are worthy of sociological exploration. Firstly, such tools incorporate and reproduce specific ways of understanding disease, the body and/or the patient. As we saw with the UPDRS in chapter 3, clinical assessment tools function by extracting manageable, quantifiable, easily-to-circulate data from highly complex and

²¹ One team member stated that the BFM was developed in a particular part of the US with large Ashkenazy Jewish and Amish-Mennonite populations, both of which have a high frequency of a particular genetic abnormalities that cause primary dystonia. Consequently, primary dystonia is more common than it would be in other regions of the world. This may have shaped the development of the tool – verifying this would make an interesting project in its own right.

contingent local contexts. This occurs via a process of filtration, where some bodily attributes or phenomena are designated as ‘representative’ of a patient’s condition and are subsequently rated, measured and pooled-together, while innumerable other phenomena are elided or ignored as irrelevant. This is similar to the process of purification that takes place within laboratory clinical work, where particular biological parameters are used to represent ‘health’ (Mol 2008). Inevitably this filtration process will reflect what Goodwin (1994) has referred to as the *professional vision* of those who created the tool: particular modes of perceiving and understanding disease and illness are encoded within clinical assessment tools. They do not, then, provide unmediated accounts; rather, they are (to borrow some phrasing from Haraway) *constructed perceptual systems*; highly specific and partial ways of seeing and assessing disease and the body (Haraway 1988). As such tools are adopted into various clinical and research contexts, these particular modes of perceiving health and illness, these partial, highly specific perceptual systems, become locally embedded. Indeed, as clinical assessment tools become part of clinical infrastructure, particular understandings of health and illness gain institutional ‘weight’.

Within neurological clinical research and practice it is possible to characterize clinical assessment tools into four groups, based on the type of attributes and phenomena (or ‘outcomes’) that are used to ‘stand in’ for health and illness. These include: the underlying disease process; impairment; disability; and quality of life (QoL). Not surprisingly some of these tools tend to reify the biomedical model of disease and the body. This assessment of underlying disease process, for example, may include determining the degree of underlying tissue or organ damage, the level of disease-related particles in the blood, or the frequency of some sort of disease-related acute event. Similarly, impairment-based tools are those that measure the deleterious effects of the disease on the functioning of body parts or organs. An example of this is the common Unified Parkinson’s Disease Rating Scale which assesses the degree of tremor in various regions of the body (Martínez-Martín et al. 1994). With such tools it is particular biological or biochemical elements, or particular clinical signs, which are deemed to be ‘representative’ of ‘health’, and it is that these become the basis for measuring the effectiveness of an intervention. Such outcome measures provide no allowance for the viewpoint or experiences of the patient.

Tools that assess disability or QoL are based upon less reductive understandings of health and illness. The measurement of disability involves assessing the degree to which a condition reduces or restricts an individual's ability to perform tasks within their physical and social environment. Generally, this is done by measuring the individual's capacity to carryout activities of daily living (ADL), such as eating, washing hands, or self-dressing (Buskens and van Gijn 2001). QoL-based tools attempt to quantify an individual's overall sense of well-being and life-satisfaction. This is usually done via a questionnaire and/or interviews that prompt patients to report on various physical, social and emotional aspects of their life. The perceived advantage of such tools is that they measure phenomena that patients themselves find meaningful.²²

In addition to incorporating and reproducing particular ways of understanding disease, assessment tools also link disease, the body and/or the patient into a wider set of relations involving statisticians, commercial institutions, regulatory agencies and other 'macro' actors. They have become part of what Clarke and colleagues have referred to as the integrated infrastructure of biomedicalization; infrastructure that enables medical knowledge, technologies and capital to become ever more co-constituted (Clarke et al 2010). As we saw in regard to the development and dissemination of DBS technology in chapter 3, clinical assessment tools transform local, contingent and potential diverse phenomena of particular research sites into a set of easy-to-circulate numbers (immutable mobiles) that can be pooled-together, compared, and used as a body of evidence to justify the use of an intervention. In short, clinical assessment tools are one of the crucial technologies that enable populations of individuals to be brought into an 'experimental order' (Petryna 2006).²³

Given their importance in contemporary healthcare and clinical research, therefore, clinical assessment tools are worthy of sociological examination. By

²² The COPM which we explored in previous chapter is another good example of such a tool.

²³ As we saw in chapter 3, clinical assessment tools enable commercial industry to conduct large scale, multisite international clinical trials. Not surprisingly pharmaceutical companies tend to prefer tools that measure disease process or impairment, as they can be easily quantified by an investigator, they are perceived as objective, and even when used with small trials, they 'lend themselves to statistical massage from which some significant advantage can be made to emerge' (Buskens and Van Gijn 2001: 37).

examining how health professionals use and adapt assessment tools in specific contexts, we can explore how various understandings of disease, the body and the patient may be perpetuated or disrupted, and we can explore how local contexts can become implicated a wider set of relations involving other clinical sites. Here we will examine the activities of PMDS team members as they use the AMPS, a disability-based measure. As we will see, this has implications for how the patient and ‘dystonia’ are rendered intelligible: the patient is required to carry out a domestic task (and ADL) within a mock domestic setting, and consequently the AMPS entails an examination of what could be called the patient’s *domestic body technique*. First, however, we will see why the PMDS felt it necessary to adopt the AMPS in the first place.

7.3 The problem with the Burke-Fahn-Marsden Dystonia Rating Scale

The Burke-Fahn-Marsden Dystonia Rating Scale was developed in the early 1980s (Burke et al. 1985). It is a composite scale containing two sections: a ‘dystonia movement scale’ for quantifying impairment (the effect of dystonia on different areas of the body), and a brief ‘disability scale’, which quantifies impact of dystonia on a few basic activities. For the first section, the patient is required to sit upright in a chair and perform a series of basic movements. These include, for example: “elbows and hands resting on the arms of the chair or the thighs... hold both arms out, extended and supinated... opening and closing both hands... touching the nose with the index finger” (Burke et al. 1985). As the patient performs these tasks, they are video recorded by the clinician or investigator, and at a later time this recording will be used to score the patient’s dystonia. This involves noting for each region of the body which actions exacerbate the dystonia (‘provoking’ factor), and the severity of the dystonia (‘severity factor’). By multiplying the two score together and then adding the result for each body region, an overall score is obtained for that individual patient. For the disability section of the BFM, the patient, or the patient’s family, are required to score the patient’s ability to carry out five basic tasks using a scale from zero to four. The tasks are speech, feeding, eating, dressing, writing hygiene and walking, and patients (or their families) are provided with a description of what qualifies as a zero or a one, or a two etc for each task. Ideally the BFM will be undertaken with patients as part of a pre-intervention assessment in order to

obtain a ‘baseline’ score, and it will subsequently be repeated at regular intervals after the intervention, enabling the effectiveness of the intervention to be calculated.

Generally, as a scale for primary dystonia, the BFM has received positive reviews within the field of neurology, rating well for validity, reliability and responsiveness (Burke et al, 1985; Krystkowiak et al. 2007). And indeed for the PMDS the scale is considered as a useful and effective means of measuring effects of DBS on patients with primary dystonia. This is not to say that it is without its problems or that it is easy to use. The PMDS therapists who carry out the BFM talk of the work required to get impatient, tired, or playful children to sit and carry out the tasks as instructed, and they refer to the noticeable lack of specificity in the BFM instructions, which, they state, leads to inconsistent application. While these challenges are relatively minor and are managed by the therapists,²⁴ using the tool with some patients, particularly those with secondary dystonia, is more problematic.

First, the movement scale component of the tool can be difficult to implement because it is not always clear whether the body area being scored is being affected by dystonia alone, or some other component of the patient’s condition. Anxiety is common among this group of patients and it can temporarily exacerbate dystonic movements. Patients tend to become more anxious and thus more dystonic when videotaped. Here, the occupational therapist illustrates this with specific example:

There was one the other day when the child – it’s so funny because he had no dystonia at all during four hours of working with me. But as soon as you put the camera on him, he’s like this [*mimics involuntary movements*]. I say, ‘Can you look at the camera?’ And he goes [*mimics involuntary facial movements*]. And I’m like, ‘Is that a plethora spasm? That’s not a plethora spasm.’ But, ‘Oh his eyes are closed.’ You know, and it ends up being such a meaningless measure for some of the kids (Occupational therapist, interview).

Second, the tool fails to register improvements that, while they may appear minimal, are nonetheless considered important to patients and their family. This is

²⁴ The therapists deal with the first of these problems by engaging in ad-hoc work to entice children to comply, such as using toys as props and humour. In order to deal with the second problem the occupational therapist has created a standard guidelines for carrying out the BFM.

particularly so with severely affected patients who may be unable to participate in the BFM in the first place. Here is an example from a team meeting discussion between the occupational therapist (OT) and a neurologist (neur):

OT: We have had six cases where there has been no change in their BFM score [after DBS system has been implanted]. But, rather than each patient needing three people to bath them and two to dress them, they now only need one carer. This is a significant improvement, but how do we demonstrate this when it cannot be demonstrated with the available scale?

Neur: With one patient, we managed to give him the use of a finger and thumb. This actually translates into quite an improvement in terms of daily living.

OT: That might be so, but how could we demonstrate that to funders?

For a patient, gaining the use of a finger and thumb may have important implications for their day-to-day life; it may, for example, enable them to operate a communication aid. Such improvements, however, cannot be detected with the BFM, and consequently it often fails to generate evidence that could be used to justify the use of DBS as a therapy of children with secondary dystonia. With regard to the PMDS patient cohort, therefore, the tool fails to meet the ‘responsiveness’ criteria of ‘scientific soundness’ requirements of a clinical assessment tool. During an academic meeting, team members discussed whether it was worth dropping the tool from their assessment regime altogether. It was decided, however, that for the meantime they would continue to use the tool as it was nonetheless a useful measure for patients with primary dystonia, and it provided a means of communicating with other centres:

PT2: So why do we need to use an impairment scale anyway? It is because all the other research out there uses these scales?

S&L: And the BFM specifically – what is the point of it?

CRF: It does enable a common language with other centres.

Dr M: The problem is, if we have different scales, different languages for primary dystonia and secondary dystonia, that makes it difficult to compare.

The team has therefore retained the use of the tool and at this stage it is generally carried out with all capable patients as part of the extensive pre-surgical baseline assessment, and at regular intervals after the DBS system has been implanted. The

PMDS is not the only team to note the shortcomings of the BFM. Several other centres working with children with secondary dystonia have also stated that, while it is certainly not useless, it can produce potentially misleading data (Marks et al 2009; Monbaliu et al. 2010). Nonetheless, the PMDS' response to this particular challenge is unique: the team has adopted clinical assessment tools from occupational therapy into their assessment regime. These adopted tools are used to assess disability, or the patient's ability to carry out activities of daily living (ADL). Team members argue that because of this focus on disability rather than impairment, these tools are more suitable for capturing and measuring improvements that are relevant to patients and their families. They are, in other words, considered more responsive to the effects of the DBS intervention.

7.4 The Assessment of Motor and Process Skills (AMPS)

The main tool that was adopted from occupational therapy for use as an outcome measure is the Assessment of Motor and Process Skills, or AMPS. It was developed in the early 1990s by the occupational therapist Anne Fisher, and it is designed to evaluate the impact of interventions on patients with any form or degree of disability (Fisher 1995). Like the COPM we explored in the previous chapter, its design was informed by the patient-centred 'mantra' of occupational therapy: it is intended to evaluate patients' capacity to engage in occupational and domestic activities that patients themselves feel are important (Fisher, 1997). Generally the AMPS is carried out with patients in the community in their 'natural' domestic setting. It is, nonetheless, designed to be a highly standardized, carefully controlled means of evaluation. In order to ensure that it is applied with minimal variation and as few inconsistencies as possible across various clinical and research contexts, the AMPS is part of a network of actors which attempt to dictate who can use it and how it can be used. This network consists of a standard AMPS manual (Fisher 1995), a 'regulatory' agency called the 'Center for Innovative OT Solutions', and an AMPS computer software program. These elements restrict who can conduct the AMPS, and they play a role in coordinating the actions of the therapist and patient while the AMPS is being undertaken in specific clinical contexts.

Firstly, although patients can choose the occupational or domestic activities that they would like to carry out as part of the assessment, they must do so from a list of 120 standardised 'activities of daily living' provided in the AMPS manual. For

each ADL, the manual provides a description of what the patient is required to do if they choose that task. Each ADL has a corresponding code and tasks are divided into levels of difficulty, from “Very Easy Tasks” (such as putting on socks and shoes), to “Much Harder than Average Tasks” (making fried rice). In order to evaluate the patient’s ability to complete a task, the therapist will examine and rate (from one to four) 36 specific *skills items* that constitute all of the ADLs. These include sixteen motor skill items (such as walking, reaching, gripping, objects) and twenty process skill items (such as choosing objects, pacing), all of which are defined by the AMPS manual. The manual also stipulates how these should be rated for each task (ie, what constitutes a one or a two and so on).

Second, the AMPS can only be conducted by an occupational therapist who is a fully certified and calibrated AMPS scorer. In order to become certified, therapists must attend an appropriate five-day training course, and in order to become calibrated, they must undertake ten AMPS ‘trial’ assessments and send their resulting scores to ‘Center for Innovative OT Solutions (previously called ‘AMPS Project International’). The Center will then assign each therapist with a calibration value indicating their rating ‘severity’, calculated by comparing their ratings with those of other therapists. This value will then be used to adjust (or calibrate) the therapist’s subsequent AMPS measurements. The certification and calibration can be seen as gate-keeping activities: only those therapists with a particular set of mandated skills can access and use the AMPS.

And third, in order to ensure that only certified, calibrated occupational therapists conduct the AMPS, software is required to undertake a critical step in the AMPS rating process. In order to generate an overall score for a particular patient, the therapist will input the ADL code scores for each of the 36 skill items into the software, which will then generate an overall score for the patient. First, however, the therapist must ‘unlock’ the software with a personal code which can only be obtained by the Center for Innovative OT Solutions. Importantly this personalized code indicates the calibration value of the therapist, which is subsequently used by the software when computing a final score. In effect, the software system restricts who can conduct the AMPS and it attempts to reduce the influence of individual rater idiosyncrasies on their patient’s overall score. Indeed, the AMPS software is an example of the materialization of a power relation (Berg 1998): the gate-keeping role

of the Center for Innovative OT Solutions has been encoded within the software, and non-certified, non-calibrated therapists are 'locked-out'.

The aim of this system of certification and calibration requirements, the personalized code and software system is to maintain the inter-rater reliability of the AMPS and ensure its 'scientific soundness' as an assessment tool. Indeed, as Timmermans and Berg have pointed out, the creation of standards and ensuring that standards are maintained often requires such strategies and techniques that aim to stabilize particular relations of power and control (Timmermans and Berg 2003). If such measures are effective, then compliant, correctly configured therapists will conduct the AMPS in a manner that is mandated by the Center for Innovative OT Solutions. This will mean that the 'patient-centred' sensibility that informed the construction of the tool will come to have some sort of effect on those local contexts in which the tool is applied.

The AMPS has become a widespread tool within occupational therapy. Advocates claim that it has been validated for use with patients from various cultural backgrounds (Goto et al. 1996) and with a range of disorders. This includes children with cerebral palsy (Van Zelst et al. 2006), and it was while working with this group in the community that the PMDS occupational therapist became familiar with the AMPS tool. When the occupational therapist later became part of the newly formed PMDS (which works with patients with dystonic cerebral palsy), and once she and other team members became aware of the limitations of the BFM, this familiarity encouraged her to suggest that the team adopt the AMPS. The tool has subsequently been used as a standard part of the team's regime of assessments for the last five years or so. While the tool has been adopted in other clinical settings (Nygard et al. 1994), the PMDS is the only team using the AMPS to assess the efficacy of a DBS therapy.

7.4.1 Using the AMPS with patients

It is the occupational therapist (henceforth 'OT'), then, who undertakes the AMPS with patients in the PMDS. She has undergone the AMPS training course, her severity as rater has been calibrated by the Center of Innovative OT Solutions, she has access to the appropriate software and a copy of the manual, and in order to maintain her skill-set, she attends regular AMPS-based meetings with a local group of OTs.

Before the AMPS can begin the patient must choose five daily living tasks. In the PMDS these are the same five tasks chosen by the patient and their accompanying family members during their initial interview that later became the basis of the COPM-scripted goal setting session. The AMPS manual states that these must be tasks that the patient “wants and needs to perform” but is having difficulty doing so (Fisher 2006). Importantly, each task must also correspond to one of the 120 standard ‘Activities of Daily Living’ listed in the AMPS manual. The patient will be asked to perform the five tasks during their subsequent assessments, and the video recordings of these performances will later be used to score the patient. Here I will use extracts from my observation notes of both a performance session, during which a patient performed a task, and a scoring session, during which the OT analysed video-recordings and the AMPS software to provide an overall score. I will argue that conducting the AMPS assessment involves the formation of a carefully coordinated assemblage including the patient and various domestic objects. This assemblage enables the assessment of body technique: the patient’s ability to utilize their body efficiently as an instrument to carry-out domestic, cultural practices.

A domestic assemblage

In many occupational therapy contexts the application of the AMPS takes place in the patient’s home. This provides the OT with an opportunity to observe a patient as they attempt to perform tasks that are important to them in the environment in which they would usually perform these tasks. As the manual states:

[OTs] need to observe and evaluate ADL task performances in natural spaces: bedrooms, family or living rooms, kitchens, gardens – ones like those where the client typically would be performing ADL tasks (Fisher and Jones 2010: 4-5).

In the context of the PMDS, where patients and their families may spend several days undergoing an assortment of assessments, it is necessary to recreate these ‘natural’ spaces within the hospital. Thankfully, as we saw in chapter 4, the hospital contains a diversity of spaces (such as kitchenettes and play areas), some of which provide the OTs with well-equipped settings to undertake AMPS assessments. It is in one of the spaces that we will follow the OT as she conducts the assessment of

Carl. Carl is again accompanied by his mother and two of the tasks he chose were washing the dishes and making a sandwich.

Carl's AMPS assessment takes place in a large room with a kitchenette. His mother spends most of the session seated in the corner of the room, knitting, and saying very little. Along one side of the room is a large sliding door that opens to a kitchen sink and dish rack, a fridge, an oven with a stovetop, bench-space and cupboards both under and above the bench (See figure 7.1, page 198). The OT, who is accompanied by the therapy assistant (TA), announces that they will begin with the 'washing the dishes' task. It transpires that the task was chosen because Carl would like to attend university in a few years and this would require him to live away from his mother and clean-up after himself.

As with the GMFM assessment we followed in chapter 4, the AMPS takes place within a layout of objects that has been carefully arranged by the therapists. This spatial layout, as we will see, enables particular information to be extracted from the patient, in much the same way that the careful arrangement of a laboratory assemblage enables information to be obtained from an entity of interest (Latour and Woolgar 1986; Mol 2002). The assemblage created by the OT is, to a degree, standardized. The AMPS manual stipulates how the task is to be performed by the patient, and in doing so it designates the types of objects to be included and how they should be arranged within space: indeed, we could say that the description within the AMPS manual is materialised as a specific place, thus (as we will see) enabling the creation of standardized knowledge. 'Washing the dishes' corresponds to ADL task "J-2" in the manual, which states that the task must be performed as follows:

The client is expected to wash and rinse 10 to 15 dishes... Rinsing soap suds off the dishes is expected... Appropriate dishes include an assortment of plates, glasses, silverware, small pans and related utensils. [After the dishes have been cleaned] the client is to drain water from the sink, wipe the counters dry, wring out the dishrag or sponge (Fisher 2003: 100).

The task description also outlines the responsibilities of the therapist during the performance:

The client should be completely familiarized with the set-up of the environment including the location of all needed tools and materials (Fisher 2003: 100).

Having checked the manual she has with her, the OT arranges the kitchenette so the task can be carried out correctly. She and the assistant have brought with them a box of dirty dishes from the staff offices on the upper levels. The dishes (bowls, plates and cutlery) are piled on one side of the sink and the dish rack is placed on the other. The OT checks that there is dishwashing liquid, a sponge and a tea towel in the cupboard below the sink. In effect, part of the home is brought into the clinic. The assemblage created by the OT is intended to mimic the spatial layout of objects in an 'average' domestic kitchen. The OT then familiarizes Carl with the ADL task:

OT: Carl – The washing up. How do you normally do it at home? Do you normally do it at home?

Carl: No. I don't usually do it.

OT: For this one, you are going to rinse and wash the dishes, stack them, dry them, and then put them away, and then you are going to wipe the bench and the sink clean. Got it? Now, you will put the clean plates here and the clean bowls here [in the dish rack] and we will put the cups and utensils over here [next to the dish rack]. You can also put the sponge and the tea towel where they should go when you have finished. Happy?

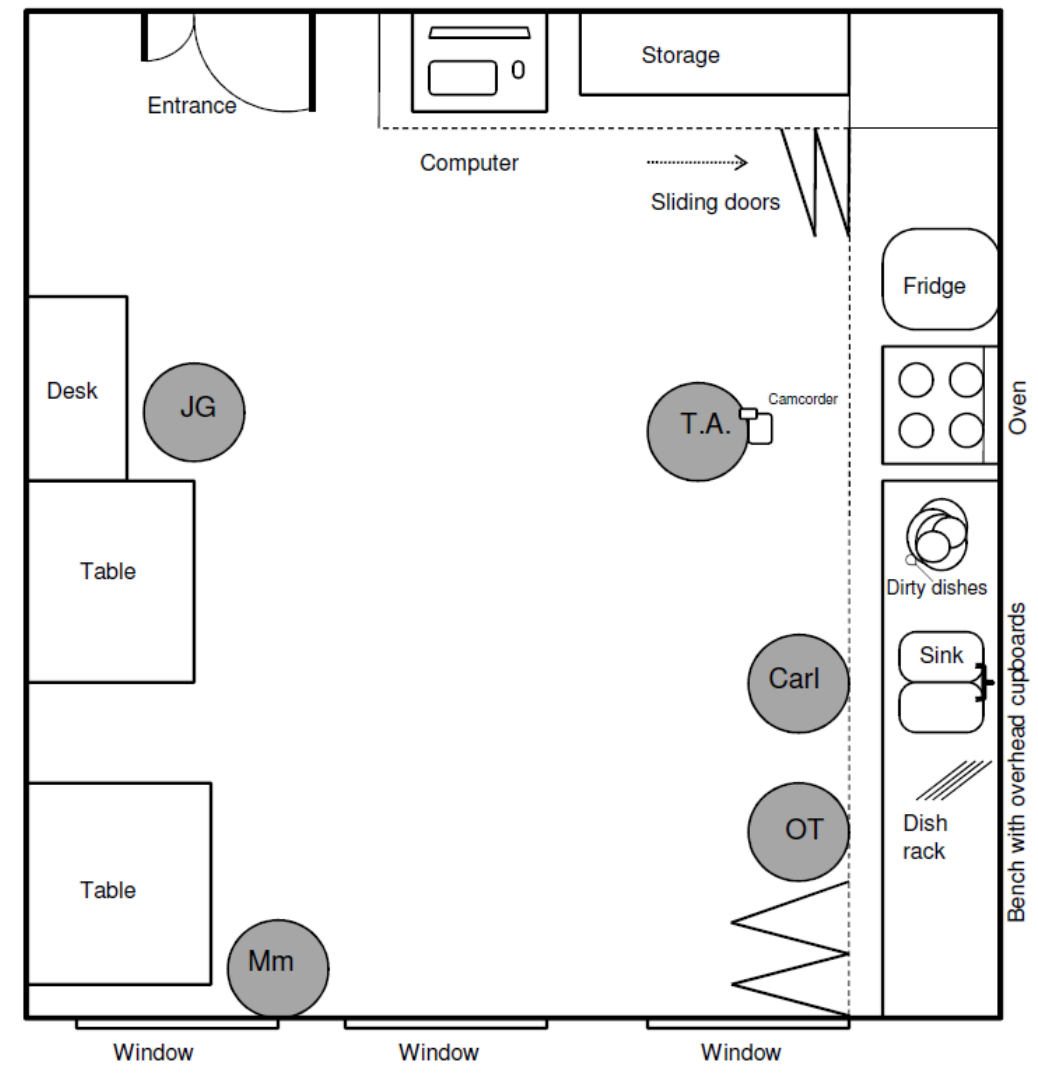
Carl: Yip.

Before he begins, however, the OT instructs Carl to ignore everyone else in the room, particularly his mother. She adds:

OT: Now, I'm not going to interfere with you at all, and neither is mum – isn't that right mum! I will step in, though, if it looks like something is going to fall or something bad like that happens... Great. Ready when you are.

Here the OT is attempting to limit which entities can become involved in the domestic assemblage. Indeed, if an assemblage is to yield particular, sought after information, it is necessary to prevent intrusion from unwanted influences that create noise or could throw a carefully coordinated interaction off course.

Figure 7.1: Room layout during the ‘washing the dishes’ task



The built environment of the location where the AMPS is being conducted also reduces unwanted intrusion. In laboratories, for example, such intrusion is reduced by partitioning of space with physical boundaries, thus creating an ordered place of knowledge-production shielded from disorderly outside space (Guggenheim 2011; Henke and Gieryn 2008). The room in which Carl performs the task is already partitioned from the noisy surrounding ward, and with the door closed, the outside world is barely audible. Indeed, those elements and activities that usually constitute a hospital environment are shut out from the AMPS assessment.

Within this ordered space Carl is encouraged to interact with the other elements of the domestic assemblage in much the same way as an ‘average’ individual would at their home. After receiving his instructions, he stands up and walks to the bench, sighs loudly, and begins to get on with washing the dishes and

putting them on the rack one-by-one. The OT watches closely and takes notes with a pad and pen, and the therapy assistant stands nearby recording Carl with a small handheld camcorder (The layout of the assessment is illustrated in figure 7.1, page 198). Once all the cleaned dishes have been placed on the rack, Carl rinses the sponge and wipes the bench and sink. Carl appears tired and moves slowly, and his body shakes and jerks due to his movement disorder, but he appears to complete the task without much trouble.

At the end, the therapy assistant has produced a video recording and the OT has created a series of notes. The OT will subsequently use these to closely scrutinize Carl's performance and provide scores for each of the 36 motor and process skill items, thus enabling an overall score to be calculated.

7.4.2 An assessment of body technique

For each of the motor and process items the OT must assign a number between one and four, where four equates to “performs skill item readily and consistently”, and one equates to “severe deficit or inability to perform skill item” (Fisher 2003). In order to illustrate the scoring process and its implications we will follow the OT as she uses video recordings to provide scores for patients who had carried out various tasks several weeks earlier. One recording is of a patient who had earlier performed the preparing ‘Cold cereal and beverage’ ADL task (task C-1). The patient, William, is seven years old and has primary dystonia. This performance was one of several conducted as part of a post-surgical review: William has had the DBS system implanted for one year.

Before scoring each skill item the OT watched the video recording of the performance from start to finish. It begins with the OT giving William his instructions: He is to get the milk from the fridge, a glass from the top right cupboard, and use the jug of water that has been provided. The OT shows William where these various objects are. William begins by grabbing a bowl from the cupboard and placing it on the bench. He then picks up the box of cereal and attempts to pour cereal into the bowl. Nothing comes out so William opens the inner bag up some more. After several attempts he gets enough cereal in the bowl and uses his fingers to level it. He then gets a large bottle of milk from the fridge and places it in the bench next to the bowl. He stops and looks perplexed, and then pours the milk into the cereal. He over-pours and some splashes onto the bench.

Using a paper towel he cleans up the mess. Once this is done, he pats the cereal down into the milk with his fingers and then stares at the bowl – he has forgotten what to do next. He asks the OT, who instructs him to get a glass of water. He searches the cupboards looking for a glass, locates one, and places it on the bench. He then drags the jug of water across the bench towards himself, lifts it, and then pours the water in. He then stops for several seconds before picking up the glass and pouring some water into the bowl of milk and cereal. He puts the glass down on the bench, pauses, and he then (oddly) picks it up and pours more water into the into the cereal until the liquid level reaches the very top of the bowl. At this point the recording ends.

The OT then begins scoring each of the 36 motor and process skill items that constitute William’s performance, one by one. In effect, the scoring process involves an examination of the way in which William uses his body to negotiate and interact with other objects within the domestic assemblage. Each skill item draws the OT’s attention to a different aspect of this performance.

Several motor and process skills, such as ‘Aligns’ and ‘Positions’ relate to the *position of the body* relative to other objects within the domestic assemblage. Importantly, body alignment and position are rated according to the degree of functionality: a higher score is achieved if the body is orientated in such a way that the ADL task can be completed efficiently. If the body alignment results in ‘unacceptable delay, unacceptable effort’ or “task breakdown”, it is scored as a one (Fisher 2003: 189). Here is an example from the scoring of William’s performance (as the OT scores each item, she explains her reasoning to me):

OT: The second [skill item] is ‘Aligns’ – this is also a four. He had no problem positioning himself to do the task. [Next skill item is] ‘Positions’ - this is something you would notice when their elbow is way up in the air while they are trying to pour something for instance. There was a bit of that with William. It kind of looks a bit awkward. Lets give him a two.

Some motor and process skill items pertain to specific *interactions between the body and other objects* within the domestic assemblage. For example, ‘Grips’ refers to the ability of the patient to grasp an object (such as a plate or a pan) or to open containers, ‘Lifts’ refers to the patient’s ability to lift (and not slide) an object from one position

to another, and ‘Manipulates’ refers to dexterity or in-hand manipulation of task objects. Again, body-object interactions are rated according to their functionality:

OT: ‘Grips’ - there was no grip slip – four. Even if you see a quick grip slip then you give him a two, but there was nothing like that here... ‘Lifts’ – If you slide an object rather than lift it, then you score it down. Did he do it? I think he slid the jug of water across the bench. This is where the video is useful [*the OT consults the recording*]. He did! He gets a two... ‘Manipulates’ – there was some fumbling with the cereal when he was trying to get it out of the box. He gets a two for this.

Body-object interactions are also graded according to their cultural *appropriateness*. The ‘Uses’ skill item refers to whether or not the correct object has been selected for a task: using ‘a plate as a plate, knife as a knife’ (Fisher 2003: 207). Here, then, the scoring process reflects social conventions regarding the use of particular objects. This is illustrated in the following extract, where I am asked for my opinion on the appropriateness of an interaction between the body (William’s hand) and an object a (bowl of cereal):

OT: ‘Uses’ – this is about hygiene. For instance, does a stroke victim use a toothbrush to brush their hair? There is an issue with William’s hands in the cereal. What do you think?

JG: For me, seeing him use his hand to adjust the dry cereal in the bowl looked quite normal. It is something that I would do. But when he used his hand to move the milky cereal, that was different. That seemed unhygienic.

OT: Yes, I agree. He gets a two.

Other skill items pertain to the *movement of the body* as the patient navigates other objects within the assemblage. For example:

OT: ‘Reaches’ – he was fine here. Had no problem getting the milk from the fridge. He gets a four... ‘Bending’ is also a four. There was no increase in effort while picking up the paper towels... ‘Walks’ – no instability when walking to the fridge and back, so he gets a four.

The *fluidity of body movements* while performing the task is also graded. ‘Flows’ pertains to the ‘fluid quality’ of arm and hand movement. Smooth movement scores highly, whereas movement that is disrupted, perhaps from “tremor, stiffness, increased tone” is scored down (Fisher 2003: 196):

OT: ‘Flows’ - This is hard, I will look [at the manual]. I don’t think the spillage was due to “marked spillage due to tremors”, which would qualify as a one in the manual. I think it was due to orientation. So, I will give him a two.

Scoring skill items also involves *differentiating ‘erroneous’ movements from functional movements*. Movements that are not directed towards the completion of the task, or hinder the completion of the task, may result in a lower score. For example, a “wobbly while walking or interacting with task objects” will result on low score of ‘Stability’ and ‘Transports’. A patient’s inappropriate persistence with a task will also be designated as erroneous movement:

OT: ‘Terminates’ - William gets a one for this. He continued to pour water into the bowl of cereal even when it was full of milk. He did it twice!

Other skill items pertain to the patient’s control over their body while moving and interacting with other objects. For example:

OT: ‘Calibrates’ – Here we are grading his movement and how he adjusts the force of his movement depending on the object. Does he use too much force? Not enough? Well, you can see how much milk he spilled. He gets a one.

The temporal dimension of the performance is also rated. ‘Sequences’ for example, is scored highly if various steps are performed “in an effective order for efficient use of time” (Fisher 2003: 214) similarly, ‘Gathers’ refers to the patient’s ability to efficiently collect the necessary items required for a task:

OT: ‘Gathers’- He collected everything from the fridge that he needed to in one trip. It would be scored down if he made multiple trips. He gets a four.

And 'Paces' pertains to the overall rate of the task:

OT: 'Paces' – I think he is slow. He is consistent, but he is slow. So, he gets a two.

Thus, by the time all 36 skill items have been scored the OT has scrutinized: the positioning of the William's body within the domestic assemblage, the interactions between the body and other elements within the assemblage, body movement and fluidity of movement, and the rate at which sequences of body movements occur. Importantly, as William's example illustrates, these various aspects of the performance are rated according to their functionality and efficiency. It is, therefore, the patient's ability to use the body as an *efficient implement* that is being examined: an implement for carrying out particular domestic tasks in a culturally permissible manner. To borrow a term from Marcel Mauss (1973 [1934]), we could say that the AMPS is an assessment of specific domestic *body technique*. Mauss defines body techniques as the way in which "from society to society men know how to use their bodies" (1973: 70). They have, he argues, three characteristics, all of which are scrutinized as part of the AMPS assessment: they involve a specific series of bodily movements and forms; they are social in that they are learned within cultural contexts; and they are efficient in that they serve a specific purpose or function.

Importantly for the PMDS team, the AMPS enables the patient's proficiency in domestic body techniques to be quantified. Once the OT has decided upon scores for all 36 items, she enters them into the AMPS software, along with the ADL task code, the age of the patient, and, of course, her personal AMPS code (which unlocks the software in the first place and ensures the final score will be calibrated according to her severity as a rater). The programme combines these details with scores from several of William's other ADL performances. From these combined scores the programme generates an overall set of scores for William at that point in time. The programme enables the OT to compare these to those of the 'average, able-bodied' seven year-old child, and with those of William's pre-surgical baseline assessment: The OT notes that William's scores are within the normal range of an average seven year old, despite scoring poorly on several skill items (It is expected, she states, that an average child of that age would have the same difficulties). And, she adds, when compared with his pre-DBS scores, "his motor

skills have improved significantly, although his process skills are largely unchanged.” It is according to such comparisons of body technique proficiency that that the AMPS enables the impact of the motor disorder, and the effectiveness of DBS as therapy for managing dystonia, to be assessed for each patient.

7.5 Discussion: The shift towards patient-centred tools

As we have seen, undertaking an AMPS assessment involves the construction of domestic assemblage that is carefully shielded from unwanted influences. Within this controlled space the patient is coaxed to perform domestic tasks, to use their body as an efficient implement to perform ADL tasks in a culturally permissible manner. This, I have illustrated, enables the OT to scrutinize the elements of domestic body technique: the sequence of bodily movements and forms employed by the patient as they negotiate and interact with the other elements of the assemblage. It is, then, the patient’s practical relationship to and involvement in the world that is being assessed. As a consequence, dystonia, and the effectiveness of DBS in managing dystonia, are rendered intelligible in terms of their impact on this practical relationship and involvement. To borrow the language of Annemarie Mol (2002) we can say that the domestic assemblage has enacted dystonia as a reduced ability to engage in the world, or in other words, as a disability. Perceiving dystonia in this way is useful for the team. It enables team members to capture and measure clinical improvements that patients themselves find meaningful; improvements that may not have been captured with the impairment-based BFM. Of course the AMPS is just one data-gathering activity: Results from the AMPS and the BFM, as well as the COPM and various cognitive, speech, and pain assessments, are all combined to form an overall body of knowledge that will be used to assess the effectiveness of DBS.

This example of the adoption of the AMPS within the PMDS provides another glimpse into the means by which transformations (or innovations) within clinical practice can occur. Here, in an attempt to develop a clinical service using DBS technology, the PMDS team has incorporated the AMPS tool into their routine clinical practice. Like the team’s adaption of the COPM, this is an example of learning-in-practice; they have developed a new routine in order to manage a specific challenges associated with the integration of DBS technology. And as a consequence the perceptual system entrenched within the tool has become

embedded within the clinical context of the PMDS. The PMDS subsequently enacts a central principle of occupational therapy: that a condition or illness should be understood in terms of a patient's (in)ability to engage in occupational activities (which includes domestic and work activities). In a sense, the AMPS tool has functioned as a vector, a means of transporting elements of the professional vision of occupational therapy into a hospital-based paediatric neurology context.

We can also see here another example of the broad clinical gaze of the PMDS that we saw during the team meeting and during the COPM-scripted goal setting session. Again, the clinician's attention is directed towards various 'non-biomedical' aspects of the patient. As with the COPM-scripted goal setting session, it is the consequence of a carefully coordinated interaction (involving a well-trained 'mandated' OT) that enables the 'patient-centred' mantra of the tool from occupational therapy to be expressed. In the following chapter I will relate this insight on the PMDS clinical gaze to current discussions on the implications of new neurotechnologies; At this point it suffices to say that it demonstrates that clinicians working with new neuro-interventions, like many patients subjected to neuro-interventions, resist reductive, biomedical brain-based explanations of disease and the patient.

It is also worth noting here that while the PMDS is the only DBS service to have adopted the AMPS so far, it not unique it is adoption of this type of clinical assessment tool. Indeed, it is perhaps best seen as part of the shift identified by Armstrong and colleagues towards the creation and adoption of QoL measures within medical practice more broadly (Armstrong et al. 2007). Despite the pharmaceutical industry's proclivity for easy-to-implement 'objective' measures, there has been a trend away from methods of data collection that rely exclusively on clinician (or investigator) reporting, toward those that employ greater patient involvement (Hobart and Thompson 2001). This shift is often explained as a consequence of the emergence of 'patient rights' movement within healthcare and the growing body of evidence illustrating that clinicians and patients often have different perceptions of the impact of an illness (Reiser 1993; Hobart et al. 1996). Armstrong argues that it represents a deeper transformation within medical thinking: an awareness that the underlying pathology of an illness does not necessarily correspond to the symptoms experienced by the patient, and if health

interventions are to be adequately assessed, it is these ‘distal’ symptoms and experiences that must be measured (Armstrong et al 2007, Armstrong 2011).

While patient-perceived changes are often derided for being ‘less objective’ than those measured by investigators or clinicians, they are nonetheless now considered an important component of evidence-based health research in neurology. In effect, disability-based and QoL-based tools manage a tension between evidence-based medicine on the hand and the patient-centred healthcare movement on the other: tools such as the AMPS essentially convert particular aspects of illness (as experienced by the patient) into a set of ‘objective’ data (May et al 2006). To some degree this shift towards such tools has been institutionalized: the FDA has taken the stance that new drugs for neurological diseases will not be approved based on measurements of disease process or impairment alone. Improvements that patients themselves consider relevant (such as improvement in disability) must also be illustrated (Buskens and van Gijn 2001). Similarly in the UK it has become standard practice to report patient-based outcomes alongside more traditional biomedically-defined outcomes (Fitzpatrick et al. 1998).

Despite this apparent sea-change, the adoption of the AMPS tool has created additional challenges for the PMDS. The team is, in effect, attempting to redefine ‘what counts’ as data in the field of paediatric neurology in such a way that it supports their activities. Thus, ensuring the longer term survival of DBS as a therapy for secondary dystonia depends on their ability to convince other agents that their framing of ‘what counts as data’ is legitimate. Like the COPM, the AMPS is prevalent in occupational therapy settings but it is largely unknown within the neurology community, where the BFM is still considered the standard tool for measuring the effectiveness of interventions for dystonia. So despite successfully incorporating the tool into their clinical practice, and despite successfully using it to capture clinical improvements that patients and their families feel are meaningful, the team must still convince the wider neurological community that the AMPS is a scientifically sound, appropriate measure, and that the data it generates therefore count as sufficient evidence of DBS effectiveness.²⁵ This can be seen as part of a more significant dilemma encountered by the team that I will briefly touch upon in the next, final chapter of this thesis: convincing other clinicians that the novel

²⁵ One of the team’s strategies for doing this is to publish peer-reviewed articles that systematically demonstrate the shortcomings’ of the BFM while highlighting the utility of AMPS.

activities that take place within the PMDS, including the DBS therapy, are indeed 'innovative' and 'progressive', and thus worthy dissemination amongst the wider paediatric neurology community.

8 Discussion: Reconceptualising medical innovation

8.1 A brief recapitulation

In the introduction to this thesis I argued that the Morlacchi-Nelson model of medical innovation would provide a useful starting point for this exploration of deep brain stimulation in paediatric neurology. The advantages of using this as an underlying conceptual tool should now be apparent. Firstly, it has encouraged us to explore the ‘conjunction of circumstances’ that has shaped the development and dissemination of DBS technology, and in doing so, we have provided some context for the activities of the PMDS. Deep brain stimulation, as we have seen, has its genesis in the knowledge and material infrastructure of stereotactic neurosurgery, and the DBS technology emerged from advancements in the development of the cardiac pacemaker. The advent of medical device regulation along with the development of clinical assessment tools for specific illnesses shunted the development of DBS towards specific therapeutic applications, most notably Parkinson’s disease. The development of additional clinical assessments tools has enabled Medtronic to sponsor additional clinical trials and thus widen the market of their technology. Thus, in answer to the first research question of this thesis, (What factors have shaped the development and dissemination of DBS technology?) we can say that the development and dissemination of DBS technology has been shaped by an intertwining of professional and commercial interests, the advent of medical device regulation and the co-development of particular clinical assessment tools.

The second advantage of using the Morlacchi-Nelson model of medical innovation as a starting point is that it has encouraged me to explore the learning-in-practice entailed in the implementation DBS technology within an actual clinical service. In order to explore this learning-in-practice I identified what PMDS team members perceived to be key challenges associated with their work, and examined how PMDS clinicians had developed strategies for managing each of these challenges through the second research question: ‘What are the challenges associated with the integration of DBS technology into a therapy for children and young people with dystonia?’; and the third research question: How do members of the PMDS team attempt to overcome these challenges in clinical practice? The first challenge we explored was coordinating multidisciplinary; or ensuring that the

diverse professionals who constitute the PMDS work together as a collective. I argued that the built environment of the hospital enabled multidisciplinary team work, and I also illustrated how the crafting of a team diary and the regular team meetings both functioned to coordinate multidisciplinary team work. The meetings, for example, provided an opportunity for Dr Martin to discursively unify the team and alleviate tensions, as well as providing an opportunity for encouraging team members to complete and circulate multidisciplinary documents.

The second challenge that I focused on was identifying dystonia and differentiating it from other manifestations of neurological pathology such as spasticity – this is necessary in order to help identify which patients with secondary dystonia are suitable deep brain stimulation candidates. I demonstrated that the team's strategy for overcoming this challenge was to utilise the embodied skills of the physiotherapists. By engaging in communicative body work and utilising carefully-honed tactile skills, the physiotherapists are able to identify dystonia and evaluate its impact on the patient's gross motor function.

The third challenge that I explored was managing the expectations of patients and family members. Here, I demonstrated how the team had adapted a tool from occupational therapy, the COPM, into a goal-setting session. Provided that those individuals involved in the session stick to the script, the goal-setting session prompts a particular mode of communication: it prompts patients and family members to be explicit about their hopes, and it encourages team members to convey their expectations in terms that are accessible to patients and families. And the fourth challenge we explored was measuring clinical outcomes. Specifically, the team considers the standard clinical assessment tool for measuring dystonia (the BFM) to be inadequate for measuring improvements that patients and families find meaningful. Consequently, the team has adopted an additional tool from occupational therapy, the AMPS. The team, therefore, is attempting to redefine 'what counts as data' when assessing interventions in dystonia paediatric neurology. These strategies are examples of the varied work that is required to implement an emerging medical technology within clinical practice. Obviously a technology on its own is useless: if the potential benefits of a promising technology are to be realised it will need to become integrated within an actual clinical service. The ability of such a service to make the most of a technology will depend upon the ability of clinicians to work effectively with one another and with patients, to identify appropriate

candidates, to successfully manage expectations, to demonstrate the effectiveness of their service, and to manage any other challenges that they encounter. This adaptive work, as Morlacchi and Nelson (2011) point out, is a vital component of the innovation process. Economists have also made this point. Localised learning processes, according to Antonelli, produce technical knowledge which is the “primary input in the generation of new knowledge at large, together with the scientific advances... and the acquisition of external knowledge spilling in the atmosphere” (2009: 632). What I have illustrated in the preceding chapters is the diverse nature of this adaptive work; it involves embodied skills and tacit knowledge, emotional labour, and a variety of profession-specific knowledge and tools.

This ‘adaptive’ work is transformative. As Hopkins and colleagues point out, realising the potential of new technologies requires the construction of “new elements and linkages to reconfigure existing socio-technical systems” (Hopkins et al 2007: 568). It requires, in other words, the creation of novel assemblages. In the case of the PMDS these novel assemblages involve a diverse array of tools, bodies, skill-sets, fields of knowledge, and elements of the built environment. Indeed, the multidisciplinary nature of the team has enabled it to draw on a diverse array of resources from a range of professions, which together have resulted in a service that is unique within hospital-based medicine and unique within neurology (paediatric or otherwise). The team’s use of the COPM and AMPS are good examples of this: both have been adapted somewhat to suit the local clinical context, and both entail clinician-patient interactions that are unusual within tertiary neurological services. And if the PMDS is successful in convincing the wider neurological community that the AMPS is a legitimate assessment tool for dystonia, then the transformative effect will not be limited to their local context. We can see here how the development and dissemination of a technology can prompt wider changes within clinical practice: an emerging technology has enabled the formation of a novel collection of professionals; this novel collection of professionals has, by bringing together an eclectic array of resources, created a unique service; and this service may prompt wider changes among a specialist community.

It is worth noting here that innovative activities of the PMDS team correspond to what some economists, drawing on complexity theory, have referred to as the complexity theory of change (Rosser 1999; Foster 2005). According to this

model, ‘change’ (some of which may be referred to as innovation) emerges from a collective “cluster” of heterogeneous individuals each possessing a distinctive set of skills. These individuals are creative: they may adhere to the local rules that characterise the cluster, but they also draw-upon their skills and available resources (or capacities, if we employ the parlance of material semiotics) to overcome constraints in original ways. These individuals also possess bounded rationality (rationality resulting from a myopic understanding of the world) rather than Olympian rationality (rationality based upon a full awareness of all available tools, resources and constraints). According to this model, innovation emerges from the many creative activities of these agents within the heterogeneous collective, and can be stifled by top-down, imposed decision making: individuals must be provided with some ‘creative space’. This has certainly been the case with the PMDS. While it was Dr Martin’s explicit intention to create a team of individuals from specific professional backgrounds, he did not stipulate which tools and resources these professionals were to utilise in their roles (and he would have had a limited knowledge of the many, profession-specific tools available to them), and team members have been left to their own devices to work-out which tools would be most appropriate.²⁶

8.2 The socio-political trends shaping medical innovation

According to this ‘complexity theory school’ of economics it is not possible to predict the form of innovations that will emerge from such clusters: this would require an impossible foresight of the many interweaving forces that shape a local context. Nevertheless, this school argues, there are discernible patterns of innovation. These reflect what complexity theorists have referred to as *attractors*. Attractors are, in effect, the limits of possibility for a given system of activities.²⁷ Such limits may be the consequence of, for example, government policies, prevalent ideologies or existing material infrastructure that subsequently induce patterns of

²⁶ The occupational therapist, for example, made the decision to bring in the COPM as a replacement for the Goal Attainment Scale (GAS) that she felt was inadequate: “I started using it by myself with the psychologist. So that’s how it started” (Occupational therapist, interview).

²⁷ The technical definition of an attractor is: “a set of values in phase space to which a system migrates over time, or about which the system iterates” (Meade et al 2004). They have what DeLanda refers to as a real, *virtual* existence, rather than an *actual* existence (DeLanda 2002): Attractors influence perceivable phenomena, but they themselves are not directly perceivable. Hence, they have a real existence in ‘phase space’.

organisation and action. We saw a good example of an attractor in the historical development of deep brain stimulation technology: Medtronic created an extensive set of skills, resources and procedures for producing cardiac-pacemakers. This embedded ‘technology platform’ presented a pathway for subsequent innovative activities; a pathway which closes some possibilities while making others more likely, thus providing structure for the development of neurostimulator technology. Subsequently the neurostimulator and the cardiac pacemaker share componentry and are visually similar: we can say that the technology platform created an ‘attractor’, around which particular patterns of devices emerge. My point here is not to specifically adopt this notion of ‘attractor’ into my account of deep brain stimulation and the PMDS, but rather to argue that despite the significant diversity that may exist among innovative biomedical sites, particular patterns in innovation will nonetheless emerge, patterns that are the result of various structuring influences. As I stated earlier, these are what Faulkner has called “powerful structuring forces that affect the capacity of groups to shape a technology” (2009: 24). I have referred to these forces as socio-political trends, and in the preceding chapters I have identified several (thus addressing the fourth research question of this thesis: What socio-political trends influence the development of PMDS’ DBS service?)

During the historical development and dissemination of deep brain stimulation I illustrated that commercial industry and the motivation for profit could be considered one such socio-political trend: Medtronic, which formed alliances with key clinicians, was a key driver in the dissemination of deep brain stimulation. I also argued that this dissemination and stabilization was shaped by the emerging prominence of evidence-based medicine and the rationalization of healthcare. This trend became ‘encoded’ in legislation that created medical device regulation and redefined ‘efficacy’ as something that is objectively verifiable. This has created a context where the development of new technologies is directed towards therapeutic applications for illnesses which can be quantified with such tools.

Other authors have also noted the transformative effects of commercial industry and rationalisation in healthcare. Blume, for example, argues that the influence of commercial industry has created a common pattern of medical device development: devices typically have their genesis in the ‘tinkering’ activities of an

engineer or physicist, or a clinician with some training in these areas who plays around with a newly acquired material (Blume 2010: 8; Blume 1992). This entrepreneur then seeks guidance from the manufacturing industry, leading to an alliance that gradually expands to include other clinicians and hospitals, and during which the device undergoes ongoing incremental modification. Inevitably large companies will come to dominate later stages of development and dissemination as they possess the necessary capital to obtain regulatory approval. Blume states that the artificial hip, the intraocular lens, the artificial kidney, obstetric ultrasound technology and the cochlear implant followed this pattern – a pattern that characterised the development of deep brain stimulation technology.

Several commentators have drawn attention to the role of commercial industry in facilitating EBM and rationalisation in healthcare. Timmermans and Berg argue that pharmaceutical companies, since the advent of pharmaceutical regulation, have become strategic supporters in EBM (Timmermans and Berg 2003: 167). In an effort to secure access to markets, pharmaceutical companies have supported the construction and dissemination of standards that can be used to ‘objectively’ establish the effectiveness and superiority of their drugs. Rationalisation creates a degree of uniformity and reduces uncertainty, which provides companies with clear ‘pathways’ for accessing markets and thereby enable drug companies to construct comprehensive business models and thus secure investment. Clarke et al (2003) argue that this alliance between the pharmaceutical industry and rationalisation has been ‘greatly facilitated’ by information technologies which have enabled distinct, heterogeneous research and clinical sites to become subject to centralised management operation.

We have seen the same phenomenon in regard to the medical device industry: Medtronic has facilitated the diffusion and standardization of outcome measures (particularly the UPDRS) across research sites in order to access lucrative markets for their deep brain stimulation technology. For Clarke and colleagues (2003), this alliance between commercial industry and rationalisation is one manifestation of the BiomedicalTechnoService Complex Inc; a contemporary form of the Medical Industrial Complex identified by Relman (1980). As we will see further on, Clarke and colleagues believe that this complex generates particular healthcare practices that are producing new bodies and health identities.

We also saw that EBM and rationalisation has structuring effects on the learning-in-practice activities of the PMDS. As we saw in chapter 6, team members have an obligation to ‘objectively demonstrate’ the efficacy of DBS, very much in accordance with the EBM movement. And, the standard tool for generating this evidence (the BFM) was established as such by the activities of Medtronic in its attempt to gain regulatory approval. Interestingly, the team’s response to the perceived limitation of this clinical assessment tool, namely, to adopt another tool and attempt to redefine ‘what counts as evidence’ is not unique. Blume has noted the same occurrence in regard to the cochlear implant (Blume 2010). Proponents of the controversial implant were able to define the criteria according to which its success would be judged: they strategically defined the desired outcome as ‘improved speech perception and production’ and were thus able to demonstrate its effectiveness using tools that were available only to medicine and audiology (2010:176). Other more comprehensive ways for measuring the effect of cochlear implants on the lives of children were disregarded. Blume suggests the dissemination and stabilisation of new therapies in the era of EBM does not necessarily entail using evidence to build consensus among agents, it entails *creating a consensus about what counts as evidence*.

In Blume’s example this consensus was crucial to the success of the cochlear implant. It also had the effect of strengthening the authority of the medically-trained clinicians who were promoting the device: its success was defined using their tools and according to their terms. These tools and terms were, of course, derived from an understanding of deafness that was based upon the biomedical model. Consequently, this rendering of deafness as a biomedical problem requiring technological intervention was perpetuated during the dissemination of the device, much to the abhorrence of those who had less-reductive understandings of deafness, particularly those who understood deafness an important part of self- and collective-identity. The device, then, was something of a vector for the biomedical model of disease. Other commentators have made a similar link between the development and dissemination of new medical technologies and the perpetuation of reductive, biomedical model-derived understandings of health and illness (eg, Corea, 1985; Pasveer 1989; Klein et al 1991). Pickstone has argued that as clinical practice has become increasingly reliant on technologies, there has been a shift from biographical medicine (where illnesses are understood as disturbances to individuals’

lives) to techno-medicine (Pickstone 2000: 10). Similarly, Brown and Webster suggest that new technologies and their innovation networks tend to confirm the power of the biomedical model and, more generally, biomedical-based research (Brown and Webster 2004: 169). For Clarke and colleagues, this *biomedicalization* is a key feature of the BiomedicalTechnoService Complex Inc. It is a consequence of the increasing intermeshing of commercial interests, rationalisation and new medical technologies, and it is, they argue, generating new individual and collective identities based around biomedically-defined criteria (Clarke et al 2003). As we will see in section 8.4, new neurotechnologies have also been implicated in this trend towards reductive understandings of disease and the body.

Despite the influence of commercial interests and rationalisation, our exploration of DBS in paediatric neurology reveals a different picture. In the process of exploring the learning-in-practice activities of the team I identified other socio-political trends which have, in effect, led them to enact less-reductive understandings of disease and the body. I argued that the multidisciplinary structure of the team reflects a prevalent belief that multidisciplinary teams can provide better health services for patients, particularly children. This belief has been encoded in the tariff structure for children's healthcare services as well as other policies which seek to remove financial and structural barriers to multidisciplinary. It has also been encoded in the material, physical form (the structural layout) of the children's hospital. The physical form of the hospital facilitates the multidisciplinary activities of the PMDS by providing them with a diversity of spaces for carrying out a diversity of interactions with patients. I argued that the team's activities have been influenced by a trend in healthcare that promotes patient-involvement in decision making and which aims to protect the autonomy of patients. This is a trend which has become embedded in NHS policy and is reflected in the team's attempts to carefully manage the expectations of patients and families, resulting in their adoption of the COPM tool. And, I argued, the COPM and AMPS tools reflected a 'patient-centred' approach to health service provision that is prominent in occupational therapy, and has subsequently, via the adoption of these tools, become embedded in the activities of the PMDS. The multidisciplinary structure of the team and the multidisciplinary nature of their tools and activities have brought about a clinical gaze that extends far beyond the biomedical elements of the patient's body. In addition to neurological and gross motor function considerations, team members

scrutinize a patient's cognitive abilities, speech and language skills, their capacity to carry out tasks of daily living, their expectations regarding the intervention, and as we saw during the team meeting, a patient's relations with peers and family members, as well as a patient's schooling. Team members may draw upon knowledge of any number of these elements when deciding upon an appropriate course of action. The PMDS, as I have argued, enacts a clinical gaze that has a broad remit. It is for this reason that the PMDS' attempt to redefine 'what counts as evidence' stands in striking contrast to that of cochlear implant proponents. The PMDS' extensive assessment regime means that the effectiveness of DBS is defined according to a broad array of characteristics: changes in gross motor function, impairment and ability to perform ADLs (as we saw in the preceding chapters) and changes in cognitive and speech and language abilities (which we did not explore here). As a result, various allied health professionals, particularly the occupational therapist and physiotherapists, have been granted considerable authority in defining and determining the effectiveness of DBS within the PMDS.

The development and dissemination of many new biomedical technologies may involve a perpetuation of the biomedical model and the elision of other modes of understanding disease and the body, but this has not been the case as far as the PMDS is concerned. This is because the activities of the PMDS, indeed its very structure, have been influenced not only by EBM, rationalisation and commercial interests, but also a by pro-multidisciplinary socio-political trend, and by a trend towards patient-centred care. Indeed, the PMDS represents a confluence between these various trends; a confluence that is unique within hospital-based medicine.

May and colleagues have explored a similar convergence of trends within the practices of UK primary care, where the patient-centred approach to clinical practice is more prominent than it is in hospital settings (May et al 2006). Increasingly, clinicians working within primary care must manage a potential conflict between EBM and its insistence on evidence-guided decision making on the one hand, and patient-centred care, which insists on incorporating patient's experiences and narratives of illness into decision making, on the other. Interestingly, the potential tension between the two has spawned technological solutions: novel tools that embody both approaches. May and colleagues provide the example of decision support tools which provide space for patient-input and prompt clinicians to divulge available data about an intervention (2006: 1026). We

have seen the generation of such tools within the PMDS: the COPM-scripted goal session being a good example of this. In this light, we can see that the novel strategies developed within the PMDS parallel strategies developed elsewhere, where a similar conjunction of socio-political trends occurs.

The innovative activities of the PMDS, then, have not occurred in isolation. They reflect broader trends in contemporary healthcare; trends that have become encoded in legislation, in tools, in architecture, in NHS policy, or in the modes of thinking of clinicians. In effect, these trends present pathways for individual teams such as the PMDS: they constitute a set of constraints and resources which make some innovative activities more likely than others. While the development of deep brain stimulation therapy for children with dystonia parallels other innovations in medicine, it is also characterised by some divergences: these are a consequence of the particular confluence of socio-political trends which structure the activities of the PMDS.

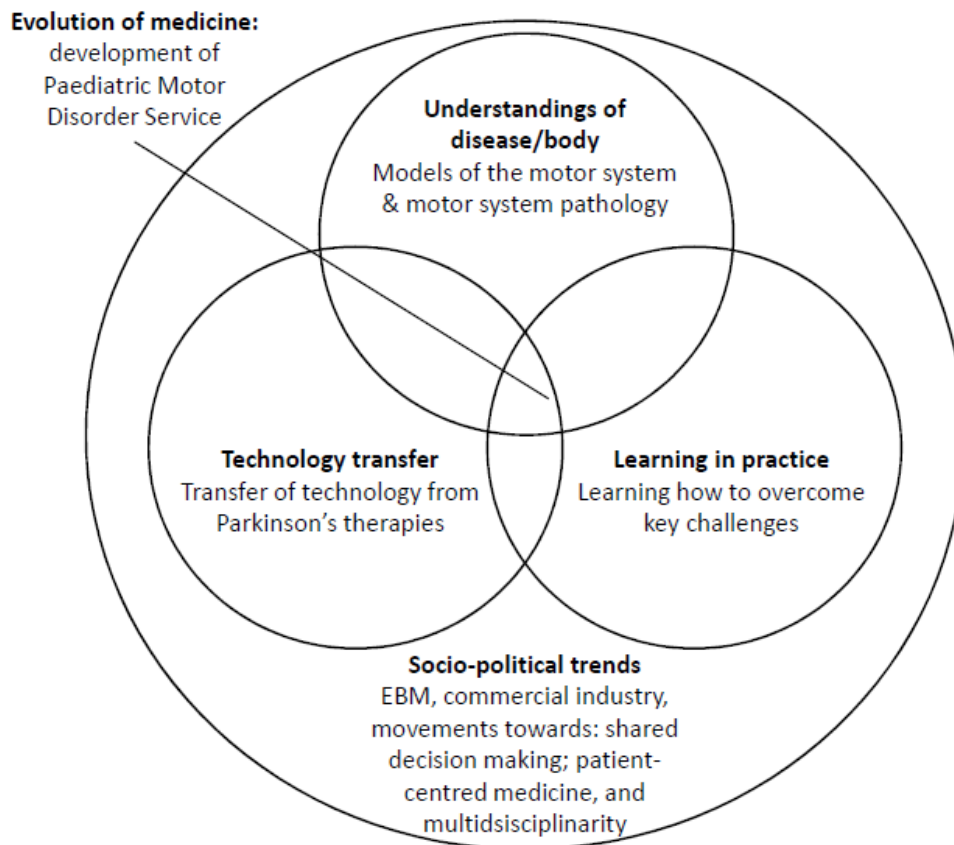
8.3 The Complex Model of Medical Innovation

Shortly I will relate these observations to a current discussion on the implications of new neurotechnologies. Firstly, however, I will outline the ‘Complex Model of Medical Innovation’, which I believe has been validated by our exploration of deep brain stimulation in paediatric neurology. As I stated in the introduction to this thesis, the Complex Model being suggested here is largely derived from the Morlacchi-Nelson model. The key difference between the two is an additional ‘sphere of influence’ representing socio-political trends which, to some extent, structure the local context within which innovation occurs. This complex model is represented below in figure 8.1. I have used the activities of the PMDS team to provide detail.

The ‘sphere of influence’ representing socio-political trends encapsulates all three other spheres. This is to indicate that socio-political trends are structuring forces that can shape learning-in-practice, technology transfer, and understandings of disease and the body. Thus, according to this model, evolution in clinical practice (which we might refer to as ‘innovation’) results from the interaction of technology transfer, understandings of the disease and the body, and learning-in-practice (as

stated by Morlacchi and Nelson), all of which are structured to some degree by various socio-political trends.²⁸

Figure 8.1: The Complex Model of Medical Innovation



Following Morlacchi and Nelson (2011: 512) we can say that the relative influence of each sphere in the process of innovation will differ from case to case. The development of a DBS service for children and young people with dystonia has been heavily influenced by technology transfer, learning-in-practice, and socio-political trends, but we might imagine other cases where the evolution of a clinical

²⁸ As I stated earlier, Faulkner (2009) has also illustrated that particular 'macro structuring forces' have shaped the development of several medical devices. He does not, however, put forward a model of innovation to conceptualise this relationship between macro forces and local innovative practices. Nor does he differentiate the innovation process into 'technology transfer' 'learning in practice' and 'understandings of disease'.

therapy has been radically influenced by the dissemination of new scientific understandings of the disease. It is also important to keep in mind that the learning-in-practice activities may lead to new scientific understandings of disease (Morlacchi and Nelson 2011: 512), a phenomenon that was not explored in this particular case study.²⁹

A legitimate question here is: why bother producing a model of medical innovation? If innovation emerges from a complex intertwining of forces, would it not be more appropriate to provide a rich detailed account of a case study, and refrain from producing an abstract model that is sufficiently general that it can represent all cases of innovation? Surely the generality of such a model would render it meaningless? An answer to this is that such a model can serve to counter the prevalent and misleading linear model of innovation that was discussed in the introduction. Godin has argued that various agents have used the linear model as a rhetorical device to secure funding for basic science, and that its simplicity grants administrators with a sense of orientation when allocating funding for research and development (Godin 2006). Hence, as Morlacchi and Nelson have suggested, research into other important aspects of innovation, aspects that are elided by the linear model, has been underfunded. As we have seen, the clinical implementation of a novel technology and the creation of a useful clinical service involve considerable work on the part of clinicians. A more comprehensive model can be used to draw attention to the importance of this work, and possibly help garner additional support for clinicians attempting to utilise new technologies. Further on (in section 8.5) I will demonstrate the utility of this more comprehensive model: the findings from this project's examination of the innovative activities of the PMDS can help inform recommendations on 'preparing the future for deep brain stimulation'.

²⁹ PMDS team members, however, are engaged in research activities that are generating new understandings of the disease and the body. The clinical research fellow has been attempting to draw a correlation between clinical outcome (and reduction of dystonia in various parts of the body) with the exact position of the electrodes within the GPi. The goal is to determine if specific regions of the GPi are implicated in the movements of particular body regions. So far he has found no meaningful correlation, which may suggest that the GPi is not divided in this way.

8.4 Neurotechnologies and the march towards neurocentrism?

According to Peter Keating and Alberto Cambrosio (2003), during the 20th century there was a great transformation from medicine to biomedicine. The former was characterized by what Pickstone (2000) referred to as biographical medicine (in which illnesses are understood as disturbances to individual's lives), whereas in the latter, biology and medicine have become entwined to such an extent that health and illness are rendered intelligible in terms of an array of biological entities: oncogenes, DNA profiles, cellular markers, viral load counts and so on. Keating and Cambrosio describe this transformation as being characterized by the emergence of *biomedical platforms*.³⁰ These are configurations of healthcare policy, architecture, machines, infrastructure, reagents and 'ways of thinking' that reify and perpetuate this biomedical mode of clinical work. These platforms are embedded within hospital settings (in the form of diagnostic laboratories, for example) and have a structuring effect on clinical research and clinical practice.

Importantly, as I have alluded to, these platforms are implicated in the formation of new individual and collective identities, in which biological traits have become the basis of social life. Rabinow's term (2006) *biosociality* is often used to capture this phenomenon (Rose and Novas 2004, Novas 2006; Brekke and Sirnes 2011): Biomedical diagnoses can influence how individuals' perceive themselves, and this altered self-perception prompts individuals to engage in new social and political activities that appropriate and perpetuate the language of biomedicine. Rose has argued that in this era of biomedicine, our sense of individuality derives from our knowledge of biomedical traits and is "increasingly grounded within our fleshy corporal existence" (Rose 2007: 26). The emergence of biomedical platforms, then, has involved a change in the way which health and illness are rendered intelligible, and it has prompted the formation of new identities and social collectives which draw-upon and perpetuate biomedical knowledge.

³⁰ In a sense, the term 'biomedical platform' can be seen as a synonym for 'biomedical paradigm'. Keating and Cambrosio use the term platform because they wish to highlight the material and institutional basis of this mode of clinical work. The notion of a biomedical 'paradigm' could give the impression that a biomedical 'way of thinking' preceded and brought about biomedical technologies and pro-biomedical institutional arrangements, rather than being mutually co-constitutive.

In this project, we have seen the emergence of different kind of platform; a platform that exists in addition to those identified by Keating and Cambrosio. This ‘multidisciplinary’ platform is characterized by pro-multidisciplinary healthcare policy, architecture (the built environment) that encourages multidisciplinary team work, a multidisciplinary team structure, and clinical assessment tools and ‘ways of thinking’ that reify and perpetuate what I have referred to as a broad clinical gaze. In the process of addressing the fifth research question of this project (how are dystonia and the patient rendered intelligible within the PMDS?) we have seen that this broad clinical gaze has the effect of foregrounding particular social aspects of an illness and aspects of the patient’s experience of illnesses during clinical interactions; the team meetings in which a patient’s family dynamics and schooling were discussed is a good example of this. It is according to these aspects that dystonia is rendered intelligible within the PMDS, and it is according to these aspects – as illustrated by team’s use of the Assessment of Motor and Process Skills - that the effectiveness of deep brain stimulation is measured and assessed. Whether or not such platforms exist in other countries or in non-paediatric contexts is matter for further research. But in the setting where I have been doing my fieldwork, this platform has shaped the way in which a new neurotechnology has been integrated into clinical service, and it is structuring the type of patients, bodies and illnesses that are being enacted by within this service.

Thus, in addressing the fifth research question I argue that, just as Mol (2002) illustrated in regards to atherosclerosis, PMDS patients and dystonia are enacted in multiple forms. As patients pass through the service they become entwined in various assemblages which render the body and dystonia intelligible in multiple ways: in the GMFM and musculoskeletal screen, dystonia is enacted as impaired gross motor function; during the AMPS and COPM-scripted goal setting session, dystonia is enacted as a reduced ability to undertake tasks of daily living, or a reduced ability to engage in the world. It is the patient’s practical relationship to and involvement in the world that is being assessed, and they are not, then, reduced to their biological and biochemical, (or cerebral) composition. And as we saw during team meetings the patient was rendered intelligible as an individual who was part of a wider network involving family members, peers and schooling. Understanding dystonia in this way, and understanding the patient as an agent-in-the-world has a utility for the PMDS clinicians: these understandings are drawn-upon during

decision making processes. Within this platform that structures the activities of the PMDS, the patient and the patient's illness are not simply reduced to its biomedical elements.

It is important here to relate these findings to some of the emerging scholarship on the cultural impact of the neurosciences. As briefly illustrated in the introduction to this thesis, social scientists have noted that neuroscience and neurotechnologies are increasingly reshaping the way in which health, illness and personhood are understood, and are potentially influencing how people understand themselves (c.f. Vidal 2009; Pickersgill and Van Keulen 2011; Rose and Abi-Rached 2013). Indeed, this work explores what could be described as the emergence of *neurosociology*, a form of biosociality in which neuroscience-derived understandings of brain networks, brain chemistry and brain functioning are drawn upon by actors to make sense of health and illness, and are increasingly used by actors as a basis for self-understanding. Psychiatric disorders, for example, are being recast as neuro-circuit disorders, and problems 'of the mind' have become problems 'of the brain'. As Rapp argues, "psychodynamic explanations of human variation and suffering" are being eclipsed by "brain-orientated, hyper-materialist explanations" (Rapp 2011: 8).

Various sociological studies have explored specific manifestations of this neurosociality. Mautoud's account (2011) of DBS recipients who attributed their emotions and behaviours to their neural networks (and the effect of stimulation on these networks) is one example. Similarly, during her study of a clinical research sites using functional-MRI to study the brains of children with learning disorders, Rapp noted (2011) that many mothers saw their children as 'cerebral subjects' and adopted language from neurology and neuroscience when accounting for their children's behaviour. Other studies have noted that while actors may adopt elements of this neurologic discourse, they may nonetheless avoid equating the self with the brain. Singh has noted (2013) that children who had received a diagnosis of ADHD (and had thus been exposed to neuroscientific discourse) often creatively made a distinction between themselves ("I") and their brain, and some children stated that their actions were a consequence of negotiations between the two. Focus group research conducted by Pickersgill and colleagues has also illustrated the creative ways in which actors draw upon ideas from neuroscience. Participants, who came from a variety of backgrounds including the neurosciences, teaching and

social care, were encouraged to talk about the relationship between ‘the self’ and the brain. For some of these participants (particularly the neuroscientists), neuroscience discourse provided a valuable set of tools for understanding personhood and illness, but for others (such as those professionals involved in social care or education) it was ignored or integrated into already-held understandings that draw on an array of resources for making sense of oneself and others. Pickersgill and colleagues suggest that individuals are bricoleurs; agents that “assemble frameworks for understanding personhood by piecing together different knowledges concerning psyche, soma and society” (2011: 361). In this regard, then, neuroscience discourse is simply an additional resource that people draw-upon when accounting for their behaviour and constructing a sense of self.

Indeed, many of the participants involved in Pickersgill and colleagues’ focus groups produced a complex account of personhood that related neuroscience discourse to sociological and psychological explanations of personhood. A number of participants believed that brain-based explanations of illness and personhood alone were too reductive, and stated that mental illness, for example, should be seen as having its origins in early life experience. Here, participants employed a neurodevelopmental narrative that drew attention to the importance of nurture and social interaction: problematic behaviour is a manifestation of neurological abnormalities, but these abnormalities are a consequence of neglect during early childhood (Pickersgill et al: 358-359). Personhood is not simply equated with the brain: it is seen, at least in part, as product of a person’s childhood social ecology: “the multidimensional web of actors, structures and experiences within which they [were] situated” (Pickersgill 2009: 58). While this narrative was articulated by participants in reference to mental health, it is nonetheless salient to this project as it seems to align with the activities of the PMDS team. As we have seen, the team’s broad clinical gaze is very much concerned with examining their patients’ social ecology, and many of the team’s activities are directed towards ensuring that participants can engage more fully in day-to-day activities. Within the PMDS deep brain stimulation is understood as a tool for ‘unlocking’ the body and enabling patients to engage in the world.³¹ Here, then, the neural structures of the brain are implicated in identity and personhood, but only in so far as they limit an individual’s

³¹ This point was explicitly stated by the clinical research fellow (see page 96).

ability to immerse themselves in culturally-mediated activities. Indeed, the activities of the PMDS team would suggest that for them, it is this immersion which is seen as the ultimate source of the self.

Despite the team's reliance on imaging technologies, and despite that fact that they put electrodes in the brains of children, their activities do not, then, appear to perpetuate neurocentric discourses in which health, illness and personhood are equated with the structures of the brain. This is, as I have argued, because a particular 'multidisciplinary' platform has shaped the way in which these neurotechnologies have been integrated into a clinical service; a platform that has structured the type of clinical activities that take place, and has thus structured the way in which patients, brains and illnesses are enacted. The case study, then, suggests that the social impact of the neurosciences and new neurotechnologies will depend very much on the way in which they are integrated within (and hybridized with) existing platforms. It is quite possible that new neurotechnologies will perpetuate neurocentric, biomedical based understandings of health and personhood, but as yet this has not been the case in regards to paediatric deep brain stimulation.

8.5 Policy implications: Preparing the future for deep brain stimulation

The findings from this project can help guide the formation of policy recommendations relating to deep brain stimulation. In June 2013 The Nuffield Council on Bioethics launched its report *Novel Neurotechnologies: Intervening in the Brain* (the report I referred to at the very beginning of this thesis). The report had several principle aims. First, it sought to identify "the economic pressures and regulatory controls that shape and challenge the development pathways of novel neurotechnologies." The 'great need' for such technologies, the report argues, necessitates the formation of a climate that facilitates innovation and directs "research, development and investment towards the production of safe and effective products" (2013:xix). The report also sought to explore the ethical and social issues that arise from the application of novel neurotechnologies. Such technologies, the report argues, raise unique social and ethical concerns due to the special status of the brain. The brain plays "a central role in the operation of our bodies, our capacities for autonomous agency, our conceptions of ourselves and our relationships with others" (xix). Technologies that intervene in the brain have the

potential to disrupt a person's sense of self and their ability to exercise autonomy. This is complicated by the fact that the workings of the brain are an enigma: the processes which underlie a person's mental functioning are largely unknown and the relationship between mind and the brain are the subject of considerable debate. Hence, there is "considerable uncertainty" surrounding the potential impact of novel neurotechnologies.

And third, the report sought to develop a series of recommendations that will help those developing novel technologies to navigate this tension between great need and great uncertainty. These recommendations are the elements of "responsible research and innovation" and include (amongst others):

1. **Securing safety and efficacy:** It is important, the report states, that the risks of a novel neurotechnology be assessed relative to their efficacy, and relative to the availability of other treatments.
2. **Generating robust evidence:** It is important, therefore, that the processes of innovation generate robust evidence. Such evidence on efficacy and safety is necessary to support autonomous decision making among patients and research participants (and therefore bears directly on seeking and obtaining valid, informed consent). Additionally, the report states, robust evidence will ensure that interventions will only occur when there are sound reasons for doing so.
3. **Co-ordinated interdisciplinarity:** There are valuable advantages, the report states, to an interdisciplinary approach to innovation. Groups containing actors from different professional backgrounds can deliver outcomes not so readily achieved by professions working in isolation. Specifically, such groups may be better suited to obtaining a more comprehensive picture of the capabilities and limitations of novel neurotechnologies.

These recommendations are sensible and laudable, and hopefully they will guide future UK and EU regulatory and funding policy. A potential criticism of the report, however is that these recommendations are too general. Indeed, it could be argued that they reflect a lack of information on how the tension between "great need and great uncertainties" actually manifests in the day-to-day routine research and clinical environments of those working with novel neurotechnologies. As this project has shown, researchers and clinicians may already be aware of the necessity

of ‘securing safety and efficacy’ and ‘generating robust evidence’; indeed, PMDS team members spend a great deal of their time attempting to achieve these tasks. There are specific contextual factors, however, that make these tasks complex and difficult. These are factors that have not been explored in the report and it is for this reason, I argue, that the recommendations of the report are perhaps too general. Similarly, the recommendation that innovation takes place within interdisciplinary groups also lacks specific detail: how, exactly, can a collection of individuals from different professions enable a more comprehensive assessment of the benefits and effects of a novel technology? And what professions should be involved in these groups?

In a similar vein, several ethicists have identified what they believe to be the ethical challenges associated with DBS, and have put forward a series of recommendations on how these challenges should be managed. Bell and colleagues (2009) have identified what they believe to be the five main potentially problematic ethical issues of deep brain stimulation based on a review of the emerging clinical literature. The first of these is securing informed consent (2009: 580). The authors argue that the process of attaining informed consent can be difficult because: patients may have cognitive difficulties that affect their capacity to reasonably assess the available information; DBS is often a last resort and patients are often desperate for therapeutic relief; and it is difficult for clinicians to provide predictions about how individual patients will respond. The authors also state that caregivers should be included in the decision making process, since patients will inevitably remain reliant on their assistance.

The second issue Bell and colleagues identified as ethically problematic is resource allocation (DBS therapy costs around £35,000 per person for the first two years, and up to £6000 per person per year from then on). While there is emerging evidence to suggest that, in the long run, it is more cost-effective than other, medicine-based therapies (Fraix et al 2006), the large up-front cost may mean that it has to be rationed in health settings where rationing is central (such as public health systems). It is important, therefore, that clinicians do their best to ensure that only those patients who are likely to receive the optimum benefit from DBS be offered the therapy. Indeed, patient selection is also identified as a potentially problematic ethical issue of DBS. The authors argue that it is necessary to establish selection criteria that will enable clinicians to identify which candidates will obtain and retain

the greatest benefits from DBS. As yet, such criteria have not been established. Poorly selected patients will undergo unnecessary hardship and be exposed to unnecessary risk: good patient selection is therefore necessary to adhere to the principles of beneficence and nonmaleficence (Bell et al 2009: 579).

The fourth ethical challenge is dispelling miracle-like narratives about DBS. The authors point out that the over-optimistic portrayals of DBS in the media should, ideally, be counterbalanced with more realistic information. A better transfer of information between those working with and developing DBS, the media, and the public is needed to ensure that members of the latter do not have distorted and fanciful impressions of DBS. The fifth potentially problematic ethical issue identified by Bell and colleagues pertains to the apparent psychosocial adverse effects experienced by some DBS recipients. If such effects do occur, then any appraisal of the effectiveness of DBS therapies must take such changes into account: the reduction of motor symptoms must be balanced with any changes in a patient's sense of self and well-being.

As with the Nuffield Council report, Bell and colleagues suggest that one of the best means of managing the ethical issues is for DBS to be delivered by multidisciplinary teams. They propose that such teams should include, in addition to a neurosurgeon and neurologists, neuropsychologists, psychiatrists and an advanced care nurse (2009: 579). Such teams, the authors argue, can draw on a range of professional perspectives in order to assess the suitability of patients, and to comprehensively identify the effects of DBS therapies on patients' lives. Indeed, other commentators on the ethics of deep brain stimulation and neuro-implants have made similar proposals (Agid et al 2006; Ford and Kubu 2006; Kubu and Ford 2007). And, in a similar vein to the Nuffield Report, Bell and colleagues argue that the appropriate means of managing the uncertainties around DBS is to ensure that clinicians are committed to the generation of robust evidence on patient outcomes. Specifically, they propose the establishment of a registry of deep brain stimulation patients. The idea is that every single DBS recipient, along with data on their response to DBS and any adverse effects, would be recorded on the registry.

Again, these recommendations are laudable but their generality may limit their utility. The findings of this project, for example, suggest that the formation of a registry would pose additional challenges: what type of data should be recorded on a registry for patients with dystonia? BFM-derived data? If so, this registry would

present misleading evidence (at least according to members of the PMDS team). This project has explored how such challenges actually manifest in clinical practice and how clinicians attempt to manage them. Because of this we are well-suited to build upon the recommendations made by the Nuffield Council and Bell and colleagues. Indeed, some of the novel activities developed within the PMDS may be worth disseminating – they may help other clinicians working with neurotechnologies overcome similar challenges. In this light, I make the following recommendations:

1. DBS should be delivered by multidisciplinary services. In accordance with the recommendations made by both the Nuffield Council report and Bell and colleagues, I suggest that deep brain stimulation be delivered by multidisciplinary teams. However, the selection of professionals involved could be widened to include other allied health professionals, particularly occupational therapists and physiotherapists. This multidisciplinary team should not only be involved in selecting candidates (as stated by Ford and Kubu 2006), but also the regular assessment of patient outcomes. Occupational therapists, for instance, have access to a pool of resources enabling what could be called a more comprehensive assessment of clinical outcomes. It would be necessary to ensure that multidisciplinary teams had access to the appropriate diversity of space and resources which is needed for them to undertake the varied assessment tasks.
2. Using goal setting session for the management of patient expectations. In this project we have witnessed the use of a novel strategy for managing the expectations of patients and supporting family members. During the goal setting session the COPM tool encouraged a mode of communication between clinicians, patients and family members that facilitates informed decision making. If we consider informed decision making to be ethically favourable, then use of the COPM-scripted goal setting session should be encouraged in other settings. Indeed, it is important to recognise the role of non-human elements in facilitating ethical work in biomedical settings, and promote the dissemination of such tools. This would also entail training clinicians how to use such tools.

3. Creating a body of evidence using a flexible registry. Following the recommendation of Bell and colleagues, I suggest that all DBS cases be recorded on a registry. For the registry to be useful, however, it would need to provide space for various forms of patient outcome data: for patients with dystonia, this could be data generated using the BFM, the AMPS and COPM, QoL-based tools, and so on. The danger is that an overly rigid registry would prematurely delimit 'what counts' as data, thus preventing the generation of knowledge that may have been of some use. As Bell and colleagues point out, it is necessary to decipher which patients experience the greatest improvement in life satisfaction: A registry containing various forms of data on outcomes is more likely to present a more comprehensive picture of the impact of DBS.

8.6 Project limitations and future research possibilities

In this project I have explored the activities of a specific team over the course of twelve months. While this has enabled me to examine key aspects of the innovation process, there are, of course, limitations with this project. First, given that one aim of this project is to explore how dystonia and the body are rendered intelligible within the PMDS, it would have been ideal to observe interactions involving the neurosurgeon and the patient, and also interactions in which the patient is subjected to various neuro-imaging procedures (such as MRI). Here, no doubt, we would have witnessed the enactment of a body based very much on the biomedical model, and we would have witnessed the enactment of dystonia as an abnormality of brain functioning.

Secondly, it became clear to me while conducting this project that many clinical decision making interactions were made outside of regular weekly team meetings. This was particularly the cases for decisions that were medical in nature; decisions relating to medications and stimulation parameters and so on that were made by the neurologists or the nurse and did not require input from the therapists. Presumably many 'routine' decisions in which the best course of action is relatively straightforward were also made outside of team meetings. Because ethical considerations meant that I could not simply follow my participants around the hospital, I was not able to observe participants as they made these decisions. Thus, I was probably presented with a lop-sided picture of decision making within the

PMDS; a picture of decision making that included a high proportion of complex cases requiring significant input from the therapists. It may be that many patients pass through the PMDS without having their schooling and relationships with family members and peers subject to the 'broad' PMDS clinical gaze.

Another limitation of this study is its focus on one case study. Ideally, a study that is attempting to generate a general model of medical innovation would do so by abstracting from several case studies, not one. The Texan-based DBS service for children and young people with dystonia would provide a useful point of comparison to the PMDS: it exists within a markedly different healthcare system to the NHS and is no doubt subject to a different arrangement of socio-political trends. Comparing the two teams would have enabled a more comprehensive assessment of how such trends can actually 'structure' innovative activities.

The absence of patients and family member perspectives in this project is a notable limitation, as is the relatively short time period that I spent with PMDS team. Both of these limitations suggest further research possibilities.

8.6.1 Exploring the perspectives of patients and family members

In this project I have explored the perspectives of clinicians, and the interactions involving clinicians, patients and family members. A logical follow on from this would be to explore the perspectives of patient and families who have been involved in the PMDS. As I mentioned in the introduction, small studies on the perspectives of Parkinson's patients with DBS have been conducted by a clinical team. These studies revealed that while DBS was generally effective in reducing many of the symptoms associated with Parkinson's, it was having a mixed impact on their overall sense of well-being: some lamented their reliance on technology, many had a negative anticipation of the future, some felt considerable despair over the years of their life that they had lost to the illness, and some felt a sense of being dehumanised due to their reliance on mechanical technology. These patients represent a different cohort to that of the PMDS (they are adults with a progressive neurological condition rather than children with generally static conditions), but nevertheless, it would be worthwhile to explore whether PMDS patients are having similar experiences.

A particularly interesting avenue would be to explore the impact of DBS on a patient's sense of self. Such a project could explore how their motor disorder is

implicated in a patient's sense of self, and how this is subsequently affected by the implantation of a DBS system. This project would also enable us to explore, from the patient's perspective, whether DBS did actually encourage a 'cerebral' sense of self. With older and more articulate patients, I envisage that such a project could make use of Fox and Ward's strategy for exploring health identities (Fox and Ward 2008). Here, in-depth interviews are used to encourage participants to provide context to their world and descriptions of their day-to-day life, and they are then encouraged to reflect on the meaning of these experiences. The intention of this interview method is to identify the assemblages which participants inhabit, and identify the affective characteristics of these assemblages as experienced by the patient. Similarly, family members could also be included in such a project, enabling the impact of DBS on the dynamics of family life and roles of various family members to be explored. Such a project, then, would be exploring the wider impact of novel-neurotechnologies on health identities and family relations.

The impact of various PMDS assessments on patients and families could also be explored. I have suggested, for example, that the COPM-scripted goal session is a useful tool for managing expectations. In order to verify its effectiveness it would be necessary to explore the viewpoints of patients and family members: did they feel that they were adequately prepared for DBS? And did they feel that the PMDS as a whole provided adequate channels for articulating their own expertise about dystonia and well-being?

8.6.2 Creating visions of the future to construct innovation alliances

This project has explored the activities of one team during a twelve-month period. Ideally a comprehensive exploration of medical innovation would explore the activities of the team over a longer time frame as they attempt to convince other clinicians that their service is indeed 'innovative' and 'progressive' and thus worth maintaining or replicating elsewhere. Indeed, a potential criticism of both the Morlacchi-Nelson Model and the Complex Model of Innovation is that they imply that any novel therapy emerging from the interactions between learning-in-practice, technology transfer and understandings of disease is intrinsically 'progressive' and 'innovative'. Yet, as a body of work from the sociology of expectations has made clear, whether or not a novel set of practices and/or novel knowledge is indeed 'progressive' or 'innovative' depends very much upon the ability of proponents to

frame it as such (Brown et al 2000). In short, other actors (clinicians, commissioners and funding bodies, regulatory agencies and patients) have to be convinced that a novel therapy is necessary. Proponents, then, must form alliances with such actors by enrolling them in a particular vision of the future in which the novel therapy does indeed offer much needed relief to patients in need. Any number of techniques may be used to construct futures and form such alliances: proponents, for example, may employ 'breakthrough' narratives (Brown 2000) and the use of future-orientated metaphors (Wyatt 2000) to create performative expectations. And, as Borup and colleagues points out (2006), expectations can be either rhetorical or material in nature: they may be expressed as utterances, or inscribed in texts, bodies or objects. According to this body of work the process of innovation involves the active and collective construction of the future.

A fruitful avenue of research would be to explore how PMDS team members actively 'construct' the future in order to consolidate and possibly disseminate their innovations. Such a project would provide a window into an aspect of medical innovation that has not been addressed in this current project. Interestingly, the PMDS team is about to begin working on a proposal to conduct an international, multi-centre clinical trial exploring the effects of deep brain stimulation to manage children with secondary dystonia. The goal is to produce an overwhelming body of evidence that indicates the effectiveness of DBS for secondary dystonia, and thus encourage the formation of other DBS teams in paediatric neurology. I observed a team meeting where initial plans for the trial were discussed: ideally, the team would like to enrol Danish, Belgium and French research groups working with children with cerebral palsy to help recruit and assess participants, and they would like the trial to utilise the regime of assessments developed by the PMDS. In other words, the PMDS is attempting to determine how data should be collected within these sites, and thus define 'what counts as evidence'. If the team is successful in having their regime adopted, then their 'local' innovations will have become more widespread within the paediatric neurology community, and importantly, their framing of 'what counts as data' will have become something of a standard. Thus, the process of producing a proposal and bringing these other teams 'on-board' would provide a fascinating study into the dynamics of medical innovation. Such a project could explore how the PMDS constructs a future and creates a set of expectations in order to create alliances between the groups; that is, what

concessions need to be made for such groups to be brought into the project; how the PMDS regime of assessments is altered or reconfigured when ‘transported’ to other clinical sites; and how the definition of ‘what counts as data’ is altered during the formation of alliances.

8.7 Concluding comments

In this project I have used deep brain stimulation as a case study to explore the dynamics of medical innovation. I have explored the historical development and dissemination of the deep brain stimulation technique, and the activities of clinicians as they develop a clinical service providing deep brain stimulation for children and young people with dystonia. I have argued that innovation emerges from technology transfer, the dissemination of new knowledge, and the learning-in-practice activities of clinicians. In the case of the PMDS, learning-in-practice has been shaped by elements of the built environment and it has involved utilizing embodied know-how, tools and knowledge from several professions, reflecting the multidisciplinary structure of the team.

In the process of exploring the history of deep brain stimulation and the activities of PMDS clinicians, this project has also identified several socio-political factors which have shaped the innovation process. These include the evidence-based medicine movement and rationalization in healthcare more broadly, the influence of commercial interest and the profit motive, a prevalent pro-multidisciplinary sentiment, the patient-centred healthcare movement, and (related to this patient-centred approach) a trend towards shared-decision making. Using these as examples, this project has put forward a conceptualisation of innovation which I have called the Complex Model of Innovation. By situating ‘technology transfer’, ‘understandings of disease’ and ‘learning-in-practice’ within a broader socio-political context, this conceptualisation builds upon the Morlacchi-Nelson model of medical innovation.

This project has also illustrated that the PMDS clinicians utilise what could be called a broad clinical gaze. In addition to various biomedical concerns, the PMDS clinicians scrutinize many aspects of the patient and the patient’s relationship with the world, such as their ability to carry out domestic tasks, their relationship with peers and family members, and their schooling. Thus, during their time with the PMDS patients and dystonia are enacted (or ‘constructed’) in multiple ways. For

example, dystonia is enacted as impaired gross motor function, and as reduced ability to perform domestic tasks. Using this insight, I have argued that new neurotechnologies do not necessarily reify reductive, biomedical model-derived understandings of the patient and illness.

I have also suggested that the findings of this project can provide some guidance on preparing the future for deep brain stimulation. Some of the activities conducted by the team may be worth replicating in other clinical contexts. In particular, these include the multidisciplinary structure of the team which enables access to a vast array of tools and resources for overcoming day-to-day challenges, and the goal setting session used by the team to manage the expectations of patients and young people.

No doubt the reader has noted that I have adopted what could be described as a positive tone throughout this thesis. By emphasizing the innovative aspects of the PMDS, I have represented team members in a favourable light. Thus, some commentators may suggest that I have ‘sided with the clinicians’ and failed to maintain the critical, or at least the impartial, perspective that is often expected from a social scientist. At the risk of prompting a debate on the role of the social sciences more generally, it is worth explicitly stating that I have been, and still are, knowingly supportive of the team’s activities.

I will justify this position by drawing upon the Nuffield Council’s report on neurotechnologies (2013) that I referred to at the very beginning of this thesis. There is, as the report states, a genuine and urgent need for new therapies for debilitating neurological disorders such as dystonia, and there is a need to encourage responsible research and innovation. The PMDS team is, in my opinion, one good example of how responsible research and innovation may be undertaken at the level of service provision – as I have suggested, several of their innovations are worth perpetuating among other groups working in similar situations where “great need meets great uncertainty”. The PMDS team is innovative, but this did come at the expense of compassionate care: During my fieldwork I witnessed some horrendous examples of suffering – children with some of the worst, most complex cases of neurological pathology, in severe pain, with very poor prognoses. Yet, I also witnessed some very admirable examples of human interaction. These children were at the centre of an enormous amount of care, attention and affection from parents

and staff members, and a great deal of resources were directed towards improving their quality of life. It was because of this that I came from fieldwork excursions feeling hopeful and inspired. This type of clinical environment and the support they offer should be encouraged.

Appendices

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Appendix 1: Letter of approval from NRES Committee

Page one:

NRES Committee London - Surrey Borders

Charing Cross Hospital
Research Ethics Committee (REC) Centre Charing Cross
Room 12, 4th Floor West
Fulham Palace Road,
London
W6 8RF

Telephone: 020 3 311 7294
Facsimile: 020 3 311 7280

Date: 13th February 2012

Professor Clare Williams, Professor of Medical Sociology
Brunel University London
Gaskill Building
Kingstone Lane
UB8 3PH

Dear Professor Williams

Study title: A Sociology of Innovative Medicine: A Qualitative Study
of the Use of Deep Brain Stimulation to Manage Children
with Dystonia

REC reference: 11/LO/1762

Thank you for your letter of the 21st December 2011, responding to the Committee's request for further information on the above research and for submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Letter of approval from NRES Committee (Page 2):

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering Letter		12 th October 2011
Covering Letter		14 th December 2011
Evidence of insurance or indemnity		4 th August 2011
Investigator CV	2	14 th October 2011
Letter from Sponsor		7 th October 2011
Other: Mr John Gardener		13 th October 2011
Other: Letter from Funder - Wellcome Trust		3 rd July 2008
Other: Draft Interview Topic Guide - CMD5 staff and associated health professionals	1	7 th October 2011
Other: Leaflet for children, young people, and their parents	4	3 rd October 2011
Other: Assent Form for Young People (under 16 years)	1	7 th December 2011
Participant Consent Form: Consultation Observations (Health Practitioners)	4	3 rd October 2011
Participant Consent Form: Consultation Observations (Patient and Family Members)	4	3 rd October 2011
Participant Consent Form: Team Meeting Observations (Health Practitioners)	5	7 th December 2011
Participant Consent Form: Interview One (Health Practitioners and admin staff)	5	7 th December 2011
Participant Consent Form: Interview Two (Health Practitioners and admin staff)	5	7 th December 2011
Participant Information Sheet: Interview One (Health Practitioners)	3	3 rd October 2011
Participant Information Sheet: Interview Two (Health Practitioners)	3	3 rd October 2011
Participant Information Sheet: Team Meeting Observations (Health Practitioners)	3	3 rd October 2011
Participant Information Sheet: Consultation Observations (Health Practitioners)	3	3 rd October 2011
Participant Information Sheet: Leaflet for children, young people, and their parents	5	13 th December 2012
Protocol	2	25 th September 2011

Letter of approval from NRES Committee (Pages 2 & 3):

REC application	IRAS 3.0	14 th October 2011
Response to Request for Further Information		21 st December 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/LO/1762 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Hervey Wilcox
Chair

Email: joan.bailey6@imperial.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting.*

"After ethical review – guidance for researchers"


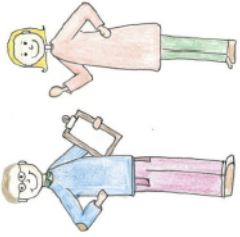
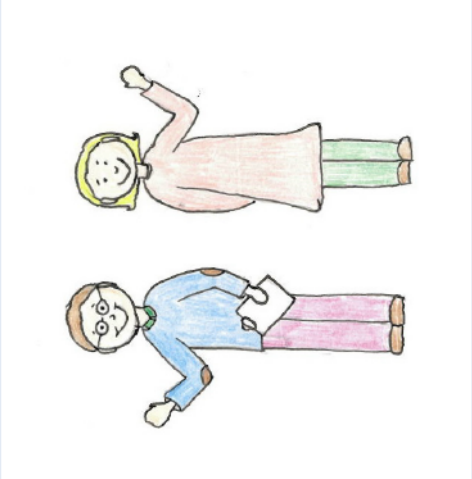

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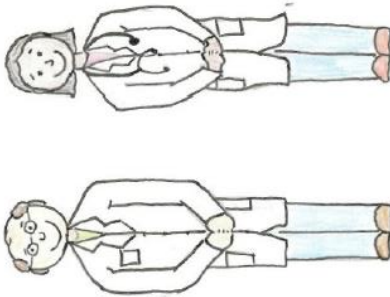
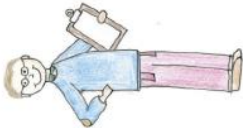
Appendix 2: Participant information leaflets

Leaflet 1: Children and young people, for consultation observations


Page 1 (to be folded into a and inserted with other pages to form a booklet)

<p>Version 5, 13/12/11 REC: 11/LO/1762 R&D: RJ112/N102</p>	<div style="text-align: center;">  <p>Working with new medical treatments</p> <p>A PhD research project February 2012 – July 2013</p> <p>This leaflet is for children, young people, and their parents</p> <p><i>Please will you help us with our research?</i></p> <p>This leaflet gives some detail about the project. We have set out the questions you might want to ask, with our answers, so you can talk about them together before you decide if you want to take part.</p>  <p>Please contact us, John or Clare, if you want more details and/or if you think you might like to join the project.</p> <p>John Gardner 078 95547635, john.gardner@brunel.ac.uk Clare Williams 078 500 93522, clare.williams@brunel.ac.uk Brunel University Uxbridge UB8 3PH</p> </div>
<p>Version 5, 13/12/11 REC: 11/LO/1762</p>	<div style="text-align: center;"> <p>If you decide to take part, please keep this leaflet.</p> <p>Thank you for reading this!</p>  <p>The researchers, John Gardner and Clare Williams, do research and write reports about new medical treatments.</p>  <p>The project is funded by the Wellcome Trust Biomedical Ethics Programme. It was approved by the London – Surrey Research Ethics Committee (11/LO/1762)</p> </div>



Information leaflet for children and young people (page 2):

<p>Version 5.13/12/11 REC: 11/LO/1762</p>	<p>1. Why is the research being done? Hospital staff sometimes need to use new medical treatments. We want to find out how staff work together when using new medical treatments to help children and young people with dystonia. We will listen to the staff and we will watch them as they work with children and young people. Then we will write reports about their work. We want to help other health care staff and officials know more about the best ways to work with new medical treatments.</p>	
<p>Version 5.13/12/11 REC: 11/LO/1762 R&D: R/J112/N102</p>	<p>8. Who will know if I am in the research? The staff at [redacted] Hospital will know if you are in the project, but no one else will know. We will keep your assent forms and our notes about your meeting in a safe lockable place. Our notes will not have any named details, and we will destroy all notes and forms 8 years after the project has finished. When we write reports, we will not use your name or any identifiable details, so no one will know you took part in the project.</p>	
<p>9. Will I know about the research results?</p>		<p>We will put all reports from this project on the internet. You will be able to find these on the Brunel University Webpage: www.brunel.ac.uk/ssss/research/ebas You can also ask us to send you a copy of the reports.</p>

Information leaflet for children and young people (page 3):

<p>Version 5.13/12/11 REC: 11/LO/1762</p>	<p>6. Could there be any problems if I take part?</p> <p>A few people may feel uncomfortable when they are being watched by others. If you want us to stop, we will stop straight away.</p>	<p>Version 5.13/12/11 REC: 11/LO/1762 R&D: RJ112/N102</p>	<p>2. What questions will the project ask?</p> <p>Which hospital staff treat children with dystonia?</p> <p>What are the good and bad points about working with new medical treatments for dystonia?</p> <p>How do hospital staff tell children or young people and their families about these new treatments?</p> <p>How do hospital staff decide which treatments to use for which children?</p>
	<p>7. Will doing the research help me?</p> <p>We hope that you will like taking part in this project. But our main aim is to write reports that help hospital staff give the best care possible in the future.</p>	<p>3. Who will be in the project?</p> <p>Some staff at [] Hospital will be helping with this project. We would like to watch them as they work with children and young people.</p> <p>This means some children will also be involved in the project. We would like ten children or young people to be involved in this project, who are aged between 5 and 18 years.</p> <p>We want to watch a normal meeting between hospital staff, you, and your family.</p>	


Information leaflet for children and young people (page 4):

<p>Version 5, 13/12/11 REC: 11/LO/1762</p>		<p>Version 5, 13/12/11 REC: 11/LO/1762 R&D: RJ112/N102</p>	<p>5. What will happen to me if I take part?</p> <p>If you think you might take part in the project, one of us will meet you at the hospital to talk to you, your mother, or father.</p> <p>If you decide to take part, we will ask you to sign or mark an 'assent form' to say you agree.</p> <p>Then we will arrange with you and the hospital staff to watch one or your meetings.</p> <p>One of us will sit quietly at the side of the room and write notes. We will not make any audio or video recordings. We will not write down any named details about you.</p> <p>You will not have to talk directly to us, and you will be with your family the whole time</p>	
<p>4. Do I have to take part?</p>	<p>You decide if you want to take part or not.</p> <p>Even if you say 'yes', you can drop out at any time. If you do decide to take part, you can tell us to stop watching during the meeting. You do not have to give us a reason.</p> <p>If you want to drop out within 3 months after you have taken part, we will remove all information about your meeting from our report.</p> <p>Whether you take part or not, you will still go on having the same care at the hospital.</p>			


Leaflet 2: Participants over 16 years of age, for consultation observations

Front side:

Version 4, 03.10.11	REC: 11/LO/1762	R&D: RJ112/N102	The Use of DBS to Manage Dystonia in Children
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NHS Foundation Trust



INFORMATION SHEET
Consultation Observations (Patient and Family Members)

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

<p>Introduction</p> <p>We would like to invite you to participate in a research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Contact me if there is anything that is not clear or if you would like more information.</p> <p>What is the purpose of this study?</p> <p>This study aims to explore the benefits and challenges associated with the application of innovative therapies in paediatric neurology.</p> <p>One part of this study involves observing a routine consultation between members of the medical team, the patient and their accompanying family members or care givers. This will enable the researcher, Mr John Gardner, to explore how various challenges are dealt with in a clinical setting. You are invited to participate in this study by having one of your routine consultations observed by the researcher, Mr John Gardner.</p> <p>Who is conducting the research?</p> <p>John Gardner, will be observing consultations. Professor Clare Williams is the supervisor of the PhD Project. The study is one of several projects being carried out as part of the LABTEC (London & Brighton Translational Ethics Centre) programme, which is hosted in the Centre for Biomedicine & Society, Brunel University, West London. LABTEC consists of a team of co-applicants from universities in London and Brighton (see http://www.kcl.ac.uk/schools/sspp/interdisciplinary/cbas/research/projects/labtec.html).</p>	<p>This research has been registered with the</p> <p style="background-color: #cccccc; height: 15px; width: 100%;"></p> <p>Who is funding the research?</p> <p>This study is funded by the Wellcome Trust Biomedical Ethics Programme.</p> <p>What will you be invited to do?</p> <p>If you are interested in participating, you and your child will be given at least another 24 hours to decide. If you have any questions during this time please feel free to contact the researcher, Mr John Gardner. After at least 24 hours, Mr John Gardner will approach you while you are at [redacted] hospital, at a time that is convenient for you. If you and your child do decide to participate, you will both be asked to sign an "informed consent" form.</p> <p>The observation will involve Mr John Gardner unobtrusively watching the consultation and making written notes. If you decide to participate, he will arrange with you and the members of the medical team which consultation is suitable for observation. Even if you give consent to participate, it is your right to later withdraw consent, ask Mr Gardner to leave the consultation at anytime, or have any data pertaining to the observation withdrawn from the study up to three months after your participation.</p> <p>Possible risks of participation</p> <p>You may feel uncomfortable having a consultation involving you and your family members observed. If you do feel uncomfortable you are free to ask Mr Gardner to leave at any time.</p> <p>Possible benefits of participation</p> <p>Once the research is finished, it could provide information about the various factors that</p>
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For Participants over 16 years of age, consultation observations (reverse side):

Version 4, 03.10.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DBS to Manage Dystonia in Children

facilitate and hinder the application of innovative medicine, which may be of benefit to health professionals, scientists, policy makers and regulatory bodies. It may also help contribute to a more informed public perception of Deep Brain Stimulation therapy.

Will the information you provide be kept confidential?

All information that is collected about you and about clients during the course of the research will be anonymised and kept strictly confidential, in accordance with the 1998 Data Protection Act. Any notes we make will be given a code number to ensure that they are not traceable to an individual. All the notes will be stored securely in a research office for 7 years from project completion. Professor Clare Williams and Mr John Gardner will be the only people with access to this stored data.

What will happen to the results of the research study?

The data provided by this study will be used to write a PhD thesis and a number of reports and papers in academic journals. Participants and the research site will not be identified in any report/publication. You can obtain publications from the Brunel University webpage.

Who has reviewed the study?

The Wellcome Trust, who is funding this study, has scientifically reviewed this research project. This study has also been approved by the London-Surrey Research Ethics Committee.

What do you do now?

It is up to you to decide whether or not to take part. If you are interested in hearing more about the study then please contact John

Gardner who will be happy to answer any questions you may have. If you agree to participate, then observations will be scheduled at a time and place convenient for you. If you do decide to take part you will be asked to sign a consent form and be given a copy of this and the information sheet to keep.

What if you decide not to take part?

You are free to decide not to take part. Even if you do agree to take part, you are free to withdraw from the study at any time without giving an explanation, and Mr Gardner will not use data from your consultation. *Withdrawal will not be possible once data has been used in publications (3 months after your participation).*

What if you have any concerns?

If you have any concerns or questions about this study or the way it has been carried out, then please contact, in the first instance, me. If this does not resolve your concerns, please contact Professor Clare Williams, Director of the Centre for Biomedicine & Society, Brunel University.

What if something goes wrong?

If you are harmed by taking part in this project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms should also be available to you. Information about Independent Complaints Advocacy Services is available on the webpage:

www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Complaintspolicy/NHScomplaintsprocedure/DH_4087428

CONTACT DETAILS

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Professor Clare Williams,
Centre for Biomedicine & Society
Brunel University
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West London
Email: clare.williams@brunel.ac.uk

Thank you for reading this information sheet

Leaflet 3: Health professionals, for consultation observations

Front side:

Version 3, 03.10.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DBS to Manage Dystonia in Children

INFORMATION SHEET
Consultation Observations (Health Practitioners)

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

Introduction
We would like to invite you to participate in this original PhD research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of this study?
This study aims to explore the benefits and challenges associated with innovative therapies in paediatric neurology.

Currently there is a lack of empirical research exploring the challenges faced by health professionals working with Deep Brain Stimulation (DBS) to manage children with complex motor disorders. This study will explore the various social, clinical and ethical issues that arise in the treatment of dystonia with DBS, noting how such issues are dealt with by health professionals in practice. I wish to gain an in-depth understanding of health professionals' perspectives by observing them at work and talking to them about their views.

Who is conducting the research?
I, John Gardner, will be observing consultations. Professor Clare Williams is the supervisor of the PhD Project. The study is one of several projects being carried out as part of the LABTEC (London & Brighton Translational Ethics Centre) programme, which is hosted in the Centre for Biomedicine & Society, Brunel University, West London. LABTEC consists of a team of co-applicants from universities in London and Brighton (see <http://www.kcl.ac.uk/schools/sspp/interdisciplinary/cbas/research/projects/labtec.html>).

Who is funding the research?
This study is funded by the Wellcome Trust Biomedical Ethics Programme.

What will you be invited to do?
I would also like to observe up to ten consultations involving patients and their accompanying family members. This will enable me to explore how various challenges are dealt with in a clinical setting. The observation would involve me unobtrusively watching the consultation and making written notes. Consultations will not be recorded. If you decide to participate, and you are to be involved in a consultation with a patient and their accompanying family members who have also decided to participate, I will arrange to observe a consultation that suits all participants. If you consent to be involved in an observation, it is your right to have data pertaining to you withdrawn three months of the consultation, or ask me to leave the consultation at any time.

Possible risks of participation
You may feel uncomfortable having me watching aspects of your work, or you may be worried that the patients will be adversely affected by my presence. You or the patient (and their family members/carers) have the right to ask me to leave the consultation at any time.

Possible benefits of participation
You may find this topic interesting, and relevant to your professional work. Once the research is finished, it could provide information about the benefits and challenges involved in the application of innovative medicine. This may be of benefit to health

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For health professionals, consultation observations (reverse side):

Version 3, 03.10.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DBS to Manage Dystonia in Children	
<p>professionals, scientists, policy makers and regulatory bodies.</p> <p>Will the information you provide be kept confidential? All information that is collected about you and about clients during the course of the research will be anonymised and kept strictly confidential, in accordance with the 1998 Data Protection Act. Any notes we make will be given a code number to ensure that they are not traceable to an individual. All the notes will be stored securely in a research office for 7 years from project completion. Professor Clare Williams and I will be the only people with access to this stored data. You should be aware that I am obliged to report any instances of professional misconduct to the proper authorities.</p> <p>What will happen to the results of the research study? The data provided by this study will be used to write a PhD thesis and a number of reports and papers in academic journals. Participants and the research site will not be identified in any report/publication. You will be able to access publications from the Brunel University webpage.</p> <p>Who has reviewed the study? The Wellcome Trust, who is funding this study, has scientifically reviewed this research project. This study has also been approved by the London – Surrey Research Ethics Committee.</p> <p>What do you do now? It is up to you to decide whether or not to take part. If you are interested in hearing more about the study then please contact me (John Gardner) and I will be happy to answer any questions you may have. If you agree to participate, then observations will be</p>	<p>scheduled at a time and place convenient for you and the other participants. If you do decide to take part you will be asked to sign a consent form and be given a copy of this and the information sheet to keep.</p> <p>What if you decide not to take part? You are free to decide not to take part. Even if you do agree to take part, you are free to withdraw from the study at any time without giving an explanation, and I will not use your interview data. Withdrawal will not be possible once data has been used in publications (3 months after your participation).</p> <p>What if you have any concerns or questions? If you have any concerns or questions about this study or the way it has been carried out, then please contact, in the first instance, me. If this does not resolve your concerns, please contact Professor Clare Williams, Director of the Centre for Biomedicine & Society, Brunel University.</p> <p>What if something goes wrong? If you are harmed by taking part in this project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms should also be available to you. Information about Independent Complaints Advocacy Services is available on the webpage: www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Complaintspolicy/NHScomplaintsprocedure/DH_4087428</p>
<p>CONTACT DETAILS John Gardner Centre for Biomedicine & Society Brunel University Telephone: 07895547635 (mobile) Email: john.j.gardner@brunel.ac.uk</p>	<p>Professor Clare Williams, Centre for Biomedicine & Society Brunel University Telephone: 07850093522 (mobile) West London Email: clare.williams@brunel.ac.uk</p>
Thank you for reading this information sheet	
2	

Leaflet 4: Health professionals, for team meeting observations

Front side:

Version 3, 03.10.11	REC: 11/LO/1762	R&D: RJ112/N102	The Use of DBS to Manage Dystonia in Children
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INFORMATION SHEET
Team Meeting Observations (Health Practitioners)

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

Introduction
We would like to invite you to participate in this original PhD research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of this study?
This study aims to explore the benefits and challenges associated with the application of innovative therapies in paediatric neurology.

Currently there is a lack of empirical research exploring the challenges faced by health professionals working with Deep Brain Stimulation (DBS) to treat children with complex motor disorders. This study will explore the various social, clinical and ethical issues that arise in the treatment of dystonia with DBS, noting how such issues are dealt with by health professionals in practice. I wish to gain an in-depth understanding of health professionals' perspectives by observing them at work and talking to them about their views.

Who is conducting the research?
I, John Gardner, will be observing team meetings. Professor Clare Williams is the supervisor of the PhD Project. The study is one of several projects being carried out as part of the LABTEC (London & Brighton Translational Ethics Centre) programme, which is hosted in the Centre for Biomedicine & Society, Brunel University, West London. LABTEC consists of a team of co-applicants from universities in London and Brighton (see <http://www.kcl.ac.uk/schools/sspp/interdisciplinary/cbas/research/projects/labtec.html>).

Who is funding the research?
This study is funded by the Wellcome Trust Biomedical Ethics Programme.

What will you be invited to do?
I would like to observe team meetings in order to better understand how the multidisciplinary team operates: how problems are discussed and dealt with, and how decisions are made. The observations will involve me unobtrusively watching team meetings and taking notes. Team meetings will not be recorded. Should all members of the team consent to participate, I will arrange with the team which meetings will be observed. Any member of the team has the right to refuse to have team meetings observed, or to have data pertaining to them withdrawn from the study within three months after the team meeting. It is also your right to ask me to leave the team meeting at any time.

Possible risks of participation.
You may feel uncomfortable having an observer watching aspects of your work, such as sitting in on your team meetings. If you do feel uncomfortable, or that my presence is interfering with your ability to work, you can ask me to leave the meeting at any time.

Possible benefits of participation
You may find this topic interesting, and relevant to your professional work. Once the research is finished, it could provide information about the benefits and challenges of innovative medicine, which may be of benefit to health professionals, scientists, policy makers and regulatory bodies.

Will the information you provide be kept confidential?
All information that is collected about you and about clients during the course of the research will be anonymised and kept strictly confidential, in accordance with the 1998 Data Protection Act. Any notes we make will be

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For health professionals, team meetings (reverse side)

Version 3, 03.10.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DB5 to Manage Dystonia in Children

given a code number to ensure that they are not traceable to an individual. All the notes will be stored securely in a research office for 7 years from project completion. Professor Clare Williams and I will be the only people with access to this stored data. You should be aware that I am obliged to report any instances of professional misconduct to the proper authorities.

What will happen to the results of the research study?

The data provided by this study will be used to write a PhD thesis and a number of reports and papers in academic journals. Participants and the research site will not be identified in any report/publication. You will be able to access publications from the Brunel University webpage.

Who has reviewed the study?

The Wellcome Trust, who is funding this study, has scientifically reviewed this research project. This study has also been approved by the London – Surrey Research Ethics Committee.

What do you do now?

It is up to you to decide whether or not to take part. If you are interested in hearing more about the study then please contact me (John Gardner) and I will be happy to answer any questions you may have. If you agree to participate, then observations will be scheduled at a time and place convenient for you. If you do decide to take part you will be asked to sign a consent form and be given a copy of this and the information sheet to keep.

CONTACT DETAILS

John Gardner
Centre for Biomedicine & Society
Brunel University
Telephone: 07895547635 (mobile)
Email: john.j.gardner@brunel.ac.uk

What if you decide not to take part?

You are free to decide not to take part. Even if you do agree to take part, you are free to withdraw from the study at any time without giving an explanation, and I will not use your interview data. Withdrawal will not be possible once data has been used in publications (3 months after your participation).

What if you have any concerns or questions?

If you have any concerns or questions about this study or the way it has been carried out, then please contact, in the first instance, me. If this does not resolve your concerns, please contact Professor Clare Williams, Director of the Centre for Biomedicine & Society, Brunel University.

What if something goes wrong?

If you are harmed by taking part in this project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms should also be available to you. Information about Independent Complaints Advocacy Services is available on the webpage:

www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Complaintspolicy/NHScomplaintsprocedure/DH_4087428


Professor Clare Williams,
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Thank you for reading this information sheet

Leaflet 5: Health professionals, for interviews

Front side:

Version 3, 03.10.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DBS to Manage Dystonia in Children
Interview One

 NHS
NHS Foundation Trust

 Brunel
UNIVERSITY
WEST LONDON

INFORMATION SHEET
Interview One (Health Practitioners)

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

Introduction
We would like to invite you to participate in this original PhD research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of this study?
This study aims to explore the benefits and challenges associated with the application of innovative therapies in paediatric neurology.

Currently there is a lack of empirical research exploring the challenges faced by health professionals working with Deep Brain Stimulation (DBS) to manage children with complex motor disorders. This study will explore the various social, clinical and ethical issues that arise in the treatment of dystonia with DBS, noting how such issues are dealt with by health professionals in practice. I wish to gain an in-depth understanding of health professionals' perspectives by observing them at work and talking to them about their views.

Who is conducting the research?
I, John Gardner, will be conducting the interviews. Professor Clare Williams is the supervisor of the PhD Project. The study is one of several projects being carried out as part of the LABTEC (London & Brighton Translational Ethics Centre) programme, which is hosted in the Centre for Biomedicine & Society, Brunel University, West London. LABTEC consists of a team of co-applicants from universities in London and Brighton (see <http://www.kcl.ac.uk/schools/sspp/interdisciplinary/cbas/research/projects/labtec.html>).

Who is funding the research?
This study is funded by the Wellcome Trust Biomedical Ethics Programme.

What will you be invited to do?
I would like to interview a range of health professionals involved in the application of DBS in paediatric neurology. Should you decide to be interviewed, I will contact you to arrange an interview lasting about one hour, at a time and location convenient for you. During the interview, I will ask you about the advantages and problems of working with patients and their families, the benefits of working within a multi-disciplinary team, any other concerns you may have, and how institutional and policy factors impact upon your work. It is your right to refuse to answer specific questions, to discontinue your participation, or to ask me to explain my questions. Interviews will be recorded, subject to your permission. Recordings of interviews will be deleted at the end of the project. If you do not wish the interview to be recorded, I will take notes as we talk. You are also free to have any interview data pertaining to you withdrawn from the study within three months after the interview.

Possible risks of participation
Most people enjoy talking about their work. However, some staff may feel less comfortable talking about some of the issues associated with DBS therapy in the presence of the researcher. Issues may be raised that the interview and/or study cannot resolve. Our aim is to provide all participants with safe, respectful and confidential opportunities to discuss your work, beliefs and opinions.

Possible benefits of participation
You may find this topic interesting, and relevant to your professional work. Once the

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Leaflet for health professionals, interviews (reverse side):

Version 3, 03.10.11	REC: 11/LO/1762	R&D: RJ112/N102	The Use of DBS to Manage Dystonia in Children
Interview One			
<p>research is finished, it could provide information about the benefits and challenges of innovative medicine, which may be of benefit to health professionals, scientists, policy makers and regulatory bodies.</p> <p>Will the information you provide be kept confidential? All information that is collected about you and about clients during the course of the research will be anonymised and kept strictly confidential, in accordance with the 1998 Data Protection Act. Any notes we make will be given a code number to ensure that they are not traceable to an individual. All the notes will be stored securely in a research office for 7 years from project completion. Professor Clare Williams and I will be the only people with access to this stored data. You should be aware that I am obliged to report any instances of professional misconduct to the proper authorities.</p> <p>What will happen to the results of the research study? The data provided by this study will be used to write a PhD thesis and a number of reports and papers in academic journals. Participants and the research site will not be identified in any report/publication. You will be able to access publications from the Brunel University webpage.</p> <p>Who has reviewed the study? The Wellcome Trust, who is funding this study, has scientifically reviewed this research project. This study has also been approved by the London – Surrey Research Ethics Committee.</p> <p>What do you do now? It is up to you to decide whether or not to take part. If you are interested in hearing more about the study then please contact me (John</p>	<p>Gardner) and I will be happy to answer any questions you may have. If you agree to participate, then interviews will be scheduled at a time and place convenient for you. If you do decide to take part, you will be asked to sign a consent form and be given a copy of this and the information sheet to keep.</p> <p>What if you decide not to take part? You are free to decide not to take part. Even if you do agree to take part, you are free to withdraw from the study at any time without giving an explanation, and I will not use your interview data. Withdrawal will not be possible once data has been used in publications (3 months after your participation).</p> <p>What if you have any concerns or questions? If you have any concerns or questions about this study or the way it has been carried out, then please contact, in the first instance, me. If this does not resolve your concerns, please contact Professor Clare Williams, Director of the Centre for Biomedicine & Society, Brunel University.</p> <p>What if something goes wrong? If you are harmed by taking part in this project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms should also be available to you. Information about Independent Complaints Advocacy Services is available on the webpage: www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Complaintspolicy/NHScomplaintsprocedure/DH_4087428</p>		
CONTACT DETAILS			
<p>John Gardner Centre for Biomedicine & Society Brunel University Telephone: 07895547635 (mobile) Email: john.j.gardner@brunel.ac.uk</p>	<p>Professor Clare Williams, Centre for Biomedicine & Society Brunel University Telephone: 07850093522 West London Email: clare.williams@brunel.ac.uk</p>		
Thank you for reading this information sheet			
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Appendix 3: Consent forms

Form 1: Assent form for children and young people

Version 1, 7.12.11 REC: 11/LO/1762 R&D: EJ112/N102 The Use of DBS to Manage Dystonia in Children

Assent Form for Young People (under 16 years)

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

Researcher: John Gardner
Chief Investigator: Professor Clare Williams

Child/young person to circle all they agree with (or if unable, caregiver on their behalf):

Has somebody explained this project to you?	Yes/No
Do you understand what this project is about?	Yes/No
Have you asked all the questions you want?	Yes/No
Do you understand it is OK to stop taking part at anytime?	Yes/No
Are you happy to take part?	Yes/No

If any answers are 'no' or if you don't want to take part, don't sign your name!
 If you do want to take part, you can write your name below:

Your name _____

Date _____

The researcher who explained this project to you needs to sign too:

Print name _____

Sign _____

Date _____

Thank you for your help.

Form 2: Patients and accompanying family members

Version 4, 03.10.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DBS to Manage Dystonia in Children



CONSENT FORM
Consultation Observation (Patient and Family Members)

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

Researcher: John Gardner, Centre for Biomedicine & Society; **Chief Investigator:** Professor Clare Williams, Centre for Biomedicine & Society

Please Initial

- I confirm that I have read and understand the information sheet dated 3.10.11 (version 4) for the above study and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw data pertaining to me within three months after my participation, without giving any reason, and without my legal rights being affected.
- I agree to having consultations in which I am involved observed by the researcher, John Gardner.
- I understand that data from these observations will inform the study and may be used anonymously in publications.

I agree to take part in this observational study subject to the conditions agreed above:

 Name of Participant Date Signature

I confirm that I have explained the proposed study to the participant:

 Researcher Date Signature

One copy for participant; one copy for researcher.

Form 3: Health professionals, for consultation observations

Version 4, 03.10.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DBS to Manage Dystonia in Children



CONSENT FORM
Consultation Observation (Health Practitioners)

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

Researcher: John Gardner, Centre for Biomedicine & Society; **Chief Investigator:** Professor Clare Williams, Centre for Biomedicine & Society

Please Initial

- I confirm that I have read and understand the information sheet dated 03.10.11 (Version 3) for the above study and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw data pertaining to me within three months after my participation, without giving any reason, and without my legal rights being affected.
- I agree to having consultations in which I am involved observed by the researcher, John Gardner.
- I understand that data from these observations will inform the study and may be used anonymously in publications.

I agree to take part in this observational study subject to the conditions agreed above:

 Name of Participant Date Signature

I confirm that I have explained the proposed study to the participant:

 Researcher Date Signature

One copy for participant; one copy for researcher.

Form 4: Health professionals, for team meeting observations

Version 5, 07.12.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DBS to Manage Dystonia in Children



**CONSENT FORM
Team Meeting Observation (Health Practitioners)**

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

Researcher: John Gardner, Centre for Biomedicine & Society; **Chief Investigator:** Professor Clare Williams, Centre for Biomedicine & Society

Please Initial

- I confirm that I have read and understand the information sheet dated 03.10.11 (version 3) for the above study and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw data pertaining to my consultation within three months of participating, without giving any reason, and without my legal rights being affected.
- I agree to having team meetings in which I am involved observed by the researcher, John Gardner.
- I understand that data from these observations will inform the study and may be used anonymously in publications.

I agree to take part in this observational study subject to the conditions agreed above:

Name of Participant Date Signature

I confirm that I have explained the proposed study to the participant:

Researcher Date Signature

One copy for participant; one copy for researcher.

Form 5: Health professionals, for interviews

Version 5, 07.12.11 REC: 11/LO/1762 R&D: RJ112/N102 The Use of DBS to Manage Dystonia in Children
Interview One



CONSENT FORM
Interview One (Health Practitioners and Admin Staff)

WORKING WITH DEEP BRAIN STIMULATION IN PAEDIATRIC NEUROLOGY

Researcher: John Gardner, Centre for Biomedicine & Society; **Chief Investigator:** Professor Clare Williams, Centre for Biomedicine & Society

Please Initial

- I confirm that I have read and understand the information sheet dated 03.10.11 (version 3) for the above study and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw data pertaining to me within three months after my participation, without giving any reason, and without my legal rights being affected.
- I agree to being interviewed by the researcher, John Gardner, at a time and place that suits me.
- I agree to having the interview recorded on audiotape.
- I understand that data from these interviews will inform the study and may be used anonymously in publications.
- I agree/do not agree [please circle an option] to the researcher, John Gardner, approaching me over the next year to discuss participating in a follow-up interview.

I agree to take part in this interview subject to the conditions agreed above:

Name of Participant Date Signature

I confirm that I have explained the proposed study to the participant:


Researcher Date Signature

One copy for participant; one copy for researcher.


Appendix 4: Interview topic guide

Page 1:

Version 1, 07.10.11	REC: 11/LO/1762	R&D:RJ112/N102	The Use of DBS to Manage Dystonia in Children
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DRAFT INTERVIEW TOPIC GUIDE – PMDS staff and associated health professionals
 (as per accepted qualitative methodologies, this is a draft guide, and questions/topics may be adapted as interviews get underway)
-A qualitative study of the use of deep brain stimulation to manage children with dystonia

Housekeeping

- (i) I am interested in your views, opinion and experiences of using deep brain stimulation to manage children with dystonia (no such thing as right/wrong responses) so please feel free to give examples or elaborate wherever you think it will help
- (ii) This interview is completely anonymous and will be kept confidential (the transcriber has signed a confidentiality agreement and only my academic supervisors and myself will have access to the audio-recordings and transcripts); the lab will not be identified in any publications, presentations etc.
- (iii) If it is okay with you, I would like to make an audio recording of the interview. We can turn the audio recorder off at anytime you request. We can also stop the interview at anytime you wish, and you can decline to answer any questions

Individual Work and Professional Background

What is your official position? Tell me a little bit about what your work involves. What expertise and skills does it require?

How long have you worked with the Paediatric Motor Disorder Service (PMDS)? How did you come to work with the PMDS? Do you feel your training has prepared you for working within the PMDS team?

What are some of the common tools (equipment, clinical assessment tools) that you use while working with the PMDS team?

Multidisciplinary Team work

In which aspects of your role do you work closely with others in the PMDS team? In which aspects of your role do you work more independently?

How and when do members of the team come together to discuss clinical cases? What are the purposes of team meetings? What role does the PMDS co-ordinator play in the overall functioning of the team?

In your opinion, why was a multidisciplinary team established to work with children with complex motor disorders?

1

Interview topic guide (page two):

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In your experience, what are the benefits of working within a multidisciplinary team? What are the challenges of working within such a team? In your opinion, are there any institutional or professional barriers that can hinder multidisciplinary medical work? Could you give me an example of the ways in which this manifested itself?

Have there been any major changes to the way in which the PMDS operates since it was first established? If so, why?

What role do you and other PMDS team members have in deciding which patients are eligible for deep brain stimulation? How and when are these decisions made?

What role do you and other PMDS team members have in managing patients and their families undergoing deep brain stimulation therapy?

Does the team publicise itself in any way? If so, how is this done and why?

Institutional/Professional Influences

Do you collaborate with other teams using similar therapies? If so, what types of issues would be discussed?

In your opinion, are there aspects of the current political climate, particularly in regards to the provision of healthcare, which influence how the PMDS team operates?

Working with Children and their care-givers

When patients and their caregivers first arrive at the PMDS, what do they usually know about deep brain stimulation? In your opinion, what is their understanding of deep brain stimulation when they first arrive? Could you give me an example or two of different patients/families understandings?

What information is given to children and their families regarding deep brain stimulation when they arrive at the PMDS? How is this information presented, and by whom?

What do patients and their caregivers expect of deep brain stimulation therapy? How do you go about managing their expectations?

How is consent for deep brain stimulation attained from patients and/or their caregivers, and by whom?

Are there any aspects of working with children and their care-givers that you find particularly challenging? Are there specific challenges associated with particular age-groups of patients?

Deep brain stimulation therapies

What constitutes a suitable candidate for deep brain stimulation therapy? What is taken into consideration when deciding upon a treatment option?

How does the PMDS team go about deciding on the best stimulation regime for patients? How much control is the patient and caregivers given in adjusting the stimulation regime? What information are patients and caregivers given regarding the actual DBS devices?

Interview topic guide (page 3):

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How reliable is the technology? How do you determine if it is malfunctioning?

What constitutes a positive clinical outcome, and how is that defined? How are adverse reactions managed? Are particular tools and standards used to assess patient improvement?

How are clinical outcomes recorded?

In your opinion, what are the advantages and disadvantages of using deep brain stimulation to treat children with dystonia, in comparison to other available treatments?

Other Considerations

Which aspects of your work do you find rewarding? Do you find any aspects of your work particularly difficult?

Is there anything we haven't covered that you think would help me understanding more about this area of DBS for children?

Thanks very much for your participation. If, afterwards, you think of something that was mentioned today that you would prefer not to be included in any publications or presentations, please let me know within three months and I will have the information withdrawn.

Also, resulting publications will be available on the Centre for Biomedicine and Society, Brunel University London website. If you would like, I can send you a report of the findings of this research, and I can also arrange to present the findings to you and other participants in person.

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