Account/ability: Disability and Agency in the Age of Biomedicalization

by

Rebecca Monteleone

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Graduate Supervisory Committee:

Mary Margaret Fonow, Chair
Emma Frow
Katina Michael
Heather Ross

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ABSTRACT

Over the last half century, global healthcare practices have increasingly relied on technological interventions for the detection, prevention, and treatment of disability and disease. As these technologies become routinized and normalized into medicine, the social and political dimensions require substantial consideration. Such consideration is particularly critical in the context of ableism, in which bodily and cognitive differences such as disabilities are perceived as deviance and demand intervention. Further, neoliberalism, with its overwhelming tendency to privatize and individualize, creates conditions under which social systems abdicate responsibility for social issues such as ableism, shifting accountability onto individuals to prevent or mitigate difference through individualized means.

It is in this context that this dissertation, informed by critical disability studies and feminist science and technology studies, examines the understanding and enactment of disability and responsibility in relation to biomedical technologies. I draw from qualitative empirical data from three distinct case studies, each focused on a different biomedical technology: prenatal genetic screening and diagnosis, deep brain stimulation, and do-it-yourself artificial pancreas systems. Analyzing semi-structured interviews and primary documents through an inductive framework that takes up elements of Grounded Theory and hermeneutic phenomenology, this research demonstrates a series of tensions. As disability becomes increasingly associated with discrete biological characteristics and medical professionals claim a growing authority over disabled bodyminds, users of these technologies are caught in a double bind of personal responsibility and epistemic invalidation. Technologies, however, do not occupy either exclusively oppressive or liberatory roles. Rather, they are used with full acknowledgement of their role in perpetuating medical authority and neoliberal paradigms as well as their individual benefit. Experiential and

embodied knowledge, particular when in tension with clinical knowledge, is invalidated as a transgression of expert authority. To reject these invalidations, communities cohering around subaltern knowledges emerge in resistance to the mismatched priorities and expectations of medical authority, creating space for alternative disabled imaginaries.

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INTRODUCTION

Introduction

In a 2019 blog post by disability rights activist Liz Moore, Liz Droge-Young, identified as a disabled writer, describes her interactions with the medical establishment as such: "No matter the amount of work I do on my intrinsic value and my being the expert on what I feel, being unheard, ignored, and doubted by a professional who society holds as the ultimate arbiter of health knowledge has a way of destabilizing my self-worth and trust in my own experience" (Moore, 2019, para 12). This quote captures the complex, strained, and fluid knowledge politics that characterize contemporary healthcare, the focus of this study. In a society that increasingly values the professional medical class and technologists as adjudicators of acceptable embodiment, how individuals experience themselves – their bodies, their minds, their relationships – is called into question when it comes into conflict with medical authority. Further, as medicine defines the parameters of ability, so too does it define and animate the obligations of individuals to approximate the able, productive, body. Technologies, from preventative screening to advanced prosthetics, have come to play a key role in the articulation and experience of disability and ability.

Since the mid-1980s, biomedical technologies are increasingly positioned in a rhetoric of individual autonomy and cure or prevention of disability, illness, and pain (Clarke et al, 2010). The purpose of this qualitative multiple case study is to characterize the experience and enactment of dis/ability, agency, and accountability in the context of biomedical technology use. The knowledge generated from this inquiry contributes both to the theoretical understanding of the social and political relationship between disability and technology, as well as the practice and regulation

of designing and using biomedical technologies. I draw from qualitative empirical data from three distinct case studies, each focused on a different biomedical technology: Prenatal genetic screening and diagnosis, deep brain stimulation, and DIY artificial pancreas systems. Through the use of critical sociological methods including qualitative interviews with users of biomedical technology, clinicians, and experts and analysis of user-directed guidance documents from hospitals, commercial manufacturers, news outlets, and user communities, I tease out the relationship between neoliberal personal responsibility and decision to pursue biomedical technological intervention. Additionally, I explore the generative possibilities of embodied and experiential knowledge to refute clinical and medicalized understandings of dis/ability. The conclusions of this study are informed by a literature review spanning disability studies, science and technology studies, and sociology, interviews from forty-one informants and over 600 pages of primary documents.

This chapter begins with a brief overview of the history and background that contextualizes the current study, focusing primarily on the rise of medical authority through professionalization and the subsequent the medicalization and individualization of disability. This section will be followed by a problem statement, objective, and research questions that guide this dissertation as well as an overview of the research approach and assumptions. The chapter concludes with definitions of key terminology, including bodyminds, dis/ability, and biomedical technology, and organization of the dissertation.

Background and Context

History

In alignment with disability studies scholarship, this study assumes disability is not an innate biological characteristic, but a socially and politically constructed category that changes across time and contexts. Through history, disability has been understood and enacted in many ways, from spiritual test to sociological phenomenon. Frames for understanding disability, which will be discussed in-depth in Chapter 2, expose and shape social values and pathways to epistemic authority, determining what disability means in part through who has the authority to define it and interventions to address it. The frame through which disability is understood, produced and producing certain social, political, and material realities, creates conditions under which certain people and groups have authority over disability as a phenomenon and over disabled people. For example, one of the earliest recognized models of disability is one that frames it as a moral failure or spiritual challenge (Retief and Letšosa, 2018). Under this model, religious authorities such as priests and clergy define both when non-normativity becomes disability, it's cause (such as parental failure to abide by social mores), and the appropriate intervention (such as exorcism or abandonment). In western societies, religious and moral models, particularly those emerging from Judeo-Christian traditions, have long determined authority over disability (Retief and Letšosa, 2018). However, the 20th century and the dawn of modernity marked a decline in the influence of religion in everyday life. Instead, to borrow Bruno Latour's (1993) framing, the post-Enlightenment era was characterized by a religious fundamentalism idolizing positivism, secularism, and the ostensible neutrality of natural observation. Social progress and the common good became explicitly linked to rationality and technological and scientific progress (Marx, 1987). This shift created an authority vacuum around illness and disability as

religious leaders were no longer viewed as credible knowledge producers. This gap was rapidly filled through the professionalization of medicine and the emergence of a class of medical experts (Conrad, 1992). Through the rise of professional clinicians emerged intricate gatekeeping processes and systems of epistemic privilege in which disabled bodyminds[1] become not just objects of personal responsibility (as through the moralization of disability under a religious model), but social control. In part, this control emerges from the power to categorize, name, and intervene on non-normativity-cum-pathology. Reading disability through medicine both demystifies it – ostensibly stripping it of its religious and moral connotations – and pathologizes it (Couser, 2011 as cited in Goodley, 2014). Medicine as a practice has enabled many disabled people to live or to live with greater quality of life but has also forced dis/ability to be understood solely as a biological or physiological – and therefore deeply individualized – condition. Further, with the emergence of biomedical technologies that can treat, manage, or identify disability, there is a transfiguration of moral responsibility for disability. For example, congenital disability may no longer be read as emerging from the lax moral standards of the parents in most contemporary societies, but not identifying or managing pregnancy through prenatal genetic screening is often understood as irresponsible or immoral parenting (Rapp, 1999).

With the rising authority of the medical class emerges a sociological phenomenon known as medicalization. At its core, medicalization is a definitional process by which human phenomenon come under medical jurisdiction. As disability shifts from being primarily understood as a moral failing, under a religious paradigm,

[1] Bodyminds is a term increasingly used in critical disability studies (for example, see Price, 2015 or Schalk 2018) to resist the naturalization of the division between mind and body. A more detailed definition is included at the end of this chapter).

to a social responsibility, under a charity paradigm that rose to prominence with the development of charitable organizations and institutions, to a biologically identifiable difference, under a medical paradigm, it becomes decontextualized from its social and political vectors and further reinforces the authority of medical experts to name and intervene on disability (Conrad, 1992; Carrier, 1983). Further, as medical authorities increasingly claim expertise, disabled people experience an invalidation of their own experiences if they are out of line with medical hegemony. Feminist philosopher Susan Wendell describes the realization of medical authority arising from a professional clinical class and its consequences on disabled people from an individual perspective, writing "When you are forced to realize that other people have more social authority than you do to describe your experience of your own body, your confidence and your relationship to reality are radically undermined" (1989, 121). Kristina Gupta (2020) further characterizes the distinct power dynamics of professionalization, arguing that the medical establishment is itself stratified such that the people with the most authority to make decisions are people who already enjoy systemic privileges (by virtue of their race, gender, ability, etc.), further alienating them from the experience of many disabled people. As such, the principles and values that drive medical practice are often at odds with the desires and needs of disabled people. Specifically, medical authority to intervene on disability is animated by a curative imaginary or compulsory-ablebodiedness in which the undesirability of disability is taken for granted. Disability (and often, disabled people) become pathologized and targeted for elimination (Kafer, 2013; McRuer, 2006).

Adele Clarke and colleagues (2010) identify the 1980s as another paradigmatic shift in (specifically American) healthcare, dubbing the current sociopolitical climate as an era of biomedicalization. This era is characterized by the

complexities and entanglements between knowledge, medicine, and technology. They identify five key elements of this new biopolitical economy: the conflation between and entanglement of technology and knowledge, a focus on optimization rather than pathology, increasing reliance on technoscientific interventions, a transformation of knowledge practices, and the production of new biomedical identities through engagement with biomedical technologies. This context, which valorizes technological intervention, creates new pathways into both the physiological identification and individual treatment of dis/ability, further cementing it as a discretely biological phenomenon. Technologies enable a reduction and reclassification of people through standardization as a means of determining normality and making people compatible with technologies (Clarke et al, 2010; Thompson, 2005). Linked to the moral imperative to contain unruly bodyminds is the overwhelming rhetoric of technological progress. Technological progress, at least in the American context, has become a core social value, synonymous with social betterment, regardless of the uneven distribution of that "betterment" (Smith, 1994). This discourse is particularly forceful when applied to biotechnological intervention on non-normative bodyminds; as Franklin (1997) writes in reference to infertility technologies, "there is no sense of choice or options within this depiction of scientific progress: it is as eventually inevitable as it is morally imperative to proceed forward" (p. 330).

Contemporary Challenges

Challenges to patient autonomy and responsible decision-making multiply in contexts of emerging technologies and procedures. The Nuffield Council on Bioethics (2013) reports on novel neurotechnologies notes "the lack of clear evidence of risks and benefits of some interventional techniques also presents challenges to responsible clinical decision-making" (p. xx). Gagliardi and colleagues (2017) write

that for medical devices whose potential effectiveness and side effects are not clinically proven, such as experimental devices, patient engagement in decision-making is undervalued but especially important, since "patients informed of risks and benefits might change their treatment preference" (277). The uncertainties of emerging technologies and procedures create contexts in which both "informedness" and "consentability" come into question. "The lack of adequate information makes informed consent inconceivable," Tallacchini (2011) writes of xenotransplants, "and lays the basis for additional constraints to which patients have to consent" (170). Tallacchini (2011) further suggests that emerging and experimental technologies expose their recipients not only to the burden of health risks, but to a lifetime of medical surveillance. Willey and colleagues (2015), writing about the social genealogy of autism, note a trend toward greater surveillance and control over non-normative bodyminds. Michael (2017) has repeatedly raised concerns about surveillance via medical devices, particularly noting that people are often surveilled without their knowledge or consent. Centering questions of agency and accountability allows me to consider how emerging technologies contribute to medical surveillance and systematic oppression of dis/abled people. There is a need to thoughtfully consider the tensions between uncertainty, privacy, and need and to use an intersectional lens to analyze questions of equity in access and in choice.

From the perspective of the individual clinical experience, questions of agency and responsibility also come to the fore. Recent empirical research suggests that as healthcare increasingly relies on biomedical technology as a means of intervention, "health information places inappropriate demands on patients, often assuming they understand their own health conditions and have adequate literacy skills to take appropriate actions" (Wagner, et al, 2016). Lack of accessible information

disproportionately impacts people from low socio-economic classes and other marginalized communities (ibid). This fact, compounded with a clinical inattentiveness to the financial and social costs of medical devices, results in unintended pressures and consequences for recipients of implants and other invasive and high-tech devices (Okike, et al, 2014). Further, a recent empirical qualitative study conducted with physicians in Canada suggests that user engagement in decision-making around medical devices is not prioritized (Gagliardi, et al, 2017). According to the authors, patient engagement "is desirable because it can improve patient knowledge, relationship with providers, health service use, satisfaction with healthcare, recommended treatment and other desirable lifestyle behaviors and clinical outcomes" (277) In this descriptive qualitative study of 22 physicians, clinicians question patients' ability to make competent decisions, however, ignoring their embodied experience and personal autonomy, preferring instead to simply inform patients of the devices they've already decided to use. Some medical professionals assume patients wish decisions to be made on their behalf, enforcing a paternalistic paradigm. As one interviewee in the study stated, "I think that the general population, to be quite frank, is not smart enough to engage in that discussion. Physicians quite frankly don't have the time to educate people, even in the basics that they would have to know" (279). Further, physicians may assume patient engagement is unnecessary in situations where non-intervention may result in death, asserting their right to impose their expert authority as to what constitutes a good or worthy life, regardless of the patient's wishes (ibid). This study, while small in scope, is revealing about the types of disjunctions between the expectations and desires of people pursuing medical intervention and clinicians providing care.

Further complicating this picture are the social and political pressures non-normative and disabled bodyminds endure under neoliberalism. Referring to the deregulation and privatization of markets, neoliberalism provides a backdrop upon which the able-bodied, self-governing individual becomes not just an ideal, but a mandatory requirement for full citizenship. As such, in contemporary Western societies, Goodley (2014) argues dis/ability is produced in a context of "neoliberal-ableism," which is characterized in part by "increased expectations placed on the autonomy of self-responsible individual citizens to care, educate and govern themselves" (p.63). The "able" bodymind is defined by its productivity, and responsible citizenship demands self-regulation and intervention when one's bodymind falls short. As Johnson and McRuer (2014) write about both social and political pressures and consequences of bodily accountability, "the decision to be capable…is a winding road of self-deprivation presented as a cultural good" (p. 137). Inherent in the neoliberal environment is individual responsibility. When discussing the rise of genetic screening as surveillance, Kerr and Shakespeare warn that "people are increasingly cast as responsible for their own health and welfare," as opposed to a system in which community-oriented social responsibility results in transformed environments rather than altered bodyminds (100). Feminist philosopher Melinda Hall (2017) considers how transhumanism, or the belief that human evolution should be augmented through technological intervention, arguing that transhumanist perspectives have infused Western neoliberal consciousness with a moral imperative to engage with biotechnological interventions; anything short is interpreted as an "an immoral refusal to exercise autonomy" (122). However, scholars of disability argue against the assumed superiority of modified bodies, instead arguing for an acknowledgement of the value of diverse bodies, minds, and positionalities. The knowledge arising from the embodiment and experience of

disability, resists neoliberal logics and serves as a generative place for alternative imaginaries to flourish (Kafer, 2013; Goodley, 2014).

People with non-normative bodyminds face social, political, and material pressure to intervene on their bodyminds to closer approximate the normate, to use Rosemarie Garland-Thomson's (1997) term[2]. This is not to suggest that individuals cannot or should not pursue medical care nor to invalidate individual experiences of pain, discomfort, or other elements of disability (see Gupta, 2020), but to suggest that the reliance on biomedicine as a means to correct or eliminate dis/ability is intrinsically linked to political and social realities that produce and reproduce an idealized neoliberal subject (see Garland-Thomson, 2012; Kafer, 2013; Goodley, 2014). This ideal subject is perfectly independent, perfectly self-governing, and productive in a way that is legible and beneficial to the capitalist market. Under this paradigm, disabled bodyminds are unruly, unworthy, and ungovernable unless an individual becomes self-responsible and pursues methods of body management such as biomedical technologies.

I seek to examine the tensions between the increasing prominence of a medicalized understanding of disability and the acceptability of disability as a mode of knowing and being. A medicalized framework, which understands disability as a biological characteristic detectable and curable through medical intervention, confers authority and credibility to medical experts (Conrad, 1992) while delegitimizing the embodied expertise of disabled people, potentially endangering a framework that attends to the social, political, and infrastructural dimensions of disability and inclusion. I argue that the proliferation of these technologies, not only in practice,

[2] The term "normate," according to Rosemarie Garland-Thomson (1997), refers to the figure of the ideal able-bodied, able-minded, independent person. This figure, which is an impossible standard, is understood in its opposition to disability.

but in the public consciousness, shifts accountability for managing the misfitting of disabled bodyminds away from public and social infrastructures and back onto individuals. This displacement of responsibility onto disabled individuals runs counter to prominent disability rights and justice discourses that ostensibly shape contemporary disability policy. Explicating how and when medical understandings of disability come to bear on individuals is imperative for grappling with the tensions between these liberatory discourses and lived realities. These choices to medically intervene on disabled bodyminds become moralized, and medical interventions to ameliorate bodily or cognitive difference become an expectation rather than a choice. As highlighted above, this is not to say that these technologies have no value and that no one individually should be allowed to pursue them, but rather to say that their introduction into both our healthcare systems and our public discourse changes how disability is understood and enacted in important ways. By privileging individual narratives, I seek not only to highlight where embodied and experiential knowledge resists and identifies gaps in medical authority, but to argue for meaningful inclusion of user voices into the design and use of medical technology. Additionally, my empirical work with disabled people using these technologies shows that embodied knowledge directly resists and identifies gaps in medical authority and requires additional attention.

Study Overview

This research asks necessary questions about the consequences of biomedical technologies on social, political, and ontological conceptions of dis/ability. Through a series of qualitative methods, I seek to capture the profound effects the experience of choosing and using biomedical technologies have on representations and manifestations of disability and responsibility. Issues of the social and political construction of disability have largely been attended to through philosophical,

theoretical, or autoethnographic scholarship. By constructing and conducting an empirical study, this project strengthens disability studies and science and technology studies scholarship on biomedical technologies, confirming the tensions between embodied and clinical knowledge, epistemic invalidation in under medical authority, and the importance of subaltern disabled knowledge practices.

The rhetoric of individual autonomy, independence, and choice animates the design and use of many biomedical technologies. With this discourse of increased autonomy comes an accompanying discourse of personal responsibility. Essentially, for disabled people (or the prospective parents of such people) the promise of technologically-enabled independence comes with an obligation to pursue it. Importantly, this configuring of disability as detectable and treatable through medical technology could undermine constructions of disability as a social, political, and collective phenomenon in favor of one that is wholly biomedical and wholly individual. Therefore, how people experience disability and responsibility in the context of healthcare has implications for both clinical practice and for the design, deployment, and discourse of medical technologies broadly. In research and practice, the subordination of embodied and experiential expertise and the insistence on personal responsibility has resulted in bad design, insufficient clinical care, misdiagnosis and mistreatment, guilt, and abuse (Hamraie & Fritsch, 2019; Wendell, 1989; Oliver, 1992; Monteleone, 2018). This project seeks to characterize tensions between personal and social responsibility, dis/ability, health and illness, and individual autonomy versus public health models of healthcare through the individual experience of three biomedical technologies. In doing so, I create a scholarly foundation upon which to build interventions and alternative imaginaries.

Objective and Research Questions

The aim of this study is to examine the construction and enactment of dis/ability, agency, and responsibility in the context of three biomedical technologies: Prenatal genetic screening and diagnosis, deep brain stimulation, and DIY artificial pancreas systems. It is mobilized by two interlinked questions:

1. What is the nature of the relationship between biomedical technologies and the meaning of dis/ability and experience of the non-normative self?
2. How do individual agency and accountability get constructed and enacted in the interaction between non-normative bodyminds and biomedical technologies and processes?

As discussed in greater detail in Chapter 3, this study also was originally conceived with a research question addressing intersecting axes of oppression such as race, class, gender and ethnicity, but the diversity of informants, given the exploratory nature of each case, disallowed me from addressing this question meaningfully. Instead, intersectionality was employed as a theoretical framework to address the often tacit or invisible axes of oppression that inflected all three cases in Chapter 7 to explicate the often tacit axes of privilege and oppression that animate the experiences of study informants.

The scope of this work is primarily the US healthcare system, although the globalization of healthcare and the democratization of the internet troubles these boundaries. Informants often engaged in cross-national dialogues, gathering information online from across the globe. Additionally, in the DIY APS case, the community is composed of participants from around the globe. In this case alone, informants living in Western Europe were interviewed alongside those living in the United States.

Research Approach

This study employs a qualitative methodology with a multiple case study design. Qualitative inquiry allows for an appreciation for context, ambiguity, and pluralism, key for a study in which the social, political, and material environments crucially bear on the individual experience of biomedical technology (Sutton, 1993). Multiple case studies allow for an opportunity to examine similarities and divergences across biomedical contexts, providing foundations for future work. Methods in each case included semi-structured and unstructured interviews with users of each technology, family caregivers, and medical professionals. The composition of informants varied with each case. Additionally, user-directed documents such as instructions, FAQs, informational publications, and regulatory information were collected as a means of triangulation. Analysis was conducted using a general inductive framework that draws elements from both Grounded Theory and hermeneutic phenomenology. This framework allowed for a structured and robust inductive analysis, using coding procedures inspired by Grounded Theory (Glaser and Strauss, 1967) and an attentiveness to experiential knowledge in context through hermeneutic phenomenology (Vick, 2013). Further, this analytical framework permitted the acknowledgement of personal experience as a legitimate source of knowledge while also recognizing the ways in which an individual's experience is filtered through their context.

The three case studies selected for this project – Prenatal genetic screening and diagnosis, deep brain stimulation, and DIY artificial pancreas systems – were chosen not because of their similarities or comparative potential but because they each probe the meaning and experience of disability across varying settings in which dis/ability is understood as pathology, demanding biomedical intervention. Prenatal screening and diagnosis have become routinized in obstetric care, commonly offered

to all pregnant persons in the United States. Further, it is linked in meaningful ways to both the performance of responsible parenthood (Rapp, 1999) and an articulation of the prevention of disability as a public good (Paul, 1998). It alone of the three cases examines a set of technologies designed to detect and prevent disability rather than manage it. The engagement with PGS/PGD is typically short-term, capturing only a moment in time rather than an evolving relationship between person and technology. Deep brain stimulation (DBS) as a case enables an opportunity to explore how disabled bodyminds become standardized as sets of discrete symptoms, creating substantial gaps in the lived experience of dis/ability and what is valued in the clinical setting. DBS involves complicated gatekeeping protocols that reveal both an implicit hierarchy of interventions and users. Knowledge about and access to DBS is tightly controlled by bounded groups of experts, making alternative knowledge and pathways difficult. Further, this case involves a complex biomedical technology, which previous empirical research suggests does not typically prioritize user engagement (e.g. Gagliardi et al, 2017). DIY artificial pancreas systems expose an alternative framing of responsibility and embodied expertise taken up outside of and in response to an indifferent medical establishment. Through this case, I identify the pain points where a person's embodied knowledge rubs against medical authority, and how processes can be transformed in pursuit of social, political, and medical practices that are responsive to the needs and desires of disabled people.

Assumptions

This interdisciplinary study draws insights, both empirical and theoretical, from a range of disciplines, including critical disability studies, science and technology studies, sociology, and feminist epistemologies. From each of these fields comes a set of foundational assumptions that undergird this study. These assumptions, briefly outlined here, will be explored in more detail in Chapter 2.

The first assumption, drawn from the rich scholarship of disability studies, holds that disability is not a stable category. The meaning of disability is deeply contextual and contingent on its relationship to ability or normalcy. Cultural, social, and political frameworks influence how and when difference becomes disability. As disability studies scholar Simi Linton (1998) writes in her seminal text, *Claiming Disability: Knowledge and Identity,* disability is "not simply the variations that exist in human behavior, appearance, functioning, sensory acuity, and cognitive processing, but, more crucially, the meaning we make of those variations" (2). Tobin Siebers (2010), Sunuara Taylor (2004), and others concur, asserting disability is neither simply a physiological fact nor a cultural artifact; it is both simultaneously, co-produced and co-producing. The "line that we draw between the biological and the social…is artificial," Susan Wendell (1989) writes, insisting non-normative bodyminds can only be understood as resulting from the complex interaction between the two (110). Medical categorization is not the neutral observation of a natural world, but a deeply political act that is historically, geographically, and socially contingent. Therefore, how disabled and non-normative bodyminds become legible in healthcare systems is a social question and political question.

From science and technology studies comes two key insights. First, technologies, and more broadly, the material world, are not neutrally constructed nor neutrally experienced. The technologies we use are embedded with the political and social assumptions of the people who made them and about the people who use them, which has significant consequences in the contexts in which they are deployed (Winner, 1986). Medical technologies then do not exist to fill an a priori need, such as "curing" disability, but themselves play a role in creating and perpetuating specific constructions of disability. In the context of this study, this means the design and

use of biomedical technologies both inform and are informed by social and cultural understandings of bodily and cognitive difference. From this, a second insight emerges in which the distinction between material reality and social, political, and discursive worlds becomes blurred. It is not simply that one informs the other, but that the material world, of which technology is a specific manifestation, and the social world are co-constituted and mutually reinforcing, a framework STS scholar Sheila Jasanoff refers to as "co-production." (Jasanoff, 2004). She writes, "Co-production is shorthand for the proposition that the ways in which we know and represent the world (both nature and society) are inseparable from the ways in which we choose to live in it" (2004, 2). This idiom, as Jasanoff dubs it, is a fundamental assumption for this work because it unsettles taken for granted distinctions between the natural (biological or physiological) and the social (differential values ascribed to certain bodily arrangements) when thinking about disability. Further, it rejects an assumption of a natural "truth" that needs only to be uncovered through the "right" kind of methods applying the "right" kind of knowledge. Disability then is not something that materially exists waiting to be identified, nor is it solely a social or political phenomenon, but as feminist STS scholar Karen Barad (2003) writes, "the material and the discursive are mutually implicated." (822). To understand dis/ability under this paradigm is to recognize it as infinitely contingent; there is no set of biological or physiological symptoms that definitely signal dis/ability. Rather, the social and material dimensions of disability are co-constituted as a means to produce and maintain order.

From sociology, an assumption emerges regarding the cultural significance of medicalization. As described above, the process of transforming human phenomenon into medical pathology creates distinct social, political, and ontological relationships

through the naming and standardization of fluid and contingent beings. Importantly, medicalization is key to this research in that it makes explicit the contingencies through which disability is understood as a physiological or biological phenomenon. By elucidating the process of shifting disability under medical jurisdiction, it opens up the possibilities to understand disability otherwise. By explicating *how* disability came to be understood as biomedical, medicalization reaffirms what the disability rights movement has asserted for many years: disability is socially, politically, and materially constructed through human action. Similarly, medicalization enables us to recognize "medicine…as a social and cultural enterprise as well as a medioscientific one" (Clarke et al, 2010, 51). Saliently, as Bowker and Star (1999) write, understanding the constructedness of dis/ability as medical phenomenon does not make it dismissible: "things perceived as real are real in their consequences" (Bowker & Star, 53). While medicalization is a contingent and fluid social process, it has ontological, political, and ethical consequences.

Finally, out of feminist epistemologies emerges the idea of embodiment and experience as a legitimate source of knowledge. Like scholars of science and technology studies, feminist epistemologists reject the notion of an objective or neutral framework as the only allowable pathway for "true" knowledge. In fact, according to feminist scholar Sandra Harding (1991), who coined the term standpoint theory to recognize the contextual knowledge of women, adherence to positivist frameworks, rather than cultivating neutrality, perpetuate and obscure biases. What this rejection allows for is the acceptance of situated knowledges —or contingent, partial, and subjective knowledges —that arise from the unique social positions an individual occupies (see Haraway, 1987). This study takes for granted the validity of experiential and embodied knowledge claims, recognizing also their

partiality and contingency on the unique contexts in which they are made. Secondly, I also draw from feminist disability studies scholarship, which not only recognizes the knowledge claims of disabled people, but also asserts that the misfit between disabled bodyminds and a material-discursive world that was constructed with an able-body/able-minded ideal produces contexts in which disabled people have more knowledge about that world. As such, I have privileged the accounts of disabled people both in the cases researched and in the recommendations made in Chapter 7. In the case of Prenatal genetic screening and diagnosis, where no informants identified as disabled, I was attentive to the presence or absence of disabled knowledge in discussions of congenital abnormalities and disability. These assumptions trouble the demarcation of scientific and medical knowledge as a special kind of knowledge, instead forcing an examination of the social positions that animate all knowledge claims.

Key Terminology

It is necessary to provide an explanation for the terminology used to describe disabled people in this text. Language regarding disability has historically been a fraught subject both in theory and in practice (e.g. Zola, 1993; Altman, 2001; Dunn and Andrews, 2015). While historically, these controversies involved the appropriation and degradation of medical terms (for example, "moron" and "feeblemindedness") or the reclamation of these terms by disabled communities (see the reclamation of "crip" specifically), contemporary debate often centers around the use of person-first (person *with* disabilities) and identity-first (disabled person) language (Dunn and Andrews, 2015). Proponents of person-first language, which often include disability service providers, governmental agencies, and medical professionals, argue that such structure reduces stigma by focusing on the humanity of people with disabilities. For example, the American Psychological Association

previously recommended person-first language as a "constructive way to counter negative or ambivalent attitudes toward people with disabilities, shifting them in positive directions, toward openness and understanding" (ibid, 256)[3]. Increasingly, however, both disability theorists and advocacy organizations endorse identity-first language, arguing that the alternative, person-first language, constructs disability as "something you would *want* separated from you, like a rotten tooth that needs to be pulled out" (Liebowitz, 2015, para 4). As Kathleen Downes (2014) writes, "my disability is a part of me, and I refuse to treat it as something that must be overlooked in order for one to be seen as a person. My disability is infused in my person, not an ugly outgrowth that must remain next to my person" (para 4). Following both the convention of critical disability studies and disabled activists, this dissertation will utilize identity-first language when writing about disability in the abstract or as a general term. In instances where I am writing on the specifics of an interview or case, I will use the preferred language of the person in question where it is known.

Secondly, as has be iterated throughout this chapter, this study concerns itself with biomedical technologies. As such, it is necessary to delineate what is included and excluded from this category. Biomedical technology is a catch-all term that incorporates many kinds of equipment, processes, and laboratory procedures implemented in healthcare systems. It can mean anything from a syringe to an MRI machine, although this study focuses on the high-tech end of that spectrum. It typically refers to technology used or implanted in clinics and hospitals, as opposed to assistive or everyday technologies, that are used in other settings. These

[3] The APA now suggests the use of either person-first or identity-first language is appropriate (APA, 2020).

technologies and processes will alternatively be referred to as interventions or medical interventions. This convention follows recent scholarship (e.g. Gupta, 2020) in feminist and disability studies that reframes what has traditionally been referred to as "treatment." The term treatment bears a positive connotation that with it implies both medical necessity through pathology and beneficial outcomes. Given the fluidity of the ability-disability binary and the historical and systemic harm done to disabled bodyminds through the medical establishment, neither are guaranteed.

This dissertation also draws on terminology commonly used in critical disability studies, but not often utilized in other fields and disciplines, namely "dis/ability" and "bodyminds." I have provided brief definitions of both below in an effort to encourage their uptake in feminist, STS, and sociological scholarship.

Dis/ability. I use "dis/ability" as a split term in the convention of scholars of disability such as Dan Goodley as a means to signal that ability and disability are co-constitutive, meaning that one "can only ever be understood simultaneously in relation to another" (Goodley, 2014, xiii). This is not to say that biological and physiological differences are not materially real, but to suggest that the category "dis/ability" is constructed only through the existence of a normative or idealized comparison. In this dissertation, dis/ability will be the preferred term to discuss the philosophical and theoretical dimensions of disability – which requires constant attention to the constructedness of the binary. Disability and dis/ability are used interchangeably throughout.

Bodymind. Bodymind is a term increasingly favored in critical disability studies (see Price, 2015, Schalk, 2018 among others) to both recognize the inseparability of the mind from the body, resisting the Cartesian dualism that privileges one over the other by mere virtue of distinguishing them. Further, the term signifies cognitive and

mental difference as a significant unit of analysis, forcing scholars – largely feminist disability studies scholars – to confront the social, political, and ontological implications of "able-mindedness" alongside able-bodiedness (Price, 2015).

Chapter Organization

This study is divided into seven chapters. Chapter 2 contains a literature review drawing from scholarship in disability studies, feminist epistemologies, science and technology studies, and sociology. Bridging theoretical and empirical work, I present an overview of scholarship addressing frames for understanding disability, body management under neoliberalism, epistemic authority in medicine, and situated and embodied knowledges. This chapter provides vital context for grappling with the relationship between disability, biomedical technology, and the experience and enactment of ability and accountability.

Chapter 3 provides an overview of methodology, methods, analysis, and ethical considerations for the study. I present a rationale for the methodology, a qualitative multiple case study, with methods primarily consisting of semi-structured and unstructured interviews and document collection. I then provide an overview of the analytical framework, a general inductive method drawing from both Grounded Theory and hermeneutic phenomenology. The chapter ends with ethical considerations, including reflexive practices and steps toward establishing trustworthiness (Lincoln and Guba, 1985) through establishing credibility, transferability, dependability, and confirmability.

Chapter 4, "Some Stuff You Want to Take Off the Table:" Prenatal genetic screening and diagnosis, presents the descriptive findings and inductive analysis of a series of interviews with prospective parents and medical professionals who have experienced prenatal genetic screening and diagnosis (PGS/PGD) and user-directed

guidance documents such as brochures, FAQs, and informational documents produced by commercial PGS/PGD companies, professional societies, health systems, and governmental organizations. Out of this analysis emerges a relationship between social perceptions of responsible parenthood and an obligation to pursue testing as a means to gain knowledge. Deference to medical authority, however, creates a context in which "too much" knowledge, through comprehensive testing that outstrips what was recommended by a clinician, represents a transgression or recklessness that jeopardizes the peace of mind ostensibly acquired through screening. In the context of PGS/PGD, disability is understood as future possibility rather than lived reality and presented by prospective parents and professionals along two binaries. First, disability is understood as either a medical phenomenon, located discretely in extra chromosomes or translocated segments, or a social phenomenon that is manifested through the social, educational, and relational prospects of the future child. The former is deemed as more concrete and knowable, and therefore is favored by medical professionals when sharing information about disability in genetic screening and testing contexts. The latter, however, is acknowledged by professionals and parents as important information in making decisions about pregnancy management. The second binary articulated disability as either a tragedy – manifested through negatively connoted language – or inspiration – through the perception that disabled children exist as a gift or lesson to able-bodied people. Both termini of this binary objectify and depersonalize disabled people and understand them only in relation to their able-bodied caregivers. Ultimately, this chapter exposes perceptions of the obligatory nature of screening and testing in pursuit of responsible parenthood and tensions between the knowledge sought by prospective parents and proffered by professionals.

Chapter 5, "It Was Like He Had to Somehow Conquer My Brain:" Deep Brain Stimulation, follows a similar framework to Chapter 4, providing descriptive and analytical findings for interviews with recipients of deep brain stimulation (DBS) and their families as well as guidance documents from hospital systems and neurological centers. DBS refers to a surgical implant that delivers electrical impulses to the brain to manage symptoms of neurological and psychiatric conditions, including Parkinson's disease, chronic pain, major depressive disorder, dystonia, and epilepsy. This analysis relates the design, use, and discourse around deep brain stimulation to the understanding of disability as a purely physiological phenomenon. Once disability is firmly located within the individual, perceptions of personal responsibility to manage it – particularly the elements of disability that are observable, such as tremor, or impede economic or social productivity – emerge as central to decision-making. Additionally, people with DBS often experienced epistemic invalidation or dismissal when their embodied experience challenged clinical authority in some ways, often through the experience of physical, neurological, or psychiatric symptoms related to either the precipitating condition or their implant. Beyond these individual instances of invalidation, this case also makes clear a discrepancy in how disability and "invasiveness" are understood by users (or prospective users) and clinicians or device manufacturers. DBS, while perceived as invasive by clinicians, was sometimes understood as less invasive than the surveillance and side effects of medication or the stigma of observable disability. Ultimately, this case emphasizes the relationship between medical intervention and neoliberal body management, as well as the consequences of embodied knowledge that challenge or resist medical authority.

The final case study is documented in Chapter 6, "It Could Be a Different Way:" DIY Artificial Pancreas Systems. DIY artificial pancreas systems (DIY APS), also called hybrid closed loops or automated insulin delivery systems, refer to off-label systems for managing Type 1 diabetes (T1D). These systems integrate insulin pumps, continuous glucose monitors, smart phones or smart watches, and open source algorithms to automate insulin delivery. Interviews are conducted with DIY APS users and developers, and documents included open source guidance documents for building and maintaining DIY systems, informational blog posts, and regulatory announcements. This analysis highlights a particular manifestation of personal and collective responsibility that arises in part from invalidation by the medical establishment and the failure of regulated management options to attend to the lived realities of diabetes. Further, the DIY community directly resists and challenges medical authority through the explicit endorsement of embodied and experiential knowledge and self-taught or community-based knowledge. While ostensibly animated by a community ethos that endorses transparency, collaboration, and access, tensions between this message and profiles of "successful DIYers," – educated, self-motivated, knowledgeable "super users," highlights an internalization of the principles of neoliberal body management that reinscribe self-governance and individual responsibility. Ultimately, this case exemplifies a resistance to the passive patient role that characterizes medical authority, asserting disabled knowledge as a force to destabilize hegemonic power relations in some regards while simultaneously reinforcing neoliberal self-responsibility for disability.

The final chapter, Discussion: Transgressive Responsibility and Technological Ambivalence gathers insights from the three case studies to draw conclusions about the personal experience of biomedical technology, disability, and responsibility.

Disabled people (or prospective parents of disabled people) are often confronted with a double bind of being held personally accountable for disability (which is interpreted as a physiological phenomenon) while simultaneously having embodied, experiential, or practical expertise invalidate in favor of medical authority. In other words, people are expected to manage disability while also having their experiences and choices criticized if they are in conflict with medical authority. This context is further complicated by medical understandings of and expectations for disability that are directly in tension with the embodied understanding of users. Assertions of embodied knowledge are perceived as transgression. Strained communication, dissatisfaction and trauma become common in medical settings, often resulting in the development of support communities outside of medical jurisdiction where informal knowledge exchanges occur. Further, technology itself takes on an ambivalent role in these situations, both representing hegemonic authority demanding closer approximation to the ideal bodymind and an opportunity to displace the stigma and cognitive burden of neoliberal ableism. Additionally, this chapter briefly touches on the intersectional dimensions of this study, particularly the overrepresentation of white, middle-class, educated individuals across all three case studies. Finally, I close with the theoretical and practical implications of this work and recommendations. These do not include a prescriptive recommendation for the adoption or rejection of any of the biomedical technologies examined here, but a call to make explicit the social and political complexities that frame and contextualize the individual experience of pursuing medical care. This recommendation challenges both techno-optimist discourses of hegemonic science and the techno-pessimist stance that characterizes critical studies of technology, acknowledging an ambivalent relationship Further, I recommend developing interventions in medical technology design and practice that privilege experiential and embodied knowledge, disrupting the power dynamics

characterized here. Following the main text, there are a series of appendices featuring ethics information, interview schedules, and tables of documents analyzed in each case.

CHAPTER 2

LITERATURE REVIEW

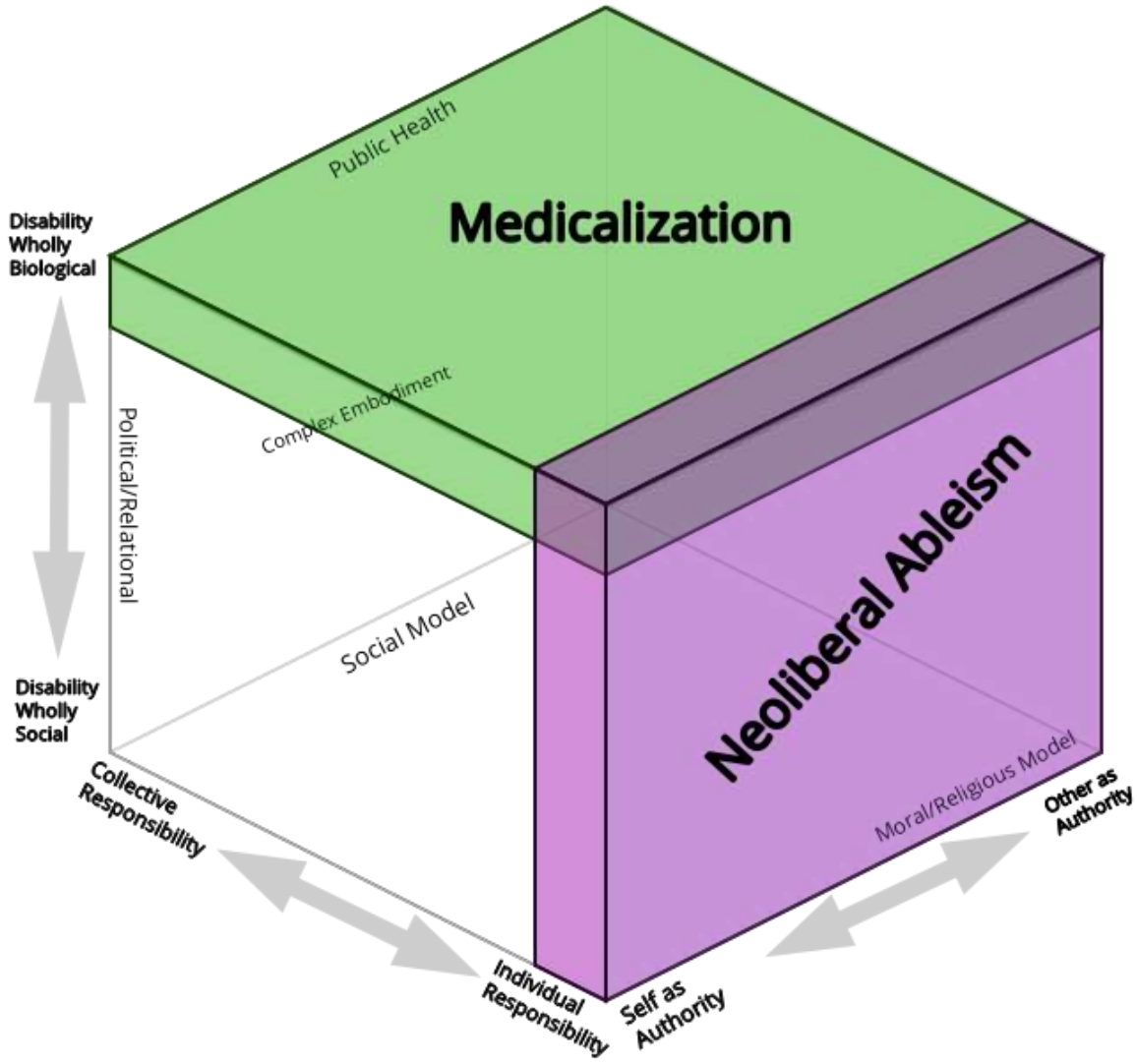
Introduction

To understand the complex relationship between nonnormative bodyminds, biomedical technologies, and constructions of disability, and accountability, it is necessary to characterize the scholarly context in which this study is situated. As an interdisciplinary study, this work draws from a diverse set of fields, including disability studies, science and technology studies, feminist epistemologies, and sociology. As such, this review brings together both theoretical and empirical work from diverse perspectives in order to illuminate both the reasons for conducting this current study as well as the theoretical framework that guides this research. I organize this literature review across a series of axes and planes that I argue create the context in which the experiences at the heart of this research can be examined and analyzed.

The following figure visually illustrates the relationship between these axes and planes.

Figure 1

Theoretical Framework



In this figure, three binaries construct a 3-dimensional field. The first, disability as wholly biological and disability as wholly social, concerns the dominant construction of disability in a given context. The second, collective responsibility and individual responsibility, articulates presumptions about who is accountable for managing and accommodating dis/ability. The third axis, self as authority and other

as authority, concerns who is considered expert and thus dictates both meaning and response to disability. Several pre-existing models of disability have been graphed onto this visual to illustrate the interaction between axes. For example, a social model of disability (UPIAS, 1975), which interprets disability as wholly sociological phenomenon of structural discrimination, is situated at the intersection of collective responsibility and disability as wholly social. Who has authority to categorize disability and determine its management is not specified explicitly in the UPIAS social model, so it is situated in the center of that axis. Complex embodiment (Siebers, 2010), in contrast, articulates disability as both biologically and socially located, and so is situated at the center of that axis. The models of disability in the figure will each be discussed in greater detail below. In this 3-dimensional model, medicalization and neoliberal-ableism appear not as points, but as planes. In the plane of medicalization, all configurations of responsibility and authority are possible, as long as disability is wholly interpreted as a biological fact. For example, a public health understanding of disability both interprets disability as a biological phenomenon, and so falls into the medicalization plane, and a collective responsibility. In the plane of neoliberal ableism, all possibilities of authority and construction of disability exist as long as personal responsibility is assumed.

The remainder of this chapter will present the literature applying to the three axes and two planes presented in the above theoretical model. The first of these binaries examines the construction of disability as either wholly biological or wholly social. Operating under an assumption that presumes dis/ability to have a contingent and contextual meaning, I argue the understanding of disability both informs and is informed by social, political, medical, and material infrastructures. This binary is explicated in this chapter by reviewing sociological and philosophical

literature on the construction and explication of frames of understanding, as well as reviewing several historical and contemporary models of dis/ability that have risen to prominence.

The second of these binaries has at its poles personal and collective responsibility to manage and accommodate disability. Reviewing literature from disability studies, queer studies, and feminist studies, I examine the construction of the ideal neoliberal subject as one that is self-governing and independent. This section examines neoliberal body management and its relationship to conditional citizenship as well as an introduction to the science and technology studies literature on human-(medical) technology interactions and technological progress as a social and political force. Finally, I review empirical sociological literature on informed consent and patient autonomy in the context of biomedical technologies. This section speaks to this study's focus on the role biomedical technologies and the sociotechnical apparatuses in which they are enmeshed play in the understanding of dis/ability and the distribution of agency and accountability.

The third binary upon which this study is situated is that between self as authority and other as authority. In this section, I will explicate the construction of knowledge, the power of medical authority, and the conditions that validate or invalidate the knowledge claims made by individuals who use biomedical technologies. Consequently, this section reviews literature on the construction of credibility, with an emphasis on medical authority, epistemic injustice, and the particular invalidation of the knowledge produced by and for disabled bodyminds. I will focus particularly on feminist epistemologies that resist and refute objectivity in favor of contextual and situated knowledge production, and specific arguments about disabled knowledge claims.

When placing these three binaries in conversation, two contexts pertinent to this study emerge: (bio)medicalization and neoliberal ableism. I will first review literature on the causes and consequences of medicalization, the process by which non-medical phenomena come under medical authority and scrutiny and biomedicalization, which specifically concerns itself with the dominance of technoscience in healthcare. Next, I will examine neoliberal ableism as a specific occurrence of neoliberal body management in which disabled people are subjected to increased pressures to care for and govern themselves for the sake of a public good. I conclude the chapter by revisiting the theoretical model and situating the current study within it.

Before proceeding, it is necessary to recognize the essential constructedness of this model and the binaries that animate it. The relationship between dis/ability, responsibility, and authority is complex and fluid, and therefore cannot be adequately captured in either a visual illustration nor the rigid topical divisions that frame this literature review. However clumsy these categorizations, I argue that such models provide opportunities to think through these relationships more explicitly. I invite critique, iteration, and collaborations to refine this model.

The Construction of Disability

The meaning and ontology of dis/ability are historically and contextually situated, fluid, and multiple. There is no one universal experience of dis/ability nor are there definitive bodily characteristics that innately cohere to produce dis/ability. Further, dis/ability can be understood as many things simultaneously in a single historical and geographic moment; emergent understandings do not necessarily obscure or eliminate older knowledge systems and framing conventions. While the field of disability studies has often dubbed these conceptual frameworks as "models,"

it may be useful to instead conceptualize them as frames. Frames, as described by Gitlin (1980) refer to "principles of selection, emphasis, and presentation composed of tacit theories about what exists, what happens, and what matters" (11-12). Erving Goffman's (1974) work on the framing of social categories and phenomena suggests that the organizing of experiences is not innate but informed by complex social and political processes. The frames that emerge from these processes in turn shape the values and pathways to epistemic authority in knowledge production about the phenomenon (Collins and Pinch, 1982). Explicating frames is a valuable practice in that it "allows us to see that events do not in and of themselves dictate the pathways along which public responses will move" (Goffman, 39). For the purpose of this research, making explicit the competing knowledge systems under which dis/ability is constructed allows me to examine how and where invalidated or illegitimate knowledge might inform biomedical technologies in design, theory, and practice. Below, I will briefly present several prominent models of disability – the moral/religious, social, and medical models – as well as several critical rebuttals. While as a scholar I am predisposed to draw from both complex embodiment and the political/relational models of disability (discussed in detail below), in the context of the sociological work presented in this dissertation, I work to acknowledge and make explicit the many competing, conflicting (and occasionally resonating) models of dis/ability constantly interacting.

Frameworks for understanding dis/ability often emerge as a means to justify or explain stigmatization of disability, although they rarely examine in depth the lived consequences of them through empirical research. In disability studies, "models" of disability are often presented as philosophical or theoretical frameworks applied universally and on the macro-level. This research contributes to this

literature by engaging these theoretical models with practical lived reality. Sociologists have previously grappled with this process of applying theory to the lived experience of non-normativity. Most famously, Irving Goffman's (1963) work on spoiled identities is attentive to the labor that the "stigmatized" must engage in simply to interact with their world. People are either forced into a representational role where they can be "approached by strangers at will" (28), act as 'normal' but only insofar as they don't "press [normal] past the point where they can easily extend acceptance" (146), and – most importantly – conceal the "unfairness and pain of having to carry a stigma…it means that normal will not have to admit to themselves how limited their tactfulness and tolerance is" (146). Goffman is prescient in recognizing that key to the "assimilation" (never true acceptance) of the stigmatized is that they act as though "neither his burden is heavy nor that bearing it has made him different from us" (147). Goffman is also careful to note that stigma is not a static state, but an interaction in which all people play both roles at some point. The models below, taken together, illustrate the fluid yet persistent stigmatization of disability.

Disability studies scholars identify the **moral model of disability** as one of the earliest frameworks for understanding and managing disability in Western societies. Alternatively known as the religious model, this frame presents an understanding of non-normative bodyminds as punishment for a failure to abide by moral codes (Retief and Letšosa, 2018). Through the moral model, dis/ability becomes both a physiological punishment and a metaphor for evil or immorality. Alternatively, in this frame, disability is understood as a test of faith, where "the challenges associated with disability are viewed as a God-given opportunity for character development" (Retief and Letšosa, 2018, 2). Often, carers and family

members are considered the targets of this "test of faith," objectifying the disabled individual as merely a vessel through which their deity communicates. While most scholars agree the moral/religious model of disability has largely been displaced by medicalization, the link between morality and normativity remains tightly entwined. For example, religious interpretations of intellectual disability as spiritual challenge or blessing to able-bodied parents remain prevalent (e.g. Michie & Skinner, 2010).

As secularization and modernization reduced the influence of religion as a governing force in the 19th century, a **medical model of disability** emerged. This model is one that privileges highly individualistic, biomedical explanations for disability and can be understood as asserting that disability has biological origins and is located solely in non-normative bodyminds. Disability becomes discrete, identifiable, and treatable through scientific and medical regimes. Salient to this model is the implicit construction of a normal/abnormal binary, in which able-mindedness and able-bodiedness are fetishized and disability is targeted for individual treatment and cure (Shyman, 2016). This model is intrinsically linked to the social idealization of bodyminds as "young, strong, healthy," implicitly pathologizing any person whose embodiment falls outside of these fictive norms (Wendell, 1989, 110). Further, this frame necessarily establishes criteria for expertise that favors clinicians as authorities over dis/ability. As Shyman (2016) writes in his analysis of medical framing of behavioral therapy for autism,

> *The medical model, then, sets boundaries as to who does the curing (and, ipso facto decides and designs the "treatment" regimen) and who needs curing (or who receives the "treatment"), allowing for a hierarchical and potentially inequitable relationship between clinician/therapist/teacher and parent/individual/student. Suffused throughout the functioning of the medical*

model is the focus on a pathological orientation of thought: a perspective that seeks to isolate a set of particular "facts" or indices of disability, usually in the form of definable physical or intellectual characteristics, which separates those for whom "normal functioning" is attainable without treatment and those for whom it is not. (368).

Under the medical model, disability becomes an individual problem discretely located in the biological bodymind. Regardless of the reality that deviation from the normative ideal is inevitable, under a medical paradigm, it is met by a response that favors biomedical intervention as a means to correct deviance. Kafer (2013) dubs this the "curative imaginary," which "not only expects and *assumes* intervention, but also cannot imagine or comprehend anything other than intervention" (27). Pathology under the medical model demands individualized intervention, as opposed to social or infrastructural change, locating disability solely in the body. As will be discussed below, this understanding of disability both informs and is informed by frameworks that demand neoliberal personal responsibility.

In direct resistance to the medical model, disability activists in the mid-20th century began advocating for a **social understanding of disability**. By some accounts originating with UK-based disability rights group the Union of Physically-Impaired Against Segregation (UPIAS) in the 1970s, the social model is a direct response to the medical/individual model of disability, arguing that impairments (the physical or biological differences that would be dubbed disability under other models) are not disabling in and of themselves, but rather that disability emerges through social exclusion, physical inaccessibility, and attitudinal barriers. Dis/ability thus becomes "something imposed on top of our impairments, by the way we are unnecessarily isolated and excluded from full participation in society" (UPIAS, 1975

3). As such, the social model is occupied with "barrier removal, anti-discrimination legislation, independent living, and other responses to social oppression" (Shakespeare, 2010, 216). The social model, which has proliferated through a multitude of disability advocacy organizations, service providers, and research, has become in many ways the hallmark for signaling alignment with disability rights. It has been an extremely effective political orientation that has enabled significant policy and infrastructural changes where it has been leveraged (largely the United States, UK, and Canada). However, recent scholarship and activism from disabled individuals poses a challenge to the social model. First, this model "so strongly disowns individual and medical approaches that it risks implying that impairment is not a problem," thus invalidating and alienating the experiences of people who experience pain or other phenomena that cannot be directly linked to social oppression (Shakespeare, 218). Further, the social model of disability does not attend to what Moya Bailey and Izetta Mobley (2019) refer to as the "particular vulnerability of Black, women, and gender-nonconforming bodies," refusing to authorize individual desire for treatment that for many has been consistently denied" (10). As uncomfortable as it may make those of us engaged in the Disability Studies field," they continue, "Some communities are actually yearning for not only care but treatment and cure. Part of corporeal autonomy as a theoretical stance—one that links both Blackness and disability—is that it allows for people to choose what is best for their bodies: treatment, cure, or a resistance to medical intervention altogether" (Bailey & Mobley, 2019, 10). Further, Shakespeare argues, it is not productive to think about dis/ability as purely social *or* purely biological, but an entwinement of the two, informing a critical realist approach to understanding dis/ability that has since been taken up in assistive technology design (Frauenberger, 2015). Finally, the social model assumes that a universally-designed environment could eliminate

disability as a social category – a claim that is both curiously curative and erroneous as it does not take into account the heterogeneity of dis/ability. Rebuttals to the social model, including Tobin Siebers' theory of complex embodiment, will be discussed in greater detail below.

As disability studies solidified as a field in the late 20th century and early 21st century, additional models for understanding disability emerged. Alison Kafer (2013), in her ground-breaking monograph *Feminist, Queer, Crip* reconceptualizes disability as a **political/relational** object, which serves to denaturalize and re-politicize it as a "potential site of cultural imaginings" (9). Under this paradigm, dis/ability is not constrained by the material or discursive models that proceeded her, but rather is a political object with enough interpretive flexibility as to encourage coalition-building. The "relational" aspect of this frame also allows for individual lived experiences to shape interpretations of disability; such an approach counters the social model's condemnation of individual desire for medical intervention.

Siebers' conception of **complex embodiment** ameliorates the tensions between the social and medical models of disability by recognizing the social and political dimensions of disability as real and significant, while also not dismissing the biological, physiological, and material impacts of dis/ability. "These last disabilities," he writes of chronic pain, aging, and other health effects, "are neither less significant than disability caused by the environment nor to be considered defects or deviations merely because they are resistant to change. Rather, they belong to the spectrum of human variation, conceived both as variability between individuals and as variability within an individual's lifecycle, and they need to be considered in tandem with social forces affecting disability" (284).

Under this paradigm, disability might be understood as a material-discursive phenomenon, in line with critical feminist STS thought that recognizes the co-constitutive nature of the social and material. To feminist STS scholar Karen Barad, "the primary ontological unites are not "things," but phenomena – dynamic topological reconfigurings/entanglements/relationalities/(re)articulations. And the primary semantic units are not "words" but material-discursive practices through which boundaries are constituted," leading to a "posthuman performativity" (818). In other words, materiality is not merely *determined* by discursive practice or vice versa, but the two are co-constituted. Material phenomena rearticulate and reconfigure discursive categories, or boundaries, while discursive practices reconfigure material realities. This "posthumanist account" extends Siebers' call for attention to the entanglement of the social and material by "call[ing] into question the givenness of the differential categories… [and] examining the practices through which these differential boundaries are stabilized and destabilized" (808). Such work becomes particularly useful when analyzing biomedical technologies, which are designed and deployed in a context in which the "givenness" of dis/ability as both a materially real and socially undesirable phenomenon is assumed. Posthuman performativity does not simply target the human as its unit of analysis, but the complex material-discursive entanglements in which it is situated, including scientific instruments, which Barad argues play a crucial role in the "dynamic (re)configurings of the world" (816). This approach inflects the current study in recognizing the social context also includes the material artifacts that detect, prevent, and intervene on disability.

The Dimensions of Responsibility

To discuss responsibility for naming and managing disability requires first acknowledging the social conditions which determine disability as a phenomenon in need of management. Ableism represents the political, material, and social consequences of categorizing dis/ability as an individual, medicalized, and curable phenomenon. Further, for the purposes of this dissertation, ableism and disablism are an integral part of the complex context in which individuals choose to pursue biomedical interventions. It is impossible to consider medical devices and the pressures to use them without considering how and when a bodymind is considered deviant and in need of intervention.

Dis/ability only exists in relation to its counterpart, ability. The manifestation of these poles necessarily also produces a preference for one, in this case, ability. Siebers dubs this preference the "ideology of ability [which] is at its simplest the preference for able-bodiedness. At its most radical, it defines the baseline by which humanness is determined, setting the measure of body and mind that gives or denies human status to individual persons" (273). Other scholars, and more recently, activists and advocates, refer to this preference as ableism. According to Gregor Wolbring (2010), ableism is characterized by "a favoritism for certain abilities that are projected as essential by individuals, households, communities, groups, sectors, regions, countries, and cultures, while labeling real or perceived deviation from or lack of these essential abilities as a diminished state of being often leading to the accompanying disablism, the discriminatory, oppressive, or abusive behavior of oneself by others arising from the belief that people without these "essential" abilities are inferior" (2).

An alternative way to examine the looming pressure of idealized bodyminds is through what Robert McRuer (2006) dubs "compulsory able-bodiedness." Inspired by Adrienne Rich's 1980 essay on compulsory heterosexuality, McRuer articulates a culture in which normative (ideal) bodies are naturalized as both an expected default and the moral obligation. In such a system, one is confronted constantly with the seeming *choice* to augment and intervene on one's non-normative bodymind, but McRuer argues there is in reality, no choice *but* to intervene. Under a regime of compulsory able-bodiedness, "able-bodied identities, able-bodied perspectives are preferable and what we all, collectively, are aiming for. A system of compulsory able-bodiedness repeatedly demands that people with disabilities embody for others an affirmative answer to the unspoken question. Yes, but in the end, wouldn't you rather be more like me?" (93). Compulsory able-bodiedness, therefore, is tightly coupled with "questions of cure, loss, and disavowal." (Kafer, 2013, 80).

Technological Progress as Moral Imperative

Linked to the moral imperative to contain non-normative unruly bodyminds is the overwhelming rhetoric of technological progress. Technological progress, at least in the American context, has become a core social value, synonymous with social betterment, regardless of the uneven distribution of that "betterment" (Smith, 1994). This discourse is particularly forceful when applied to biotechnological intervention on non-normative bodyminds; as Sarah Franklin (1997) writes in reference to infertility technologies, "there is no sense of choice or options within this depiction of scientific progress: it is as eventually inevitable as it is morally imperative to proceed forward" (330). Anthropologist Marilyn Strathern (1992) argues that the introduction of new technologies, especially medical technologies, transforms the choices and consequences for everyone, including people who refuse to adopt them. Melinda Hall (2016), writing a critique of transhumanist ideology,

similarly writes of the moral imperative to modify (and ideally escape) imperfect embodiment through technological intervention. To transhumanists, embodiment is inherently risky because able-bodiedness is ephemeral, with disability serving as a stark reminder of that risk, and not pursuing biomedical technologies is an "immoral refusal to exercise autonomy" (122). It is useful to look toward transhumanist and enhancement technologies and ideologies to understand the sociological implications of biomedical technologies in part because the line between enhancement and therapy is blurred and fluid (e.g. see Sadowski, 2014 on exoskeletons). Hall (2016) ultimately argues the distinction may be irrelevant in the context of disability because, as transhumanist ideology dictates, "to rid the world of disability *is* to enhance the human" (122). The availability (or expected future availability) of enhancement technologies also creates conditions inside medical clinics that are deeply informed by hope. According to Moreira and Palladino (2005), informed consent and patient autonomy become difficult to manage due to unreasonably high expectations among parents of patients due to exposure to "regimes of hope." Hope mobilizes innovation projects, even when visions of the future are "modest, uncertain, and ambivalent" (Gardner, Samuel, Williams, 2015). With hope comes obligation to act, because precluding hopeful futures seems morally unacceptable. Inaction becomes synonymous with irresponsibility, while at the same time personal choice and the accumulation of knowledge becomes fetishized (Hall, 2016). Under this regime, dis/ability becomes intolerable, leading to a eugenic logic Garland-Thomson (2012) suggests "tells us that our world would be a better place if disability could be eliminated" (342).

Citizenship

As adoption of technological interventions becomes a moral imperative, personal decisions about one's health and body become decisions for the public

good. Health, illness, and disability are increasingly becoming wound up in processes and expectations of good citizenship. For some theorists (Rose, 2007; Petryna 2002), "biological citizenship" is reflective of the human right to health and well-being. For others, the rights inherent in biological citizenship are less important than the responsibilities one must meet in order to obtain it.

For example, the increasing availability of genetic technologies – screening tools, diagnostics, and therapeutic tools— has co-produced what Bumiller (2009) refers to as a "conception of genetic normalcy" that creates pressure to perform as a responsible "genetic citizen." Her work centers exclusively on the geneticization of autism which, despite not having a definitive genetic marker, produces conditions under which pregnancies and children are scrutinized for their normalcy. Bumiller worries this creates a "backdoor to eugenics" couched in a rhetoric of personal autonomy. Further, resonating with biomedicalization's preoccupation with health and wellness (as opposed to illness), genetic citizenship is focused less on the reduction of suffering than the optimization of health. Rather than have access to manage disease and disability as desired, individuals are expected to approximate an able-bodied/able-minded ideal. "The concurrent forces of life optimization…and demands for personal responsibility" create a system in which a person's worthiness is dictated by their ability, genetic citizenship, and adherence to social norms (890). Berube (2010) provides a similar commentary on the pressures of good citizenship faced by parents of children (or prospective children) with disabilities, arguing that families "must be protected from state coercion yet supported by the state's apparatus of social welfare" (99).

Devlin and Pothier (2006) engage more substantially with a disability politics that address the power imbalances non-normative bodyminds are often subject to in

public life. They coin the term "dis-citizen" as a means to signify the results of a "system of deep structural economic, social, political, and cultural inequality in which persons with disabilities experience unequal citizenship" (1). Such a regime is structured around the assumption that a full citizen must be a *fully productive* citizen, where productivity is both legible by and in service to the state. They argue ultimately that such a framework can never be compatible with full inclusion, as "efficiency and productivity are irretrievably ableist discourses that can only condemn(some) persons with disabilities to a presumptive inferior status. An enabling citizenship needs to be unshackled from the ideology of productivity and efficiency" (18). Goodley (2014) writes extensively about the politics of "(crip) cynicism" and mobilization as resisting "neoliberal-able citizenship," calling for further action to examine "the politics of dis/ability as the space for challenging and contesting neoliberal discourse that threatens to get under our skin, colonise our minds and shape political resistance," a call that in some ways is taken up in this dissertation through the exploration of embodied expertise and alternative knowledge production (169).

Goodley (2014) nuances the relationship between able-bodiedness and access to full civic, social, and political participation. He suggests there are a certain suite of characteristics for the production of a valued citizen under an ableist (or in his estimation, a neoliberal-ableist) paradigm. Such a citizen is "cognitively, socially and emotionally able and competent. Biologically and psychologically stable, genetically and hormonally sound and ontologically responsible. Hearing, mobile, seeing, walking. Normal: sane, autonomous, self-sufficient, self-governing, reasonable, law-abiding and economically viable. White, heterosexual, male, adult, breeder, living in towns, global citizen of WENA (Western Europe, North America)" (23). Bailey and

Mobley (2018) further suggest that ableism and disablism is differentially applied: "Much of the Black experience is shaped by an understanding of Black bodies as a productive labor force, leaving little room for an identity-based approach to disability. Figurations of Blackness as hyper able and yet fundamentally 'crippled' by race have been used to produce Black people as ineligible or unsound for citizenship" (7). These conceptions of ableism extend it beyond an abstract preference for ability by elucidating how this preference demands social, political, and individual responsibility under an ableist paradigm. Valued citizens must be "ontologically responsible," meaning responsible for the management of their non-normative bodyminds, often through biomedical intervention.

Responsibility in Technological Interaction

As technology becomes increasingly integrated into medical care, the interplay between humans and technologies becomes increasingly important. Questions of who or what is accountable for the consequences of technological engagement come starkly to the fore as human-technological interactions increase. As Lucy Suchman (2007) writes, the categories of "human" and "machine" are increasingly blurred and unstable as we engage with technology, potentially creating crises of accountability: "responsibility on this view is met neither through control nor abdication but in ongoing practical, critical, and generative acts of engagement." (286). Technologically-enabled medicine, as Clarke and colleagues assert, transform bodies and identities through its contingencies. For example, Charis Thompson, in her work on assistive reproductive technologies (ARTs) shows this in practice, describing a functional zone of compatibility wherein a person objectifies and atomizes themselves in order to become compatible with instruments and processes. Human experiences become standardized and reduced to a narrow set of clinically-defined conditions in order to qualify for technological intervention. This reduction

and reclassification occurs in order to become legible not just to systems of medical authority, but to the technologies themselves. As Gardner (2013) writes on deep brain stimulation, "The development and stabilisation of DBS therapies were contingent upon the co-development and diffusion of standardised methods of rendering the affected body" (723). Other categories of human also come into being through engagement with medical technology. Increased pressure for specific, measurable, and actionable disease definitions (Aronowitz, 2001) has contributed to the development of biomedical technologies that can attribute mental and cognitive functioning to specific, detectable biological reactions. The intensive, focused, and as of this writing, unsuccessful, research to identify a single gene or set of genetic conditions that cause autism is one example of the increased pressure to attribute all human variation to discrete biological characteristics. Quantification and direct observation represent attempts to legitimize a certain type of medical authority over certain conditions and characteristics. Social classifications become increasingly entangled in medical classifications, impacting the lived experience of disabled individuals in profound ways regardless of their individual engagement with technology and healthcare. Individual biological and physiological characteristics are bundled together and gain signatory power; medical authorities claim sole credibility to identify syndromes, disabilities, and chronic illness, thus contributing to the social construction of disability as medical pathology.

Technology can and does play an active role in the reframing process. In order to fully grasp how biomedical technologies contribute to and are informed by the medicalization of disability, it is necessary to interrogate their social and political dimensions. Turning to Pinch and Bijker (1984), the "sociocultural and political situation of a social group shape its norms and values, which in turn influence the

meaning given to an artifact" (46). Pinch and Bijker (1984) also emphasize that their perspective, dubbed the Social Construction of Technology (SCOT) takes a symmetrical approach to analyzing technology design and uptake – essentially, such a perspective allows one to circumvent any normative assumptions about what should or shouldn't be, but rather examine how certain designs and technologies became favored over others. Such an approach is particularly useful when examining technologies associated with disability. Rather than assuming diagnostic and treatment technologies are developed to fill an obvious need in identifying and ameliorating disability, one could examine the social and political structures that led to the increasing medicalization of disability and the role that these technologies have played in shaping and perpetuating that particular construction of disability. Further, drawing from SCOT, one could untangle questions around shifting and competing meanings derived from biomedical technologies. The ability of an artifact to be read and interpreted in multiple ways is known as interpretive flexibility (Pinch & Bijker, 1984). In the example of disability, diagnostic tools contribute to pathologizing disability as a medical category both detectable and manageable through medical intervention. The social conditions that medicalize disability also contribute to the construction and use of certain kinds of technologies that reinforce such thinking. As Ilana Löwy (2017) asserts, "the complex nexus of the relationship between academic science and private industry…made possible the incorporation of ideals of individual choice, risk management and responsible parenthood into circulating, marketable items" (186). In a social context that favors the medicalization of disability, diagnostic technologies may be favored over technologies that address socio-economic disparities. Through these processes also emerge "patients-in-waiting," or undiagnosed/undiagnosable individuals who exist in a "liminal state between normalcy and pathology…characterized by a lengthy process

of medical surveillance" (Timmersman & Buchinder, 413). Pathologization (or the expectation of eventual pathologization, in the case of patients-in-waiting), which is often contingent on biomedical technology, authorizes medical social control over non-normative bodyminds.

Autonomy and Informed Consent

In the United States, the right for an individual to independently and individually determine when, where, and how to receive medical care has been the standard of practice since the professionalization of medicine. Legally, the 1914 case *Schloendorff v Society of New York Hospital* set a precedent declaring that medical consent was a civil right, thus tying medical care to citizenship. As the opinion for the case states, "every human being of adult years and sound mind has the right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault" (Para 3). Such a declaration reinforced both the individual responsibility and seeming autonomy that characterize contemporary medicine.

Key to issues of informed consent in contemporary biomedicine is communication. Poor communication is the root of many negligence lawsuits in the United States, and often communication about treatment fails to disclose that non-intervention is an option at all (Raab, 2004). One well-documented instance of this failure to articulate all possibilities for (non)intervention is prenatal genetic testing. As Patterson and Satz (2002) write, "increasingly, obstetricians do not 'offer' pregnant women prenatal testing…women often undergo such testing without becoming fully aware that they may refuse to do so" (123). Further, the legal and political basis for informed consent is grounded in the concept of the "reasonable actor" capable of neutral, unemotional, and detached decision-making (Raab, 2004).

However, such an actor does not exist. What information is relevant for decision-making, what factors inform how and when a person pursues intervention, what framework one uses to decide; these factors are highly individualized and contextual and may be "reasonable only to himself or herself" (ibid, 227). Additionally, as discussed above, choice is constrained by the expectation of responsible citizenship, and the agency and autonomy one is allowed is deeply contingent on factors such as race, gender, class and ability (Franklin 1997; Rapp 1999).

In the case of prenatal genetic testing and screening, there are additional concerns regarding consent. Despite the ostensible optionality of screening and testing, the routinization of these screening and testing strategies, alongside the perceived power imbalance between expert clinicians and prospective parents may constitute a form of coercion (Thomas, 2017; Tsouroufli, 2011). Further, the settled nature of this case, in which PGS/PGD is integrated as a routine element of obstetric care, raises further questions about informed autonomous decision-making. Prospective parents are expected to make decisions based on partial, highly medicalized information (Rapp, 2000), with little institutional support (Getz and Kirkengen, 2003) and increasing pressure to pursue technological intervention (Franklin, 1997). Overall, all three cases raise both philosophical and practical concerns about informed consent and autonomy in the context of biomedical technologies.

Authority

Authority is in many ways dictated by who has the power to create knowledge about a given topic, idea, or group of people. In this study, authority over disability is largely determined by who defines disability and mandates "appropriate" responses to it. Knowledge, however, is not simply statements of truth, but a

dynamically constructed, fluid phenomenon shaped by social, political, and material processes. The social and political conditions that privilege one type of knowledge construction of claim are produced by and produce material infrastructures that subjugate other ways of knowing and being. This section will provide an overview of the literature on the construction of credible knowledge claims, epistemic injustice, the invalidation of disabled knowledge claims, and recent empirical work on autonomy and informed consent in biomedical settings.

Credibility Construction

Credibility is the process by which knowledge (including scientific and medical) *becomes knowledge.* As Shapin (1995) bluntly states on the subject of scientific authority, "if you subtract credibility, there is no product left" (258). Scientific credibility has several consistent hallmarks. The first, examined by Shapin (1995), delineates between validity and credibility, recognizing that the perceived truth of a claim by an audience can frequently have less to do with the techniques used to validate it than the speaker's position in a "highly specialized, and very bounded, communit[y]," which grants a "monopoly of ownership" over knowledge production. (Shapin, 1995, 266). Professional credentials, which signify membership in strictly-regulated communities, serve as "the simplest and easiest route to establishing and maintaining credibility" in scientific communities, particularly in biomedical and health-related professions (Epstein, 1996, p. 334). Sheila Jasanoff (1987) similarly observes the position of scientists as authoritative and objective observers as relevant to the perceived credibility of their claims. She further asserts that any threat to their elevated image – such as the exposure of uncertainties and bias in the midst of policy – is swiftly divorced from the idea of good, rigorous, or objective science. In addition to membership in certain, tightly-bound communities, credibility is also linked to the claim-maker's position *relative* to the audience. Shapin

(1995) identifies several vectors of credibility, including "public credibility," which is contingent upon the inaccessibility of the content of a claim to the lay public. Obscuring or making proprietary the methods behind scientific claims and using specialized language when communicating about such claims are two approaches used to maintain credibility in this arrangement.

The use of jargon when communicating about scientific claims, represents the second hallmark consistent across the establishment of traditional scientific credibility. One key feature that granted them access was learning the jargon of biomedicine and research protocol. Scientific language – or language that appears scientific – confers with it a sense of objectivity. Objectivity, in turn, implies unprejudiced authority. Such authority becomes tarnished to many audiences if emotion or politics appear to influence the claim (Jasanoff, 1987). Claims made using jargon may therefore be received in a manner that emotional claims, in which objectivity is perceived as jeopardized, are not. Cohn (1987) relates language as equally essential in establishing credibility between experts. The absence of key jargon is, in her observations, perceived as incompetence among experts, regardless of level of knowledge. Attempted engagement with decision-making processes by non-expert outsiders who are not well-versed in the jargon of the field is consequently difficult.

The development of epistemic authority in medicine came in part through the conditions that enabled medicalization to be possible. Conrad (1992) points to secularization in the 20th century as creating an authority vacuum that was eventually filled through the professionalization of medical practitioners. With the emergence of medical epistemic authority comes the simultaneous suppression of other ways of knowing and being.

Other factors beyond the establishment of medical authority may contribute to a consistent sublimation of disabled knowledge. Miranda Fricker's concept of "epistemic injustice" is a useful lens through which to understand these experiences. Epistemic injustice, to Fricker, refers to processes by which "a wrong [is] done to someone specifically in their capacity as a knower" (2009, 1). In some cases, this injustice is done through prejudice on the part of the hearer that undermines the credibility of the knower, a phenomenon Fricker dubs "testimonial injustice." For example, people with cerebral palsy often experience this type of injustice due to a prejudicial assumption that their non-normative speech patterns signal cognitive disability and that people with cognitive disabilities are incapable of thought. A second type of epistemic injustice, what Fricker dubs "hermeneutical injustice," occurs "when a gap in collective interpretive resources puts someone at an unfair disadvantage when it comes to making sense of their social experiences" (1). An example of this type of injustice, particularly relevant to disability studies, is that people with non-normative bodyminds are often not believed when they assert that they do not want intervention to achieve ideal bodyminds due to pervasive compulsory able-bodiedness.

Invalidating Embodiment in Disability

The social conditions that medicalize disability contribute to and are informed by the construction and use of certain kinds of technologies that reinforce such thinking. For example, in a social context that favors the medicalization of disability, diagnostic technologies may be favored over technologies that address socio-economic disparities among individuals with disabilities. Furthermore, the medicalization of certain phenomena results in the favoring of certain kinds of authority. As discussed above, medical authority takes precedence over embodied and experiential expertise, so disabled individuals lose credibility to speak on their

own bodyminds. With this loss of credibility comes also a loss of agency to choose for oneself in social and medical interactions. Feminist critical scholar Kristina Gupta (2020) writes "Medicine increases our reliance on medical experts and undermines our privileged relationships to our own bodies, while displacing alternative ways of understanding mind-body-distress" (33). Social and medical categorization also play a role in the epistemic invalidation of disabled bodyminds because "each standard and each category valorizes some point of view and silences another" (Bowker and Star, 1999,5). Additionally, being categorized as having a disability, particularly a disability that can only be managed rather than cured through biomedical intervention, results in social stigmatization. Individuals experience "othering" at the hands of people who have not been classified as having a disability; Wendell (1989) suggests this stigmatization results from the inability of people with bodies approximating the norm to identify with those "who cannot be 'repaired' by medical intervention" (110). Thus, is the power of medicalization: a person with certain characteristics that were at one point in time not considered under the jurisdiction of medical professionals experiences social stigmatization when said characteristics are not mutable through medical intervention.

Situated and Embodied Knowledge as Sources of Authority

The way in which the problem is framed naturally dictates what variables are salient, whose knowledge has influence, and the ultimate action taken. Scientific and medical framing has historically disenfranchised and discounted the knowledge produced by individuals without access to the means to establish credibility, such as credentials, position, and knowledge of jargon. Situating a subject within scientific purview may encourage the perception that actions taken around it are objective, thus masking the value-judgements inherent in subsequent policy and practice outcomes (Jasanoff, 1987).

Drawing from feminist epistemologies of knowledge, this dissertation is grounded in an understanding that each situated and contextual experience produces unique and valid knowledge. Such an assumption is in line with sociological examinations of scientific knowledge as well, which assert that "there is nothing epistemologically special about the nature of scientific knowledge. It is merely on in a whole series of knowledge cultures" (Pinch and Bijker, 1984, 19). Further, interrogating the perspectives, knowledge practices, and expertise of users, patients, and other stakeholders with limited power is imperative for understanding the nature of agency, accountability, and the construction of disability under a biomedicalized regime. As Bowker and Star (1999) write, "if social sciences do not understand people's definition of a situation, they do not understand it at all" (289). This section will review several feminist approaches to contextual knowledge production, as well as literature arguing for the special place of disabled knowledge.

Feminist Epistemologies: Standpoint and Situated Knowledges

Standpoint theory emerged in the 1970s as a radically subjective response to positivist and empiricist scholarship. Its proponents suggested it had far-flung implications, acting as "a philosophy of knowledge, a philosophy of science, a sociology of knowledge, and a proposed research method" (Harding, 1995, 345). With its foundations in Marxist literature claiming that subjugated people can access knowledge not available to those in privileged positions, standpoint theory argues that knowledge is intrinsically linked to social position. Nancy Hartsock (1983) provided one of the first feminist critiques of positivism and asserted. As Susan Hekman (1997) writes of Harstock, she argues through Marxist theory, that women's subjugated position "provides a justification for the truth claims of feminism while also providing it with a method to analyze its reality" (Hekman, 1997, 341). Standpoint, in some of its iterations, not only links knowledge to social positions, but

suggests that subjugated group, through their positions on the margins, can both ask better questions and interrogate social structures more effectively. Harding (1991) concludes that research should thus always begin with marginalized perspectives. Harding's version of standpoint theory (which she is given credit in naming) explicitly challenges objective and positivist scientific frameworks as obscuring, perpetuating, and proliferating bias (particularly androcentrism). This assertion is particularly relevant in the current study, which sets aside medical and scientific research in favor of embodied experiences. Feminist scholars soon iterated on standpoint theory, with Dorothy Smith (1987) producing a sociological method rooted in standpoint epistemology and Patricia Hill Collins (1986) subjecting standpoint to intersectional scrutiny through the development of a black feminist standpoint. In the intervening years since its articulation, standpoint theory has both been lauded as central to feminist theory and critiqued for its proximity to Marxist theory, failure to attend to difference, and opposition to postmodern and poststructuralist thought (Hekman, 1997). Regardless, standpoint theory provides an important feminist intervention on the nature of knowledge and knowledge production (ibid).

Haraway (1988)'s approach to contextual knowledge production, which she dubs "situated knowledge," attempts to untangle the idea of "objectivity" without slipping into what she considers an unproductive feminist rhetoric of "us" (oppressed women) and "them" (masculine scientists). She seeks to understand reality without either endorsing a false omniscient objectivity or pure constructionism – essentially, Haraway seeks a feminist objectivity. She endorses a partial objectivity where the partiality (positioning) of the claim is its condition for rationality. By doing this, Haraway suggests universal knowledge claims – or "views from nowhere" – are in

themselves irrational. She argues against both unlocatable knowledge claims and romanticizing the vantage point of subjugated people (in direct opposition to Harding's standpoint). She concludes by suggesting that feminist science is about appropriately positioning objectivity and joining together partial views into a "collective subject position."

Sandra Harding (1995) later articulated a variation on standpoint epistemology meant to intervene directly on scientific research and process as well as respond to critiques of relativism, an epistemological approach she termed "strong objectivity" (1995). Drawing from science studies literature, she argues that science is intrinsically shaped by the politics of "dominant institutions structures, priorities, research strategies, technologies, and languages of the sciences," which serves to produce the façade of objectivity and neutrality in authoritarian science (335). Sexism, racism, colonialism, classism (and I would argue, ableism) are baked into the traditional scientific endeavor, and depoliticized through claims of objectivity. She claims that "in hierarchically organized societies, the daily activities of the ruling groups tend to set distinctive limits on their thought, limits that are not created by the activities of subjugated groups," and more saliently, that the work of the natural and social sciences is a form of ruling in contemporary society (341). Harding ultimately argues, similar to Haraway, that recognizing one's positionality allows for more authentic truth claims that supposed neutral scientific claims that do not acknowledge the social, political, and individual context in which they are enmeshed.

Embodied Knowledge and Disabled Knowledge Claims

Shogo Tanaka (2011) writes that embodied knowledge was first articulated by French philosopher Maurice Merleau-Ponty (1945) as knowledge that is "not distinctly explicit, conscious, mentally representative or articulated. It is, however,

well known by the body and through the body, when it is practiced" (149). Embodied knowledge was and remains a unique approach to knowledge production in that it does not separate mind from body, rather recognizing the embeddedness of the subject in the "lifeworld." While this dissertation does not take up Merleau-Ponty's framework explicitly, it does draw on the concept that bodyminds embedded in the material world have unique knowledge that cannot be separated from that bodily interaction with the world. Merleau-Ponty argues that consciousness is inherently intersubjective, acknowledging the relational and contextual aspects of consciousness. While subsequently many feminist scholars have critiqued Merleau-Ponty's work as masculinist, more recent engagement from feminist philosophy has found his understandings of phenomenology useful in the pursuit of scholarship on embodiment and subjectivity (Olkowski and Weiss, 2006).

Disability and science studies scholars have both, either directly or indirectly, suggested that the positionality of disabled, ill, or otherwise medically-subjugated bodyminds also allows access to knowledge not available to other people. Siebers (2008) calls out the value of a disabled standpoint when presenting his disability theory, writing that he is motivated by "the contention that oppressed social locations create identities and perspectives, embodiments and feelings, histories and experiences that stand outside of and offer valuable knowledge about the powerful ideologies that seem to enclose us" (273). He continues, "While all identities contain social knowledge, mainstream identities are less critical, though not less effective for being so, because they are normative. Minority identities acquire the ability to make epistemological claims about the society in which they hold liminal positions, owing precisely to their liminality."

The most prominent of these theories on disabled knowledge claims is Rosemarie Garland-Thomson's (2011) "misfit theory," which suggests disabled people have more knowledge about the material-discursive world *through* the mismatch between their bodyminds and social/physical reality. Her misfit theory both acknowledges disability as a social phenomenon and accounts for embodied experiences such as pain. She makes three broad arguments, namely 1) misfitting is contingent and particular – there is no generic disabled body that can dematerialize under the right conditions, 2) misfitting clarifies the feminist critique of universal vulnerability/dependence, and 3) misfitting confers agency and value by emphasizing resourcefulness, adaptability and subjugated knowledge as results of misfitting. A misfit importantly refers not to inherent wrongness with either body or environment, but with their juxtaposition spatially and temporally. Disability, then, is a "way of being in an environment, as a material arrangement" (594). Such an approach ameliorates the tensions bet ween able and disabled by recognizing both as contingent, and subsequently valuing what emerges from misfits. Difference becomes relational, not essential. Further, misfitting becomes an epistemic resource that produces generative possibilities for alternative ways of knowing and being. As Goodley (2014) writes, "being disabled is not a tragedy but a possibility, an affirmation, a queer or crip space for rethinking what it means to be human, to live a quality life, and a life with quality" (160).

Hamraie and Fritsch (2019) invoke misfitting in their "Crip Technoscience Manifesto," where they operate under the base assumption that "disabled people are experts and designers of everyday life," rather than passive subjects that have material and social reality enacted on them (1). They adhere to an understanding of disability as a site of cultural and knowledge formations:

Unlike typical approaches to disability that objectify disabled people and situate expertise in medical professionals and non-disabled designers or engineers, crip technoscience posits that disabled people are active participants in the design of everyday life. Not only do disabled people make access in our everyday lives in ways that do not get recognized as design, but the lived experience of disability, and the shared experience of disability community creates specific expertise and knowledge that informs technoscientific practice" (7).

The unique knowledge that can be leveraged by disabled people has been operationalized in various forms of technological intervention, often through off-label, hacked, or uses otherwise not endorsed by medical and political authorities. This is in direct response and opposition to what Hamraie and Fritsch call "disability technoscience," which is deployed *against* disabled bodyminds as a means to cure, intervene, or otherwise condemn. As Michelle Yergeau writes in a piece condemning the ableistic paradigms that drive "hackathons," "Disability hacktivism is only ethical if it is led by people with disabilities. We are the movers, not the moved-upon. We are the ones who should be hacking spaces and oppressive social systems; we should *not* have our bodies and our brains hacked upon by non-disabled people." (2014, para 27). Invoking Yergeau, "criptastic hacking" Hamraie and Fritsch (2019) write, "highlights crip technoscience as a field of relations, knowledges, and practices that enables the flourishing of crip ways of producing and engaging the material world" (4).

According to Epstein (1996), however, chronically ill and disabled people may inadvertently exchange their unique standpoint in order to obtain credibility from medical and scientific authority. His analysis centers on HIV/AIDS activists in the United States who sought to transform drug trial practices and expand access to treatments as they moved through the red-tape of FDA approval. The activists soon

evolved into "activist-experts," leveraging their innate "moral credibility" with newly found scientific credibility as they adopted the language of scientific reasoning. While they sought access and input, they did not seek to trouble the defined boundaries of scientific authority. Their shared motivation with medical experts perhaps contributes to the convergence of their identities. Activists and medical experts viewed treatment and cure to be the ultimate end goal, with ethical care, including non-discriminatory treatment and immediate access to healthcare for all serving as motivating factors for lay activists. Most importantly, the HIV/AIDS crisis was distinctly situated as a scientific problem in need of a scientific solution by both biomedical professionals and lay activists. Permission to contribute to the development of a cure rested in the establishment of a scientifically-credible identity; to impact the system, the activists had to buy in to its rules and structures. "Ironically," Epstein writes, "insofar as activists started thinking like scientists and not like patients, the ground for their unique contributions to the sciences of clinical trials may be in jeopardy of erosion" (342). This trade-off represents one of several double binds faced by individuals in pursuit of agency over their pathologized bodyminds.

(Bio)Medicalization

As discussed throughout this chapter, the sociological phenomenon of medicalization is deeply implicated in the contemporary experience of disability. Despite the proliferation of competing knowledge claims and problem-frames, the medical model of disability is currently the dominant paradigm across legal, social, political, and healthcare systems (Areheart, 2008). Out of the sociological literature emerges a related phenomenon that is directly implicated in this research, medicalization. Medicalization, and its descendant, biomedicalization, contribute to the emergence of an expert class, medicine acting as a form of social control, the

individualization of social issues, and the depoliticization of non-normative bodyminds and behaviors (Conrad, in Caplan et al 2004).

Medicalization

Medicalization, as understood by medical sociologist Peter Conrad (2007), refers to the creep of medical jurisdiction into many aspects of human life. It is, most simply, the transformation of a human condition from a phenomenon outside of medicine to one inside it. The process of medicalization, according to Conrad, is largely definitional. To become medicalized, "a problem is defined in medical terms, described using medical language, understood through the adoption of a medical framework, or "treated" with a medical intervention" (Conrad, 2007, 6). This subsuming of human phenomenon into the powerful category of medicine serves to decontextualize and generalize personal and social conditions, "misrecognizing and masking the effects of social practices and hierarchy" (Carrier, 1983, 952). For example, as congenital and developmental disability become increasing understood solely through their genetic markers, it constrains possibilities for intervention to include only genetic diagnosis and termination before birth (Scully, 2008).

Rosemarie Garland-Thomson (2012) asserts that "disability occurs when the shape and function of bodies come into conflict with the shape and stuff of the world" (p. 342). Technologies that intervene on the biological bodymind signify dis/ability as individual and are often provided to refute claims such as Garland-Thomson's, obscuring social systems that devalue and discriminate against non-normative bodies. If disability is located within the individual, social institutions are not responsible for accommodating human variance. Rather, an individual becomes responsible for seeking "treatment" and "management" through biomedical intervention.

Löwy (2017) suggests that the "rise of prenatal diagnosis has led to an increased individualization of medicine and a greater focus on personalized solutions rather than on the extension of social responsibility for the sick" (73). Jackie Leach Scully (2008) writes, "genetics is wrongly used to conflate diverse experience of anomalous embodiment within an oversimplified concept of genetic abnormality" (798). Medicalization therefore pathologizes non-normativity, thus establishing the conditions for Kafer's "curative imaginary," driven by a eugenic logic toward normalcy.

Concepts that were once defined in spaces outside of medical jurisdiction, including educational, social, and private spheres, experience a reframing and reshaping through social arrangements until they restabilize as medical conditions. In the example of disability, diagnostic tools and biomedical technological interventions contribute to pathologizing disability as a medical category both detectable and manageable through medical intervention. Furthermore, the medicalization of disability occludes the social arrangements that contribute to impairment. Wendell (1989), among others, subscribes to the ideology that disability manifests itself in part when social arrangements are incompatible with non-normative bodies, rather than when a certain number of biological characteristics are simultaneously present. Technologies that provide biological data that can be interpreted as signifying disability or intervene on biological characteristics that can be categorized as disability are often provided to refute such claims and justify social systems which devalue and discriminate against non-normative bodies. If disability is located within the individual, social institutions are not responsible for accommodating human variance. Rather, an individual becomes responsible for seeking treatment and management through biomedical intervention.

Biomedicalization

Out of the expanding medicalization of life has emerged what Clarke and colleagues (2010) refer to as biomedicalization, "the increasingly complex, multisited processes of medicalization that today are being both extended and reconstituted through the emergent social forms and practices of a highly and increasingly technoscientific biomedicine" (47). This transformation, which Clarke and colleagues pinpoint to the mid-1980s, is characterized by radical changes to the organization, practice, and meaning in biomedicine. The technoscientific component of biomedicalization is especially salient both in its transformative power and its evolution in practice. The "bio" in biomedicalization importantly flags its relationship to *biopolitics* and *biopower,* emphasizing the ways in which power is embodied through social practices – in the scholarly lineage of Foucault (1979), power here is not merely an oppressive force enacted by the state, but a generative and productive energy emerging from all social processes. Clarke and colleagues identify five key (imbricated) processes in the current era of biomedicalization in the United States:

> *"1 a new biopolitical economy of medicine, health, illness, living, and dying which forms an increasingly dense and elaborate arena in which biomedical knowledges, technologies, services, and capital are ever more co-constituted;*
>
> *2 a new and intensifying focus on health (in addition to illness, disease, and injury) on optimization and enhancement by technoscientific means, and on the elaboration of risk and surveillance at individual, niche group, and population levels;*
>
> *3 the technoscientization of biomedical practices where interventions for treatment and enhancement are progressively more reliant on sciences and*

technosciences, are conceived in those very terms, and are ever more promptly applied;

4 transformations of biomedical knowledge production, information management, distribution, and consumption; and

5 transformations of bodies and the production of new, individual, collective, and population (or niche group) level technoscientific identities." (1-2)

Biomedicalization's attention to technological interventions is particularly important for this study, which examines the meaning and enactment of dis/ability through biomedical technology.

Medicalization as Social Control

Bowker and Star (1999) write extensively on the social and political power of medical classifications, noting "How impracticable it is to try to classify human beings, for all time, into definite categories, and how much suffering has resulted from the efforts made to do this" (210). Medical categories force fluid and evolving bodyminds and social relationships into definitive and stable categories that are themselves imbued with power to shape social, political, and ontological relationships.

As Conrad and Schneider (1985) suggests, medicalization's "greatest social control power comes from having the authority to define certain behaviors, persons, and things" (8). Social control becomes legitimized through the pathologization of certain characteristics, often through the aid of technologies that measure, quantify, and surveil the bodymind. Wendell (1996) extends this idea, suggesting biomedicine's social authority not only declares to which category certain behaviors and bodyminds belong, but what is ontologically, socially, and politically real. She further suggests that disability is met with such disgust, fear, and anger because it

signifies a failure of Western medicine's myth of control. Pitts-Taylor (2016), whose monograph attempts to intervene on dualistic interpretations of the brain, suggests that social implications of difference are used to justify governance over certain bodyminds, a process she refers to as "neurogovernance." The outsized authority of biomedicine creates a context in which "we all find ourselves increasingly inside of science, heir to its immense benefits and its ambiguous burdens" (Rapp, 2000, 185).

Winner (1986) suggests that technologies must not only be judged for "their contributions to efficiency and productivity," which in this case would consist of the management of unruly disabled bodyminds, "but also the ways in which they embody specific forms of power and authority" (19). Key to management of the neoliberal (and liberal) subject is the ability to make all individuals commensurable. Disability is, in a word, incommensurable. In other words, it is necessary to take the idiosyncratic and fit it into a category that can be understood and intervened upon. As Max Horkheimer and Theodor Adorno (1944) write of the liberal subject: "Each human being has been endowed with a self of his or her own, different from all others, so that it could all the more surely be made the same. But because that self never quite fitted the mold, enlightenment throughout the liberalistic period has always sympathized with social coercion." (9). The sameness cultivated through this process of commensurability and social coercion is inherently tangled up in what kind of able body would most benefit the market. As I and Mateo Pimentel (2018) have written elsewhere, "The relationship between 'able-bodiedness' and the market is explicit. To be able-bodied—in this context meaning possessing certain privileged physical and mental characteristics—is to be fit for profitable labor" (70).

Neoliberal Ableism

Neoliberalism, in strictly economic terms, refers to the deregulation and privatization of markets, the reduction of government spending and intervention (often in the name of austerity), and an increased presence of the private sector in social, economic, and political life. In practice, neoliberalism is characterized by a preoccupation with individual autonomy, "global inequality, economic disparity, growth of unemployment, social exclusion, environmental destruction, and cultural homogeneity." (Young, 2011, 1676). In other words, it is "capitalism's global hegemonic domination" (Goodley, 2014, 26). The relationship between a functioning neoliberal market and ideally productive and self-governing citizens produces a context in which dis/ability is subjected to scrutiny and moral judgement. Goodley's theory of neoliberal ableism suggests there are "increased expectations placed on the autonomy of self-responsible individual citizens to care, educate and govern themselves" (63). People become responsible for their own health and welfare because "the functioning neoliberal self is an able-bodied and minded one" (28). As Hall writes of the transhumanist articulation of the future, in which there is simultaneously "endless autonomy" and a very narrow understanding of what constitutes an appropriate bodymind and acceptable quality of life, "parents must be responsible choosers, and so must their children" (66). Kerr and Shakespeare (2002), when considering the social impact of genetic technologies, write that the availability of these technologies as possibilities for intervention produce a context in which "people are increasingly cast as responsible for their own health and welfare" (100). Interventions on non-normative bodyminds are individualized and privatized – such as medical interventions – but are understood as being for the public good. The

moralization and politicization of the decision to pursue biomedical interventions is tightly wound up in the societal judgement placed on dis/abled and ill bodyminds. Body management in neoliberalism, as understood by Mitchell (2014), suggests that people are held personally responsible for dis/ability and illness. Ironically, even as neoliberalism demands an able and productive citizen, Goodley argues "its rapidly expanding associated markets of the psy-industries cannot prevent the production of excessive discourses of dis/ability" (170).

Neoliberal individual responsibility extends not only to one's own bodymind, but any potential future bodyminds one might produce. Scholars have paid particular attention to the texture and pressure of accountability on prospective mothers, noting the explicitly gendered imbalance. In the context of prenatal genetic screening and diagnosis, which this dissertation will explore in detail, through the expectation of care and responsible motherhood, women have "relinquished the right not to know" genetic information (Kerr and Shakespeare, 2002, 136). Such responsibility comes into conflict with the rhetoric of autonomy and informed choice that undergirds contemporary American biomedical practice. Paul (1998) writes extensively about the tensions between individual and public health models of care, noting that they are inherently in conflict. The former concerns itself with autonomy and agency of the individual to make any choice, which the latter is concerned with the "common good" and the individual's responsibility toward it (ibid). An extreme but poignant example of this tension coming to a head is the involuntary sterilization of people with intellectual disabilities in the early and mid-20th century in the United States (Stern, 2005). These individuals often wished to bear and raise children (and some had), but the hegemonic eugenic discourse of the day argued that their autonomy needed to be restricted in order to cultivate a civilized public sphere. In

the case of present day genetic testing, while there is much written about nondirectiveness and parental autonomy at the level of the clinic, in discussion of state-funded screening and testing, "that the state expects to save money is evident in the arguments actually made to legislatures, which are typically framed in cost-benefit terms" (Paul, 1998, 149).

Rayna Rapp (1999), in *Testing Women, Testing the Fetus*, articulates the double weight placed on women of child-bearing age, who are both scrutinized and surveilled while simultaneously singularly shouldered with the burden of choice: women are "culturally positioned to think about their reproductive capacities, desires and decisions as a private dimension of public life" (307). Women are forced into the role of a "moral pioneer," deciding what children are eligible to enter their community *because women are held almost solely responsible for that child's quality of life.* In other words, the introduction of these new technologies creates new responsibilities that women are expected to navigate in a way that satisfies both their private and public responsibilities. They become enmeshed in a technoscientific apparatus with profound reproductive consequences. Rapp concludes by asserting that there is a need to interrogate the social alongside the biomedical, noting that "women are both constrained and empowered through technologies like amniocentesis to serve as our contemporary moral pioneers. At once held accountable at the individual level for a cascade of broadly social factors which shape the health outcome of each pregnancy, and individually empowered to decide whether and when there are limits on voluntary parenthood, women offered an amniocentesis are also philosophers and gatekeepers of the limits of who may join our current communities" (317-18). Alexandra Minna Stern (2005) similarly concludes that women of child-bearing age are caught in a medical and moral dilemma in which they are "pulled betwixt and between the seeming autonomy of

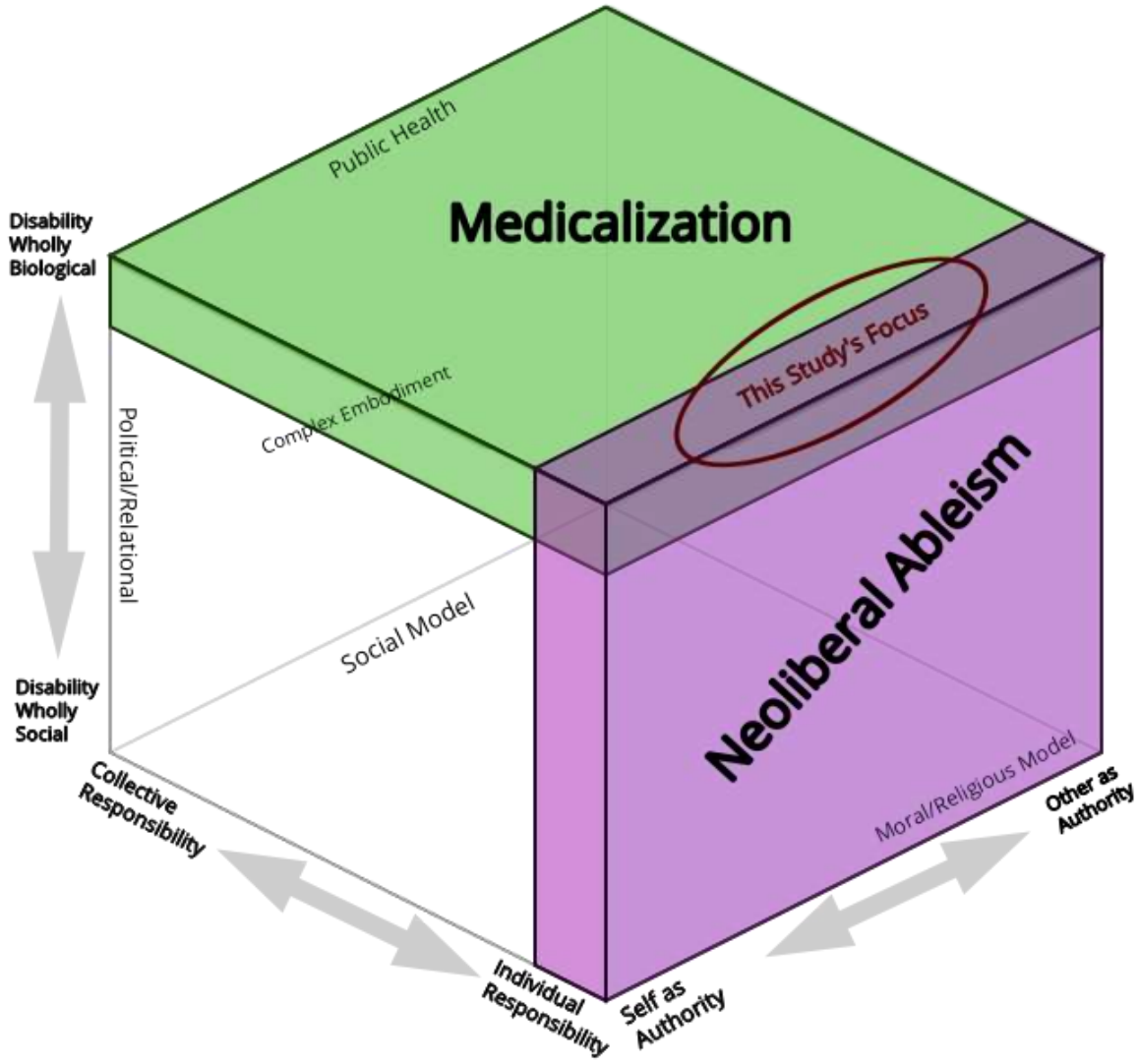
choice, diminishing reproductive control, and the burden of receiving consequential medical and genetic knowledge" (215). This example is one of many explicating the tense relationship between individual medical intervention and public good.

Conclusion

Taking into account the construction of disability, responsibility, and authority, it is at the intersection of medicalization and neoliberal ableism that I situate the current study.

Figure 2

Study Focus



I am especially concerned with tensions between the authority of self and other as expert in highly medicalized spaces in which disability is presumed biological. I argue that while theoretical work has suggested a relationship between these two phenomena, very little empirical work exists addressing their relationship and impact on lived realities. While the focus of this study is on the medicalized spaces where the biological nature of disability is taken for granted, I adopt a methodological and analytical stance that acknowledges the social realities of

disability alongside the material. An application of feminist epistemologies allows me to both acknowledge the hegemonic context in which informants are embedded while also leaving space for alternative positions.

This chapter has provided an overview of relevant literature from several fields and interdisciplines, including sociology, disability studies, science and technology studies, and feminist epistemologies. Drawing together scholarship about the social and political construction of disability, responsibility in the context of neoliberalism and technological progress, the emergence of the medical establishment as an authority figure, medicalization and biomedicalization of human phenomena, and the generative possibilities of situated knowledges, I have argued that there is a need to attend to individual experience and embodiment in the decisions around and use of biomedical technologies. The following chapter will describe the empirical methodologies undertaken in this study to tease out the complex relationships theorized in the literature above.

CHAPTER 3

METHODOLOGY

Introduction

The purpose of this chapter is to provide a detailed overview of study methodology, design, analysis, and ethical considerations for this qualitative inductive study of construction and enactment of dis/ability and responsibility in biomedical contexts. The adopted approach allows for a rich understanding of biomedical technology users' and stakeholders' interpretation of their experiences and the technologies. This attentiveness to individual experience in turn enables me to develop findings both characterizing disability and accountability in these context as well as identify potential alternative modes of knowledge production and practice. In this chapter,, I will first provide a rationale for the use of qualitative inquiry, specifically justifying the use of a multiple case study design and inductive analysis as they relate to the aims of this study. Next, I describe each of the three technologies at the heart of case studies in detail before summarizing recruitment strategies, research informants, and data collection procedures. I then provide an overview for the data collection and analysis procedures before concluding with ethical considerations, reflexive practices, and factors related to trustworthiness of the study's findings.

The aim of this study is to examine the construction and enactment of dis/ability, agency, and responsibility in the context of three biomedical technologies: Prenatal genetic screening and diagnosis, deep brain stimulation, and DIY artificial pancreas systems. It is mobilized by two interlinked questions:

1. What is the nature of the relationship between biomedical technologies and the meaning of dis/ability and experience of the non-normative self?

2. How do individual agency and accountability get constructed and enacted in the interaction between non-normative bodyminds and biomedical technologies and processes?

Given the inductive nature of the study, research questions and aims were intentionally broad in order to leave sufficient room for findings emerging from the data. Keeping these aims and questions central was key to developing a robust and meaningful research methodology and data collection strategy.

Initially, a third research question regarding the intersecting axes of oppression encountered by informants was developed, but after an initial recruitment period, the diversity of informants and sample size was not such that I could adequately address this question. The application of an intersectional lens is explored in detail in Chapter 7. While questions of intersecting oppressions, including ability, race, class, gender, ethnicity, and sexual orientation, have still been attended to throughout this dissertation, further work is needed in this area.

Methodology

This dissertation utilizes a qualitative methodology, a multiple case study design, and a general inductive analytical framework. This section includes a brief description and rationale for these methodological choices.

Rationale for Qualitative Inquiry

To answer the posed research questions, it was necessary to understand the personal experiences of users and other stakeholders as well as the manner in which users of these technologies get configured in documentation and clinical practice. Qualitative inquiry is the appropriate methodology in this case for several reasons. First, qualitative research coheres around several principles, including an attendance to context and an appreciation for pluralistic understandings of the world (Sutton,

1993). Both of these items crucially bear on this project. Contextualization is essential because the interrogation of the configuration of dis/ability, accountability, and agency across different settings requires a "healthy respect for the richness, density, and ambiguity of social life" (Sutton, 1993, 416). The social, political, and material environments in which each case exists *are* what grant them meaning and are inextricably linked to the experience of the technology. The experiences and perspectives shared by informants do not exist in isolation, and therefore quantitative methods, which divorce phenomena from their environment in order to measure them, would be inappropriate. Additionally, qualitative inquiry's tolerance for pluralist viewpoints also makes it an appropriate methodology for this project. As Robert Sutton (1993) writes, "the prospect, some would say inevitability, of relativism and pluralism is a natural consequence of the interpretive researcher's sensitivity to context and preference for comprehension and meaning over causal explanation and universal knowledge" (422). Such an appreciation allows for multiple meanings and enactments of disability simultaneously, which in turn allows a richer analysis of the context and conditions that configure bodyminds in certain ways.

Rationale for Multiple Case Study

This project was constructed using a multiple case study methodology. Yin (1994) defines a case study as an "empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not really evident." (13). This conception of case study is particularly useful in this work, which sought to characterize the complex interactions between person, technology, social world, and material environment. Case studies, by their contextual nature, allow for a "richer and more vivid picture of the phenomena under study than other, more analytical

methods" (Zach, 2006). Further, conducting three case studies enables a certain degree of comparative analysis across sites, which Gustafsson (2017) and Eisenhardt and Graebner (2007) suggests creates a greater opportunity of theoretical engagement and evolution because analysis is grounded in a diversity of empirical evidence. The dimensions and processes of qualitative case studies are intentionally flexible, and often used in exploratory studies such as this one, which can serve as a foundation for future empirical and analytical work (Gustafsson 2017). In this dissertation, a multiple case study design is adopted to highlight both the similarities in the configuration of dis/ability, agency, and accountability across disparate biomedical technological contexts and to elucidate where and how convergences occur. While the size and scope of this study cannot establish causal relationships between contexts and differing configurations, it provides groundwork for future studies.

The case studies, it should be noted, are not bounded by specific geographical parameters or individual narratives. Rather, each case attempts to capture a variety of perspectives and experiences around a specific technological intervention. While, as mentioned, a certain degree of comparison was possible, these cases were explicitly not deigned to be cross-comparison cases. To do so would have been to assume a greater degree of similarity than an inductive approach such as this one could justify. Each instead takes a unique approach appropriate to the idiosyncrasies of each case.

Rationale for Inductive Analytical Framework

In this study, I embrace what Caelli and colleagues (2003) dub a "generic qualitative approach," which is broadly defined as a qualitative analytical approach that "intentionally refuse[s] to claim full allegiance to any one established

methodology. Instead, researchers may choose to draw on a single established methodology, but deviate from its rules, or guidelines in a way that they see as beneficial to the study" (Kahlke, 2014, 39). Specifically, I use an inductive analytical framework, which does not impose a preexisting theoretical framework or seek to confirm a preconceived hypothesis. Rather, inductive analysis allows empirical data to guide theoretical findings. A generic or general inductive analytical approach is also valuable in that it can "use elements of more than one established methodology…when compatible elements are blended into a single new methodology" (Kahlke, 2014, 38). In this dissertation, the processes of Grounded Theory (Glaser and Strauss, 1967) are adopted, although I do not aim to develop a generalizable or universalizing new theory, differentiating it from traditional Grounded Theory. Further, elements of a hermeneutic phenomenological approach have been adopted to specifically attend to the experiences of interviews. By utilizing hermeneutic phenomenological frameworks, I can value my informants' experiential knowledge (phenomenology) while contextualizing it within the factors that mediate their interpretations (hermeneutics) (Vick, 2013). As such, I can acknowledge personal stories as legitimate sources of insight while recognizing that individual knowledge is filtered through one's positionality, historical context, and hegemonic discourses. As Bailey and Fonow (2015) advise, contemporary feminist inquiry troubles the concept that the "notion of informants' direct unmediated access to embodied experience an authoritative site of self-knowledge," while simultaneously recognizing situated knowledge production and transfer (68). This is not to accuse individual informants of false consciousness, but to contextualize their stated experience sufficiently, which hermeneutic phenomenology enables. Finally, elements of discourse analysis will be utilized in the analysis of both interview data and collected documents.

Generic qualitative approaches have been identified as particularly useful when applied to new fields (Lim, 2011), which aligns with this dissertation's theoretical goal of blending several fields of theory and practice in order to yield new insights and generative alternatives to epistemologies, processes, and practices that currently drive the development and deployment of biomedical technologies. Generic qualitative approaches allow for a methodological "playfulness" (Denzin and Lincoln, 2000) that "support[s] new fields of research, theoretical perspectives, new questions, or new approaches to old research problems" (Kahlke, 2014, 47).

I am considering deeply entangled assemblages of bodies, technologies and environments that are co-constituted, interdependent, and far-flung. By using a variety of interdisciplinary methodologies and theories I am attempting to grapple with that complexity, but not reduce it. As Graham (2012), paraphrasing Wittgenstein, writes "a good picture of a fuzzy object is a fuzzy picture."

Research Sample

This section will provide an overview of the three case studies, recruitment strategies, sample overview, and document collection strategies.

Overview of Cases

As discussed in Chapter 2, dis/ability is not constructed entirely through social interactions, but is deeply contingent on the complex assemblages composed of people, technologies, environments, competing expertise, and physical bodyminds, creating a unique material discursive reality. As such, no one individual case can provide a universal theory of dis/ability or responsibility, nor does this project seek to do so. Rather, three cases have been selected in order to probe how dis/ability is experienced and operationalized across unique settings, contributing to theory and practice that seeks to explain how dis/ability has come to be understood as

pathology that demands specific kinds of intervention. These three biomedical technologies, prenatal genetic testing and screening, deep brain stimulation, and DIY artificial pancreas, systems have little in common on the surface, but each illuminates issues of personal responsibility, epistemic (in)validation, and embodied or experiential knowledge. This section will provide a brief overview of each case study of these technologies and their historic and current usage.

Prenatal Genetic Testing

Prenatal genetic testing, which includes both prenatal genetic screening (PGS/PGD) and prenatal genetic diagnosis (PGD), refers to a suite of technologies and strategies intended to provide prospective parents with information about fetal genetic disorders and anomalies. Clinically, prenatal genetic testing technologies have been used since the late 1960s, with the introduction of amniocentesis (Löwy, 2017; Barnes, 2009). Initially, prenatal genetic testing relied on biochemical and cytological methods of detection for heritable metabolic and chromosomal conditions, reserved only for pregnancies deemed "high risk." The development of serum testing and ultrasound-dependent strategies shifted prenatal testing into routine obstetric care, regardless of assigned risk, simultaneously introducing the concept of prenatal "screening" as opposed to diagnosis (Löwy, 2017). Since the turn of the 21st century, prenatal testing has increasingly turned to molecular biology, especially through the deployment of cell-free DNA screening (cfDNA), sometimes known as non-invasive prenatal testing (NIPT), a technique that only requires a blood draw from the expectant parent and has rapidly proliferated clinical practice (ibid). Screening tests provide information about the *statistical likelihood* of certain conditions, while diagnostic tests confirm the presence of such an anomaly. At the time of this writing, there are no known studies about the percentage of pregnant people that receive some kind of genetic screening or testing. Current American College of Obstetricians

and Gynecologists, however, recommends that screening and diagnostic testing be offered to all pregnant people, so it is reasonable to assume the majority of prospective parents are at least presented with some form of prenatal genetic screening or testing (ACOG, 2016).

This study is concerned with experience of technologies used by prospective parents rather than those used in the lab to analyze samples. Of the three cases examined in this study, prenatal genetic screening and diagnosis has most thoroughly penetrated traditional medical care. The offering of PGS/PGD during obstetric care has been routinized and is typically offered to pregnant persons regardless of their predisposition for certain conditions (Thomas, 2017; Löwy, 2017). This case is of interest because prenatal genetic testing technologies represent an institutionalized form of medical surveillance that interacts with issues of gendered labor (Rapp, 1999) and the geneticization of dis/ability (Scully, 2008). Further, this case explores the social, political, and ethical complexities of pregnancy management, in which the non-normative bodymind in question (the fetus) is simultaneously within and distinct from the pregnant person. Finally, this case exemplifies the essential tensions between an individual choice model of health care, which assumes a prospective parent has autonomy over reproductive choices, and a public health model of testing and screening, which implements screening technologies in order to forestall costly public health expenditures on the care of non-normative bodyminds (Paul, 1998), as well as the tensions between disability and reproductive rights (Saxton, 2010).

Deep Brain Stimulation

Deep brain stimulation (DBS), also called a neurostimulator, refers to the surgical implant of a device that delivers electrical impulses to targeted areas of the

brain. The device comprises several thin electrodes, which are implanted in the brain, a pulse generator in the chest, and a wire connecting the two (Mayo Clinic, 2018). Most commonly used to manage symptoms of Parkinson's disease, dystonia, and essential tremor, DBS has its roots in 1930s and 1940s stereotactic neurosurgery. Despite its associations with Parkinson's disease in public discourse, DBS was initially developed as a neurostimulation implant surgery for intervention on chronic pain. Later, it was established as an intervention for Parkinson's disease poorly managed by pharmaceuticals (Gardner, 2013). Stereotactic surgery, which involves precise probing of the brain based on 3D modeling, originally had an ablative component, meaning specific areas of the brain were intentionally destroyed (Ford, 2010). The introduction of the medication levodopa led to a decline in ablative procedures. Once an implantable stimulator, initially developed by Medtronic in the 1960s for treatment of cardiac conditions, came to market, neurosurgeons began to test its ability to manage neurological conditions (Gardner, 2013). 1968 saw the first commercial neurostimulator, again produced by Medtronic, and in the 1970s, a range of conditions including epilepsy, schizophrenia, depression, and movement disorders were treated through stimulation of various parts of the nervous system (ibid). It was not until the late 1990s and early 2000s that the FDA approved any neurostimulation techniques as standard treatment, and even then, these approvals extend only to Parkinson's tremor, advanced Parkinson's, dystonia, and essential tremor (Ford, 2010). As of 2018, the FDA has also approved DBS for treatment of epilepsy (NINDS, 2019). There is also a Humanitarian Device Exemption (HDE)[4] for

[4] The Humanitarian Device Exemption is a designation assigned by the FDA for devices intended to benefit individuals with "rare" conditions (defined as impacting less than 8,000 people in the US per year). With an HDE, a device does not have to prove effectiveness as defined in the Food, Drug, and Cosmetics Act (21st Century Cures Act of 2016, § section 3052).

the use of DBS as an intervention for obsessive compulsive disorder (FDA, 2009). DBS continues to be trialed as a treatment for a wide range of neurological and psychological conditions including major depressive disorder, chronic pain, Tourette syndrome, autism spectrum conditions, and self-injurious behavior (Ford, 2010; Park et al, 2017).

Invasive and complex biotechnological interventions such as implants expose a site to examine agency and accountability, given previous research suggesting user education and participation in decision-making are not prioritized in the context of medical implants (e.g. Gagliardi, et al, 2017). Further, interventions that treat neurological and psychiatric conditions provide a particularly interesting case to consider how treatment success is counter-balanced with implant side effects such as personality changes, emergent mental health issues, and self-estrangement (Gilbert *et al,* 2017). Additionally, the manner in which non-normative bodyminds are identified, standardized and made legible in order to become eligible for DBS provides a site to interrogate *how* disability is understood and operationalized, and what elements of the disabled experience are delegitimized. The impact of living with chronic and/or degenerative conditions extend far beyond the narrow clinically-defined symptoms targeted by medical implants. The psychological and social impacts of these devices need to be considered, and I argue for the privileging of individual testimonials to recognize users as the experts of their own experiences.

Finally, this case provides an important site to interrogate, as Gardner (2013) notes, emergent tensions in biomedicine including "a conviction in technology-oriented solutions, a drive to alleviate suffering, a suspicion of commercial interests, doubts over the ability of regulatory initiatives, and anxiety over a precarious future."

Do-It-Yourself Artificial Pancreas Systems

Open source artificial pancreas systems can be characterized as both a set of technologies and a social movement. Sometimes known as hybrid closed loops or automated insulin delivery systems, do-it-yourself artificial pancreas systems (DIY APS) use continuous glucose monitoring, insulin pumps, smart phone or smart watch technology, and open source algorithms to control insulin delivery with limited user input (Crabtree, McLay and Wilmot, 2019). Some variants of DIY APS include additional hardware components, such as a microcomputer or a device used to bridge Bluetooth-enabled devices to other components. One such device, the RileyLink, is a device developed specifically within the DIY diabetes community (Hoskins, 2017). There are currently three DIY APS variants in regular use: OpenAPS, AndroidAPS, and Loop.

DIY APS can be understood as bridge between DIY Bio, health social movements. DIY Bio refers to a broad, undefined field of practice that has its roots in do-it yourself movements, citizen science, hackers, and the maker movement (Keulartz & van den Belt, 2016). Broadly adhering to a "hacker ethic," it is characterized by sharing, decentralization, collaboration, and access with aims toward societal betterment (ibid). Health social movements, particularly embodied health movements, challenge hegemonic science and medicine through experience of illness or disability (Brown, et al, 2004). Self-determination and individual responsibility are central in the DIY APS community. As the OpenAPS website, for example, states: "you'll have to build your implementation yourself (no one can/will do it for you!)" (OpenAPS, ND, para 3). Kelty (2010) notes that members of the DIY Bio movement are largely concerned with issues of legitimacy and credibility, as they challenge the hegemony of elite scientific authority. Further, this movement resists "Big Bio's" (universities, corporations, governmental projects) preoccupation with

economic productivity, and instead is motivated by the "demystification and democratization of science," an ethos shared by DIY APS communities (Keulartz & van den Belt, 2016, citing Landrain et al, 2013).

The DIY community also represents a departure from traditional knowledge-building and knowledge-sharing activities in research communities. As DIY APS leaders Dana Lewis and Scott Leibrand (2016) write, "the user community has valuable insight, data, and experiences that can help everyone (device manufacturers, health care providers, and users) to build better tools to better manage life with diabetes" (1). Therefore, the DIY APS movement (which often appears online using the hashtag #WeAreNotWaiting) also provides a powerful site to think through knowledge production and experiential expertise. When considering a topic area in which scientific expertise has historically trumped experiential knowledge – and credibility to speak about dis/ability has been predicated upon membership within a medical elite – it is necessary to deconstruct ideas around knowledge and truth to understand how systematic power imbalances and epistemic injustice (Fricker, 2007) have marginalized disabled people in their own lives, and how resistance movements such as DIY APS transform knowledge practices.

Study Informants

All informants in the DBS and DIY APS cases were users of the biomedical technology, family members, or partners interviewed between December 2018 and September 2019. In several cases in the DIY APS case, users and family members were also working professionally in diabetes technology as designers, engineers, or other professionals roles. In the case of PGS/PGD, interviews were conducted with users, practicing genetic counselors, and one researcher focused on prenatal interventions. Prospective parents and the researcher were interviewed between

December 2018 and September 2019. Genetic counselors were interviewed under a different protocol in July and August 2017. Informants in the PGS/PGD case had to have interacted with PGS/PGD sometime in the last five years in order to capture the rapidly developing technological and clinical space in this case. In DBS and DIY APS cases, the users needed to be actively using the technologies (although in the APS case, there was one instance in which the informant had not yet started DIY technology). All informants were over the age of 18 with the capacity for informed consent. All informants spoke English, although English needn't be their first language. There were no specific geographical limitations set on recruitment. All DBS and PGS/PGD informants were living in the United States, while five of fifteen interviews for DIY APS were conducting with informants living in Europe. Each chapter provides a brief biography of each informant.

Informants were initially recruited via online and in-person support and patient groups, through physical flyering, and through my existing professional network. Further, clinical professionals in the PGS/PGD case were recruited through the National Society of Genetic Counselors. Additional informants were recruited via snowball sampling when suggestions were made spontaneously in the interview process. Several of the informants were previously known to the researcher, although none in professional relationships that would contribute to a conflict of interest. Given the personal nature of interviews, these previously-established relationships allowed for greater rapport and richer data during interviews. Examples of recruitment materials can be found in Appendix C.

Samples were intentionally small as to allow "deep, case-oriented analysis," as is favored in inductive qualitative inquiry (Sandelowski, 1995, 183). An a priori sample size for each case was not determined before beginning data collection, but

interview recruitment was ceased on the basis of what Lincoln and Guba (1985) refer to as "informational redundancy," or the principle that no new information relating to the research questions is solicited from new interviews. Further, sample size was in some ways dictated by pragmatic reasons, such as the availability of new respondents through a variety of recruitment methods in the 9-month period in which interviews were conducted. Given the exploratory nature of these cases and the deep analytical attention given to each interview, the sample sizes were deemed appropriate. A matrix describing interviews across all three cases is presented below. Interviews were all conducted in a single session, although two informants, in the DBS and DIY APS cases, requested a follow up interview. These follow-ups were both unstructured and driven by the informant. In several cases, users and partners were interviewed at the same time. Therefore, total number of informants is not reflective of total interviews conducted. Interview protocol will be presented in greater detail in the Research Design section.

Table 1

Informants

	DBS	PGS/PGD	DIY APS	*Total*
User	9	5	10	24
Family Member	3 (all partners)	-	6 (all guardians)	9
Clinician or Researcher	-	8	-	8
Total	12	13	16	41

Document Collection

Simultaneous to conducting and analyzing interviews, a variety of primary user-directed documents were collected and analyzed as a means of triangulation. Triangulation, which refers to cross-verification of findings across several methods of data collection, attempts to provide a "confluence of evidence that breeds credibility" (Eisner, 1991). Glenn Bowen (2009) argues that document analysis, which he defines as "a systemic procedure for reviewing and evaluating documents," is particularly well-suited for triangulation in qualitative studies (27). Merriam (1988) further argues that "documents of all types can help the researcher uncover meaning, develop understanding, and discover insights relevant to the research problem" (118). Bowen (2009) identifies five key uses for documents in qualitative analysis: (a) providing context, (b) identifying new questions or sites for observation, (c) producing supplemental research data, (d) tracking changes over time, and (e) verifying evidence from other sources. In this study, documents simultaneously provide insight into the context in which informants are enmeshed as well as supplementary data.

Documents were initially collected through online keyword searches, and targeted searches of websites including known community resources, professional societies, and commercial manufacturers. Following the initial data collection period, this collection expanded to include documents referenced or recommended by informants. Documents were obtained from eclectic set of sources, including hospital or healthcare systems, commercial biomedical technology producers, professional societies, online user blogs, online community forums, and the Food and Drug Administration. This wide array of documents provides support for interview findings. Once collected, documents were analyzed similarly to interview transcripts, using an inductive qualitative approach. Analyses of interviews and documents happened

simultaneously and in parallel. As Bowen (2009) warns, documents must be evaluated critically and not as "necessarily precise, accurate, or complete recordings of events," and often purposively present information selectively (33). For example, "in an organisational [sic] context, the available (selected) documents are likely to be aligned with corporate policies and procedures and with the agenda of the organisation's principals" (Bowen, 2009, 32). The purpose, audience, and context for documents was considered when critically analyzing them in the qualitative research process. This perspective is particularly important when considering questions of knowledge production, authority and legitimacy, as this study does.

Documents for the PGS/PGD cases were primarily drawn from commercial PGS/PGD distributors, professional societies including the National Society for Genetic Counseling and the American College of Obstetrics and Gynecology, and health services. Documents for the DBS case primarily consisted on guidance documents issued by hospital systems for potential and current users. Documents for the DIY APS included the community-produced guidance documents for the three currently available DIY hybrid closed loop systems (AndroidAPS, OpenAPS, and Loop), diabetes tech blogs, online community forums, and the FDA. An overview of reviewed documents is available in Appendix E.

Research Design

Research Questions

This study is driven by two key questions:

1. What is the nature of the relationship between emerging and emergent biomedical technologies and the meaning of dis/ability and experience of the non-normative self?

2. How do individual agency and accountability get constructed and enacted in the interaction between non-normative bodyminds and biomedical technologies and processes?

As is common in the qualitative research process, these questions have been iterated on and refined throughout the research process (Agee, 2008).

Given the complexity and dispersed nature of these cases – which do not simply concern clinical interactions, but decision-making processes and post-procedure experience, methods and analytical frameworks chosen were intentionally flexible. Data were collected through semi-structured interviews with users of the three identified technologies, semi-structured and unstructured interviews with other stakeholders including clinicians, family members, and researchers, and user-directed informational guidance documents, including guidance from hospitals and clinics, overviews from commercial device and technology manufacturers, instructions and support from user-communities, FDA statements, and other documents identified through an initial search and interviews. These distinct sites and methods of data collection were used in order to triangulate findings such that conclusions can be cross-verified and made richer by their interactions. Brown and Nash (2010) note that methods themselves do not possess "inherent epistemological or ontological qualities; rather how they are deployed in the pursuit of certain forms of knowledge produced data that supported feminist ways of knowing and contested masculinist forms of knowledges" (11). Therefore, my epistemological orientation, outlined in Chapter 2, will deeply inform how I deploy my methods, analyze my data, and represent my informants in my work.

Data Collection Process

Approval from the Institutional Review Board (IRB) at Arizona State University was sought and gained for each case study individually. An additional IRB approval was obtained for interviewing prenatal genetic counselors, as these interviews were conducted at an earlier time and with a different protocol. Following recruitment, interviews were conducted in person, by phone, or by video conferencing, depending on the preference and availability of the interviewee. For interviews conducted between 2018-2019, all interviews were recorded with the permission of the informants using a TASCAM-05 voice recorder and a mobile phone. Several interviews were also recorded using video conferencing software, but only the audio was retained. No interviews proceeded without written consent[5]. Consent information was reviewed verbally prior to beginning the interview, and informants were made aware not only of the safeguards on their privacy and confidentiality, but of the processes built into the protocol to ensure their control over their narrative, including flexibility of the interview format and the ability to edit and amend the transcripts prior to data analysis. For interviews with users and families, a semi-structured interview format was followed. For professionals, an unstructured interview was conducted. For individuals who did not fall into a single category, such as DIY APS users who are also developers, the interview formats and topics were blended. In the PGS/PGD case, interview transcripts from previous protocol were re-analyzed with this study's research questions in mind. All IRB documentation can be found in Appendices A, B, and C.

I deploy semi-structured, open-ended and qualitative interviews with users and family members in order to guide the conversation while allowing space for

[5] Protocol for interviews with genetic counselors did not require written consent. See Appendix A for more information.

informants to articulate their experiences and perceptions. Questions centered on capturing the informants understanding of the intervention and themselves pre- and post-procedure, as well as discussions of personal and social responsibility. Madison (2005) refers to this category of interviewing as a topical interview, in that it captures experience and perspective on a "particular subject, such as a program, issue, or a process" (26). However, in the course of discussing perspectives and experiences of biomedical technologies, these interviews may also be understood as personal narratives, which require particular attention toward integrity and care. One additional consideration, as a science studies scholar conducting research about biomedical technologies, was the use of what Madison refers to as "native-language," or language used by informants such as slang or jargon, when communicating about conditions, interventions, and experiences. Familiarity with documents and online resources relating to user experience prior to conducting interviews enabled this, in some regards, as did building rapport with informants.

Interview questions for users and family members in each case were identical. They moved from broad, open-ended questions asking informants to describe themselves, their daily lives prior to intervention, their lives following intervention, and their understanding of the technology. As the interview progressed and rapport was built, more probing questions about expectations, personal responsibility, and perception of their condition were pursued. As relevant, questions about the impact of race, gender, ability, sexuality, or class on their experience of the technology or the healthcare system were also asked. The interviews concluded with several more open-ended questions about the future of the technology, their hopes and apprehensions, and changes they would make to their experiences. The interview schedule was developed through an iterative process with several scholars and

experts who gave feedback, suggested additional questions, and assisted in reframing others. Further, due to the nature of semi-structured interviews, the interview schedule was also adjusted in situ to respond to the flow of conversation. All interview schedules are presented in their entirety in Appendix D.

Following the interview, transcripts were primarily developed by hand, although a subset of interviews were also transcribed through a professional transcription service. This service ensured privacy and confidentiality through encryption of all data, use of a secure portal, and deletion of files from their servers upon request. In all cases except the seven interviews conducted with genetic counselors and the single written interview, transcripts were returned to informants, who had one month to comment, edit, or otherwise respond to them. Informants had the right to alter the transcript in any way, including removal of elements, clarifying comments, or removing their transcript from the study. Of the 33 informants (30 interviews) who received transcripts, 21 sent responses. Changes were typically minor, often related to factual or grammatical errors in the text. All requested changes were incorporated. Only one case involved substantial revisions to the transcript, in part because poor audio quality had produced several substantial gaps in the transcript. The remaining 12 informants did not respond within the allocated timeframe. Two informants also reached out to request follow up interviews, which were conducted upon request. A full draft of this dissertation was also made available to all participants in March 2020 with a request for feedback. Please see the Postscript for more information.

To protect privacy and confidentiality, all research products were de-identified, informants were assigned pseudonyms in transcripts and all raw data (e.g. audio recordings) was saved on password-protected servers or physically under lock and

key. Additionally, any institutions such as hospitals, clinics and providers were de-identified. All data in any written reports was not linked to informants by name, organizational affiliation, or location more specific than state or region (e.g. Southwest United States). Further, the master list linking informants to the study by name will be destroyed after 10 years as an additional means of ensuring privacy and confidentiality. Prior to consenting, informants were fully informed of all efforts to ensure confidentiality, research goals, processes, and their rights as informants prior to consenting to avoid any unforeseen harm. Regarding document collection, all documents were freely and publicly available. In several cases, documents were sent directly to me by informants. In these cases, the sender was not recorded with the document.

Analysis and Synthesis

Throughout the data collection and analytical process, memos were taken, as is common in qualitative research to reflect on the data collection process, begin analyzing concepts and ideas, and record iterative meaning-making (Groenwald, as cited in Given, 2008). Each memo was written and dated in a common document, and if inspired by a specific interview or document, that was noted as well. Memos were also used throughout the open-coding phase (described below), a process derived from Grounded Theory practices (Glaser and Strauss, 1967).

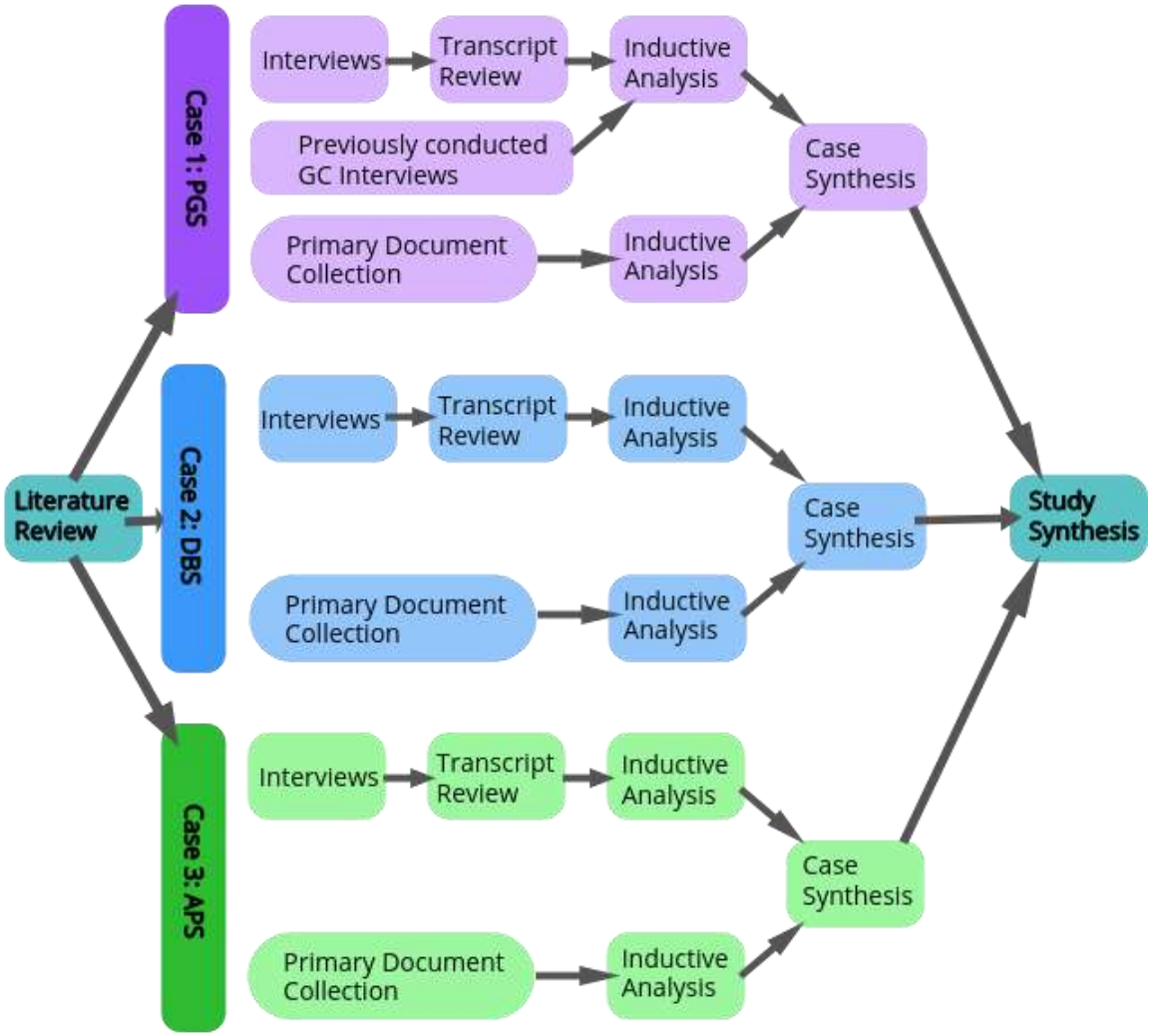
Analysis for each case began with an initial close reading of each interview transcript and open-coding, a process by which "the researcher discovers, names, defines, and develops as many ideas and concepts as possible without concern for how they will ultimately be used" (Benaquisto, 2008, para 1). Text segments were identified and labeled with words or phrases that served as initial themes. The first round of open coding was conducted by hand and then initial themes were uploaded

into the qualitative software data management platform NVivo 10. NVivo, in this instance was not used to assist in coding, but only as a repository and data management tool. These initial themes were then refined and iterated on, creating several thematic categories with nested subcategories. The coding process includes several key steps, which Thomas (2006) identifies as "Initial reading of text data" "Identify specific text segments related to objectives", "Label the segments of the text to create categories", "Reduce overlap and redundancy among the categories", and "Create a model of incorporating most important categories" (242). After several rounds of iterative coding, major thematic areas were identified, and open codes were consolidated. Each chapter contains several tables summarizing major themes and subthemes and their frequency in interviews. As this is a qualitative analysis, however, thematic areas were selected not on virtue of the number of transcripts in which they appeared, but by their relationship to the study questions and theoretical importance. Guidance documents were coded in a similar manner but were not included in the iterative process of constructing major thematic categories, as their purpose was primarily triangulation and validation.

Data collection and analysis for all three cases was done concurrently. Figure 3 summarizes this process.

Figure 3

Research Process



Ethical Considerations

This study followed a series of procedures to ensure this research was conducted in an ethical manner in line with current best practices. Prior to any data collection, the study gained approval through the Institutional Review Board at Arizona State University. The informed consent form, available in the Appendix B, was shared with each participant prior to beginning an interview and key pieces were

verbally reiterated during the interview. It contains an overview of the study's aims, explanation of procedures, potential risks and benefits, privacy and confidentiality measures, contact information for myself and the IRB, and an explanation of the voluntary nature of the interview. While verbally confirming consent prior to each interview, I reiterated that informants were welcome to leave the interview at any time, not answer any question they did not want to or withdraw their data any time prior to publication. The risks associated with this study were minimal. All informants were over 18 and determined to have the capacity to consent. According to the Mayo Clinic (2016), consent capacity is defined as "an individual's ability to understand and process information relevant to making an informed, voluntary decision to participate in research…including an understanding of the purpose of the study, its experimental nature, risks, and anticipated benefits, the right to withdraw, alternatives to participation, confidentiality protections, and the safeguards used to minimize risks" (6). Anyone who did not meet these two criteria, aged over 18 and with capacity to consent, did not qualify for participation in the study and was not interviewed.

I did not obscure or hide my identity and status as researcher during recruitment, and always provided potential recruits with as much information about the study and its aims as requested. Additionally, I made myself available for any follow up questions or concerns as they arose. All informants were also offered an opportunity to stay informed about the progress of research and receive copies of the final study. If informants raised concerns or gave feedback on the analyzed data, their comments were taken into consideration.

I also incorporated member checking as a key element of the analysis process, which included returning transcripts to informants for editing and review

prior to beginning open coding and sharing a full draft of this dissertation in March 2020. Member checking, proposed as a method to increase the credibility and validity of qualitative research by confirming findings with informants (Lincoln and Guba, 1986), has many possible forms, including returning transcripts for review, conducting focus groups with informants about study results, and returning data for feedback from informants (Birt et al, 2016). In this case, interview transcripts were made available to all informants, who were given one month to review and edit them as they desired. Additionally, a draft of this document was made available to all informants (with the exception of two who were no longer accessible through their provided contact information). Informants were asked to provide confidential feedback through a Google Form. Transcript and draft review were less precipitated on ensuring accuracy of interviews, as it might in a study using an objectivist epistemology, so much as ensuring that informants felt the transcripts represented their experiences. Under a constructivist epistemology, member checks of this type "can be used as a way of enabling informants to reconstruct their narrative through deleting extracts they feel no longer represent their experience, or that they feel presents them in a negative way" (Birt et al, 2016, 1803). Any change to the transcript was accepted and this altered transcript was used for open coding. Versions of the transcript in all forms were preserved. Feedback from informants on this dissertation will be incorporated through a variety of means, including editing the text and including informant feedback verbatim.

Reflexivity

Recognizing that individual knowledge is situated and *contingent* also forces me to grapple my own positionality in relation to my informants. Gammerl (2015), comments on balancing the recognition of emotion as situated and innate in knowledge production, writing that "pretending to proceed in a completely objectivist

fashion fails to acknowledge the effects emotions have on knowledge production, and thus renders them non-transparent. On the other hand, interpretations based on intuitive empathy and the assumption that researchers and research subjects share the same understanding of emotional phenomena can be equally misleading" (153). Despite this risk, attention to emotional and affective interactions in the course of fieldwork can, according to Gammerl, "enable insights that other interpretive means would fail to reveal" (ibid, p. 160).

Writing about the emotional and experiential realities of my informants – many of whom are disabled, chronically ill, or prospective or current parents of disabled or ill children – comes with its own ethical demands. As a feminist researcher, it is crucial for me to grapple with issues of representation and interpretation in whatever I produce (Galletta, 2013). Knowledge-production is a communal event, which Ramazanoglu and Holland describe as a negotiation between researchers, subjects, and epistemic communities (1999), and so as a researcher, I am accountable to all of the communities I engage with throughout the course of my dissertation work. I appreciate that "oppressed people have the right to name, define, and organize themselves" (Haritaworn, 2012, 9). Further, I am concerned with the historical and contemporary subjugation of disabled people in pursuit of Western scientific inquiry. As Subramaniam and colleagues (2017) note, certain categories of people have "not only served as objects of scientific inquiry, but also as the *raw materials* needed for the 'manufacture' of modern Western scientific theories and knowledge claims" (p. 411, emphasis original). Therefore, it is essential to me to produce work that is neither extractive nor oppressive and creates space for people to be active producers of their own interpretations (Haritaworn, 2012). I attended to these concerns through articulating the research purpose and interview process as

one that valued personal narrative prior to conducting interviews and encouraging member checks of transcripts and final research products as a way to own and control the personal narrative of the interviewee.

Practically, I was well equipped with the skills and experience to carry out the designed research. I have nearly a decade of experience and training in social science research, especially as it pertains to disability, health, and illness. I have extensive training in qualitative research methods and have interviewed dozens of people prior to this study in several research capacities. Further, I have both experience and training in inductive qualitative research and ethical research design.

Qualitative research, however, is not only informed by the researcher's skills, but also by their positionality, including not only their experience, but their "beliefs, political stance, cultural background (gender, race, class, socioeconomic status, educational background)" (Bourke, 2014, 2). I am a white, educated, American woman who does not identify as disabled or ill, which does impact the way that I collect, analyze, and understand data. Further, I have an extensive background in disability rights communities, including several organizational leadership roles, which predisposes me to think about disability through a socio-cultural and political lens. My advocacy background is not merely coincidental but drove me to pursue a project that resisted medicalizing paradigms about who has authority to speak about disability and illness. This informed the choice of methods to focus on individual narrative and embodied expertise as well as the form of research questions and analytical framework.

Issues of Trustworthiness

Qualitative research, in many forms, has often been criticized for a perceived lack of rigor when compared to quantitative work. However, not only does qualitative

work provide insights not possible through quantitative work, many practices and strategies for conducting rigorous qualitative work have been developed and tested over time. Lincoln and Guba (1985) suggests that the terms "validity" and "reliability," which are often deployed in quantitative research to bolster result credibility, are inappropriate in qualitative inquiry, and instead suggests "trustworthiness" as an alternative. They identify four core components, which are presented below alongside this study's approach to addressing them:

Credibility. Credibility in this context refers to the plausibility of study findings, which is contingent on data collection and analysis (Zach, 2006). In this study, credibility was cultivated through triangulation, or the collection and analysis of varied documents to supplement and validate interview findings. Lincoln (2004) notes credibility is especially important in relation to the people whose lived experience is reported. Therefore, credibility was also cultivated through the member checks described in detail in the Ethical Considerations section above.

Transferability. Rather than argue that qualitative research results should be generalizable, Lincoln and Guba (1985) suggest that research results should be transferable to similar contexts. Ultimately, the extent to which a study is transferable is determined by the users and consumers of research results (Lincoln, 2004), but tactics such as providing a detailed description of research processes, assumptions, and limitations, such as what is done in this chapter, can be employed to increase transferability to future contexts.

Dependability. Dependability refers to the "stability of findings over time" (Bitsch, 2005, 86). Dependability can be achieved through a thick description of study methods, methodology, and epistemology in this chapter. Additionally, a detailed record was kept tracking data collection. Bitsch (2005) also suggests peer

examination, or the process in which a researcher shares the process and findings with neutral colleagues with experience in qualitative methods, also promotes dependability. Preliminary results of this work were presented at four separate conferences with different audiences with relevant expertise over the course of 2019, and feedback from these audiences has been incorporated into this project.

Confirmability. Confirmability is a characteristic of trustworthiness that is primarily concerned with ensuring that findings are actually derived from study data (Anney, 2014). Confirmability was achieved through several means, including triangulation and a detailed data collection and analysis record (Lincoln, 2004).

Despite strategies to ensure trustworthiness in this study, there were several limitations. This project was executed by a single researcher, and additional analysis and comparison of themes by another researcher could have provided additional rigor. Additionally, each case study had a different profile of informants, with DBS favoring users, DIY APS blending users and family members, and PGS/PGD primarily drawing from clinical experiences, thus limiting the comparative value between cases. Finally, due to practical restraints, member checks were restricted to a review of the informants' own transcript with an additional review of the research product. Birt and colleagues (2016), however, suggest that effective member checks include opportunities to examine data from multiple informants as well as analyzed data. In future work, I intend to expand informant involvement beyond member checks to include more collaborative and co-design practices.

Chapter Summary

This chapter discussed in detail the research methodology, sample, research design for this study. It provided an overview of the three selected case studies, recruitment and data collection procedures, and an analytical framework. Finally, it

concluded by examining procedures to safeguard trustworthiness, ethical practices, reflexivity, and potential limitations. The next section of this dissertation will be three chapters presenting descriptive findings and analysis of the three case studies, beginning with prenatal genetic screening and testing.

CHAPTER 4

"SOME STUFF YOU WANT TO TAKE OFF THE TABLE:" PRENATAL GENETIC SCREENING AND DIAGNOSIS

Introduction

In this chapter, I will present the descriptive findings and inductive analysis of interviews with prospective parents and medical professionals who have engaged with prenatal genetic testing and screening. Alongside these findings, I will present supplementary material yielded from an analysis of user-directed guidance documents, including informational pages, brochures, and FAQs produced by a variety of sources including commercial Prenatal genetic screening and diagnosis (PGS/PGD) companies, medical professional societies, health systems, and the United States federal government. I relate perceptions of responsible parenthood with feelings of obligation to pursue testing, specifically as it is framed as providing essential knowledge for the responsible management of pregnancy. Disability, in these contexts, is understood in primarily medicalized paradigms and often coded with negatively connoted language. Three major thematic areas, each with subthemes, are presented below. The first two themes, Knowing and Not Knowing and Responsible Parenthood address this study's second research question, drawing a distinct connection between knowledge acquisition, technology use, and personal accountability. The remaining theme, the Meaning of Disability, addresses the first research question, summarizing the construction of disability along two distinct binaries in the context of PGS/PGD. Themes and subthemes are summarized in the table below.

Prenatal genetic screening and diagnosis refer to a suite of screening and diagnostic strategies conducted during pregnancy to provide information about the likelihood (screening) or presence (diagnosis) of genetic anomalies in a fetus or the

parents' likelihood of passing on such anomalies. It includes procedures to determine the statistical probability of an anomaly, such as non-invasive prenatal genetic testing/screening (NIPT or NIPS), and diagnostic confirmation strategies such as amniocentesis. For the purposes of this study, engagement with clinicians including genetic counselors and the gathering of familial histories are also included in the definition of PGS/PGD. There are currently many available PGS/PGD procedures, including:

Screening

Carrier Screening. Carrier screening is for prospective parents (both individuals planning to conceive and those already pregnant) that uses a blood or tissue sample to detect whether a person carries a gene for certain inherited disorders, including cystic fibrosis, hemoglobinopathies, and spinal muscular atrophy. (ACOG, 2018)

Nuchal Translucency Screening. This screening is typically conducted during the first trimester of pregnancy and involves a clinician takes measurements at the fetus's neck. Measurements outside of a certain range have been linked to Down syndrome, aneuploidies, and other conditions. (ACOG, 2019a). Additional ultrasounds are often conducted later in pregnancy.

Quad Screening. Quad screening is a common blood test measuring several substances linked to Down syndrome, Edwards syndrome, and neural tube defects.

Cell-Free DNA Screening. In this blood test that is rapidly gaining popularity in clinical settings, cell free fetal DNA, or DNA that has been carried from the placenta or fetus into the blood stream of the pregnant person, is collected and analyzed for aneuploidies, such as trisomy 21, and other data such as Rh status and sex. Cell-free DNA screening (cfDNA) is also known as non-invasive prenatal screening (NIPS) or non-invasive prenatal testing (NIPT) (Goldwaser and Klugman, 2018).

Diagnosis

Amniocentesis. Amniocentesis is a diagnostic test in which a thin needle is inserted into the amniotic sac, with the assistance of an ultrasound, to remove a small amount of amniotic fluid containing fetal cells. There is a small risk of miscarriage with this procedure (ACOG, 2019b).

Chorionic Villus Sampling (CVS). CVS is similar to amniocentesis but involves taking a tissue sample from the placenta. Like amniocentesis, there is a risk of miscarriage (ACOG, 2019b).

Preimplantation genetic diagnosis. This procedure is typically conducted when seeking fertility treatment such as in vitro fertilization and involves taking a sample from an embryo prior to transferring it into the prospective parent (or surrogate)'s uterus. According to the American College of Obstetrics and Gynecologists, "Only embryos that do not test positive for disorders are transferred" (ACOG, 2019b, para 6).

Following the collection of tissue samples with each diagnostic test, these cells are analyzed in a laboratory, often a commercial lab. These labs use a variety of technologies that include:

Fluorescent In Situ Hybridization (FISH). Fluorescently labeled DNA, also known as a DNA probe, is attached to DNA from a chromosome in order to identify where specific genes may have been duplicated or damaged (Venes, 2013). It is typically used to identify trisomy 13 (Patau syndrome), trisomy 18 (Edwards syndrome), trisomy 21 (Down syndrome) and aneuploidies on the X and Y chromosomes.

Karyotyping. This technique involves taking a picture of fetal chromosomes and arranging them to examine whether any chromosomes are missing, damaged, or duplicated (Ferguson-Smith, 2013).

Chromosome Microarray Analysis. A variant of karyotyping, this test "detects submicroscopic CNVs [copy number variations] causing or increasing the risk of human disease" (McGillivray et al, 2012, 389). It is used to identify chromosomal anomalies such as trisomies and other chromosomal differences.

Prenatal genetic screening and diagnosis was selected as a case study for several reasons. First, more so than any other case selected, PGS/PGD has thoroughly penetrated traditional healthcare systems and is routinely offered to all pregnant persons in the United States and high income countries across the globe (e.g. Thomas, 2017; Löwy, 2017). It is increasingly being introduced in healthcare in low- and middle-income countries as well (Allyse, et al, 2015). Secondly, it explores accountability from a distinct perspective, as the bodymind being managed (the current fetus/potential child) is not the one embodied by the manager (the pregnant person). Accountability and responsibility than take on the distinct tenor of parenthood or guardianship. Finally, Prenatal genetic screening and diagnosis exemplifies tensions between individual choice models of healthcare and public health models of care (Paul, 1998). In the former, it is assumed that the prospective parent has autonomy over reproductive decisions, including the decision to pursue testing, while the latter operates under the presumption that screening and testing may be a method to mitigate future health expenditures on disabled people (see Ravitsky, 2017 for more on this distinction). More broadly, this case may provide insight into other forms of routinized medical surveillance technologies.

Informants for this case were divided between prospective parents and medical professionals. While interviews were all analyzed and coded together, findings will be presented distinguishing between these two categories. Due to the analytical attention to informants' interpretation of their experiences, there were, in some cases, significant differences in the frequency of codes between groups, as well as some codes that only appear in one group or the other.

Thirteen informants were interviewed, including five users (prospective or current parents), seven practicing genetic counselors, and one medical genetic researcher specializing in prenatal genetic testing, screening, and therapy. Of the five users, four identified as female, one identified as male, and three were pregnant at the time of the interview. One interviewee had never been pregnant and instead shared her experiences with preimplantation and carrier screening during fertility treatments. Of the professionals, seven identified as female and one identified as male. Four interviews were conducted in person and the remainder were conducted via video conferencing or phone call. Interviews with users ranged from forty-five minutes to two hours, averaging seventy minutes. Interviews with professionals ranged from thirty to ninety minutes, averaging approximately one hour. Interviews were all conducted in a single session. Transcripts were returned for review to the users and genetic researcher. The genetic counselors were interviewed under a different research protocol (see Appendix A) and received a copy of a preliminary report summarizing the findings from their interviews to review and comment on. All informants also received a draft of this dissertation for review. Informants and the method of recruitment are briefly described below. Pseudonyms were assigned using a random name generator. Throughout the chapter, informants will be identified as either prospective parents (p. parent) or professionals (prof.)

Melanie (p. parent). Melanie is an academic professional and mother of one living in the southwest United States. She was pregnant at the time of the interview and received prenatal genetic testing during both her current and previous pregnancies. She received NIPT and consulted with a genetic counselor during her first pregnancy and received a first trimester screening during her current pregnancy. She was recruited through my professional network.

Rosalie (p. parent). Rosalie is an academic professional in her mid-30s living in the northwest United States. She was pregnant at the time of the interview with her first child and had received NIPT. She worked with a patient coordinator in her obstetrician's office when deciding to pursue genetic testing. She was recruited through my personal network.

Patsy (p. parent). Patsy is a 33-year-old research scientist living in the Mid-Atlantic region. In 2019, she received carrier genetic screening and genetic counseling as part of fertility treatments. She was recruited through my professional network.

Abby (p. parent). Abby is a 30-year-old woman living in the Midwest. She was pregnant with twins at the time of the interview and received NIPT during her pregnancy. Prior to conceiving, she received fertility treatments. She was recruited through my personal network.

Gene (p. parent). Gene is an academic professional living in the southwest United States. He is the father of a four-year-old and a seven-month-old, and he and his partner received genetic screening during both pregnancies. He was recruited via my professional network.

Sabrina (prof.). Sabrina is a clinical scientist, researcher, and practitioner currently working in the Mid-Atlantic region as director of a prominent research facility. She

has an extensive background in research for prenatal genetic testing and prenatal genetic therapies. She was recruited through my professional network.

Julia (prof.). Julia is a genetic counselor living and working in New England. She has worked both in general genetics and in prenatal genetics and has been practicing for approximately 40 years. She also provides genetic counseling for adult-onset conditions. She was recruited via her membership in the National Society of Genetic Counselors.

Marcie (prof.). Marcie is a genetic counselor and educator living and working in the southwest United States. She has been a medical professional for 45 years. In addition to practicing in prenatal genetic counseling, she is an educator and administrator. She was recruited via directed search and email.

Anton (prof.). Anton is a genetic counselor living and working in the Great Plains region of the United States. He does both prenatal and preconception genetic counseling. He was recruited via his membership in the National Society of Genetic Counselors.

Miriam (prof.). Miriam is a clinical prenatal genetic counselor living and working in the Midwest. At the time of the interview, she had been working for about 14 months, having just completed her professional training, including an interdisciplinary program focused on working with people with disabilities. She was recruited via her membership in the National Society of Genetic Counselors.

Carmen (prof.). Carmen is a clinical prenatal genetic counselor living and working in the southwest United States. She works in an office that provides a lot of first trimester screenings. She was recruited via her membership in the National Society of Genetic Counselors.

Pauline (prof.). Pauline is a genetic counselor living and working in New England. She has been practicing clinical prenatal genetic screening for 10 years. She was recruited via her membership in the National Society of Genetic Counselors.

Theresa (prof.). Theresa is a genetic counselor living and working in New England. She has 12 years of experience as a clinical genetic counselor and has since transitioned to working as a medical science liaison with a commercial genetic testing company, providing services such as education to medical professionals. She was recruited via her membership in the National Society of Genetic Counselors.

Approximately 200 pages of documents were analyzed, coming from 12 sources. These included resources aimed at prospective parents from two medical professional organizations, seven commercial prenatal genetic testing and screening companies, two major healthcare systems, and one governmental organization. A summary of these documents can be found in Appendix E.

Theme 1: Knowing and Not Knowing

In almost all interviews, PGS/PGD was explained or justified as an accumulation of essential knowledge in responsible pregnancy management. Importantly, however, there seemed to be a distinction, among both prospective parents and medical professionals, between the knowledge that was necessary for prospective parents to make "informed decisions" and knowledge that would only result in unnecessary anxiety. How those categories became delineated, however, was left tacit. A lack of explicit articulation of why some conditions demanded testing while others did not reinforce the idea that disability is both easily definable and obviously requires identification and intervention. Additionally, this theme includes subthemes addressing how and when knowledge moves between stakeholders, and informants' acknowledgement of the inherent uncertainty of screening and testing technologies.

Often, prospective parents felt as if there were significant gaps in their knowledge, a suspicion bolstered by professionals' confirmation that they presented certain knowledge based on assumptions made about prospective parents. Altogether, this theme highlights a distinct set of knowledge expectations and practices that define the experience of prenatal genetic testing and screening. These practices are largely tacit and ill-defined, leading to dissatisfaction and anxiety among prospective parents.

Knowledge As Empowerment

Almost universally across all interviews, informants suggested that Prenatal genetic screening and diagnosis provided some essential knowledge to empower prospective parents to make informed decisions about pregnancy management. Gene (p. parent) suggested that he and his partner pursued testing because their professional background as researchers predisposed them to gather and analyze as much data as possible when making decisions: *"We were both social scientists."* he said, *"We like some kind of nice foundation of evidence to at least provide a sense of security or comfort, if nothing else."*

Often, this language of empowerment was specifically used when discussing scenarios in which an abnormal testing result would not result in the termination of pregnancy. Choice and informed decision-making as a rhetoric was almost never introduced when discussing pregnancy termination, either among prospective parents or medical professionals. Abby (p. parent), who identified as Catholic and does not support abortion, initially balked at the idea of prenatal testing and screening, linking it in her mind only to pregnancy termination. Eventually, however, the allure of knowledge, which she decided could assist in making decisions around care, drew her to receive NIPT:

> *"So, then we were like, 'We're not going to do it, because it doesn't matter, because we're going to keep the baby. It's irrelevant.' But then, we're like, 'Well, we kind of want to know because if there is something, it's not going to affect the outcome, but it would affect all of our care up to that point,' because then we would want to see specialists. We would want to maybe deliver at [Large Medical Research Center] instead of at [Local Hospital] if there's going to be an issue. We'd want to have specialists lined up."*

She eventually conceded that curiosity convinced them to pursue testing: *"Honestly, just wanting to know is kind of the bottom line, is because we didn't know and it's something that you could know so easily and then decide, 'Okay, what are we going to do for it?' So just wanting to know, the curiosity of it."* She continued by suggesting that the knowledge NIPT can provide about gender served as extra protection against potential backlash from others who associate genetic testing with pregnancy termination, stating "*We'll just say we want to do it for the gender and then it won't look bad."*

The ease of knowledge acquisition and almost nonexistent health risk to the fetus or mother influenced other prospective parents to pursue noninvasive screening technologies as well. As Rosalie (p. parent) states, *"Since it's not an amnio [amniocentesis] anymore, since it's something you can test without a risk of miscarriage, I'm all for making really informed decisions. So, I was all about it,"* suggesting that the existence of a blood draw screening test crucially impacted her schema for making decisions. Theresa (prof.), who works as a medical science liaison at a commercial company, confirmed that noninvasive testing appeals to risk-averse prospective parents, noting

> *"I think that, um, a less invasive test is more powerful for those types of patients. Because these are the ones who are more likely to have testing now because they're like, 'You know what? I kind of would like to know ahead of time. I would never have an amnio, but if I am at risk for having a baby with Down Syndrome, I would want to know in advance. I would want to prepare, I would want to maybe, you know, deliver elsewhere.'"*

Here again, testing is associated with preparedness for a future disabled child rather than with pregnancy termination. This framing of testing as frictionless knowledge empowerment obscures the tensions and anxieties experienced by prospective parents.

Knowledge Anxiety

While both prospective parents and professionals discussed knowledge accumulation as a form of empowerment, prospective parents were much more likely to discuss knowledge as a potential source of anxiety as well. When making this point, however, they were clear to distinguish between an "appropriate" level of knowledge, which often was synonymous with whatever suite of testing was recommended by their clinician, and "too much" knowledge, which often included things like full genomic work ups or advanced testing options. Melanie (p. parent) shared an anecdote from when she was first considering genetic testing and her genetic counselor warned her against a full panel, which screens for many more genetic markers than the typically offered screening:

> *"And she goes 'Be careful with that one,' which I was very happy that she gave some type of like idea about it, because who wouldn't want to know everything, right? If you had the opportunity to know everything about your genetic background and your baby's genetic background like, do it. But then*

she did warn, like, 'You do that you're going to find something'…We knew right away that we weren't going to do the full panel one because both of us would have gone nuts."

Patsy (p. parent), who received carrier screening as part of preimplantation services, noted that she would have rather had the option of no testing, but as someone receiving fertility treatment, she did not feel as though she had much choice to decline. *"But I kind of would rather take it hands-off. You know, as long as whatever's healthy for me. I kind of would rather leave it like 'It is what it is.'"* The optionality of screening is less present in fertility clinics, nearly all of which also require screening of embryos prior to implantation. Patsy's anxiety or discomfort, like Melanie's, stems from knowing too much, which in her case would force her into a position to make decisions about what kind of child she would like to bring into the world, a situation that she does not see occurring in non-assisted pregnancies. Through testing, she becomes responsible for new kinds of decisions that would not have otherwise been possible.

The tacit assumption that knowledge about some conditions, like Down syndrome, is necessary, while other knowledge may lead to unnecessary anxiety suggests in itself that some conditions are inherently less desirable. It is unclear in the interviews what makes Down Syndrome significantly less desirable than any one of the single-gene anomalies detected through a full panel, although its prominence in prenatal testing may be in part due simply because of its relative ease of detection. Unlike Trisomy 13 and Trisomy 18, which are also screened for in most standard screenings, Down syndrome does not typically cause death in early childhood. It is possible, however, that Down syndrome's familiarity evokes a response in both prospective parents and professionals, creating conditions under

which detection and intervention feel necessary. This possibility, however, is beyond the scope of this dissertation and requires future research.

Uncertainty

Uncertainty played a key role in many informants' experiences of prenatal genetic testing. For some like Gene (p. parent), PGS/PGD was framed as mitigating some uncertainties, which was valuable to him given the inherent uncertainty of raising a child: *"We know there is going to be a whole host of curve balls and surprises of every different kind, of different scales. So, some of it we'll have a clue of what to expect and others we won't."* Abby (p. parent), on the other hand, resented the certainty with which PGS/PGD was presented to her and her partner, feeling their clinician presented testing as a definitive statement of fetal health. She commented,

> *"It's definitely presented as this is the genetic testing and if you pass, then you're going to have an okay baby. And never mind the billions of other things that could go astray during the DNA sequencing process. No, only three things ever go wrong with that, okay."*

Abby's irritation at this misrepresentation of PGS/PGD was echoed in many of the interviews conducted with genetic counselors, who often felt other medical professionals, such as obstetricians or office staff, misunderstood testing and passed that false certainty onto users. As Marcie (prof.) said when I inquired about prospective parents' (mis) understandings about screening and testing, *"We can't predict what's going to happen to your child, we can't predict for any child."* She and other interviewed professionals reinforced the uncertainty of testing and screening, adamant to resist and rebuff the misconceptions they reported encountering. It is notable that both interviewed prospective parents and professionals claimed

awareness of uncertainty, implicitly constructing a third category of misinformed or uniformed users.

Transferring Knowledge

All interviews conducted with prospective parents revealed a common experience of not having access to the information they desired or deemed the manner in which that information was presented was inadequate. This applied both to testing and screening and to pregnancy more broadly. By way of response, half of interviews with medical professionals also revealed how and when they decided to share information with prospective parents, sometimes based on assumptions about both the prospective parent and the broader social system in which they're embedded. For example, Julia (prof.) noted she only shares information about adoption when the prenatal diagnosis is Down syndrome, as she is personally familiar with an adoption agency that specializes in this; she states, *"for anything else, it's going to be 'do you want to continue, or do you want to terminate?'"* Additionally, several of these interviews called out other clinicians, particularly obstetricians, for their poor communication skills or lack of knowledge about PGS/PGD, which they felt exacerbated clinical communication issues.

Abby (p. parent) noted that she had a particularly difficult time getting her clinician to share potential next steps with her prior to receiving her testing results, making her feel underprepared to make decisions when the results did come in. She shared:

> *"I'm always like, okay, worst case scenario, what happens? And I need to have that idea in my head of, okay, what's going to happen if A, then what? Or if B, then what? That's something that I would've liked to know is what's going to happen if I get a positive result?"*

She supplemented the limited information from her clinician with independent research at home, which made her feel more capable of making decisions.

For others like Melanie (p. parent) and Patsy (p. parent), it was not *what* information was shared but *how* it was shared that made an impression. Melanie shared that her clinician first started asking her about her familial history of genetic conditions during her first appointment while conducting a pelvic exam, causing her to feel overwhelmed. Patsy received the results of her carrier testing in a PDF which was blazoned with misleading results like "Positive" and "Negative" while actually describing probabilities. While Patsy has a background in genetics that enabled her to navigate the results, she worried for others, stating *"I would kind of feel for someone else who got these PDFs that was looking through them and wasn't really sure what positive means and what that means for their health."* She added, *"It's probably scary."*

While Patsy and Abby's concerns both arise from inadequate interaction with a medical professional, Marcie's (prof.) stem from professional *overinvolvement*. Marcie, who had been practicing for forty years and had also served as director of a genetic counseling master's program, suggested that the genetic counselor aspiration to "non-directiveness," which is emphasized in training, guidance documents, and informational documents for prospective parents, is not really possible in the clinical setting. She emphasizes the cognitive dissonance between guidance, training, and the human reality of practice:

> *"You know, you can never – we do this sort of nonsense of "be a non-directive counselor", yeah, yeah, yeah, you know? [Laughs] And we strive for that, and it's good to do that, but yes there's a piece of yourself that has to go into this, otherwise, you're a robot."*

This statement is in tension with prospective parents' tendency to view clinicians as neutral producers of salient information. Marcie recognizes the human element of clinical work, which inherently shifts what information is communicated and in what way, in a way that was not evident in the experiences of prospective parents.

(Mis)Understanding Technology

In both sets of interviews, misconceptions about the technology itself produced tensions. Several prospective parents, like Melanie, felt pressure and anxiety when initially presented with the recommendation to visit a genetic counselor and receive a screening test, as she had little understanding of what it meant. Miriam, a genetic counselor, noted that many prospective parents came to see her next to no understanding of what genetic screening was: *"Some will say, 'Oh, well my OB just said it was an option, so here I am,'"* she recounted*, "and some are like, 'I really don't know what I'm here for.'"* She and the majority of the other medical professionals interviewed suggested that, due to the wide range of knowledge and experience they encountered, one of their primary roles was as a provider of information. Some, like Sabrina (prof.) and Pauline (prof.), felt these misconceptions were being perpetuated or exacerbated by commercial entities that produce genetic tests. Pauline, a genetic counselor, felt she didn't always have the ability to address misunderstandings because of the involvement of private companies:

> *"Some of [the misconceptions are] because it's not in our hands, it's in the hands of the privates, and they just say, 'Oh, everything's fine, it's perfect, you don't have to worry about anything.'"*

Sabrina, who has been at the forefront of research on genetic screening and therapy for many years, also attributes much of the misunderstandings about PGS/PGD to

the speed of rollout from commercial companies and misleading marketing. Of NIPT specifically, she said:

> "*And part of the problem, but part of the opportunity, was that the initial testing and the roll out of the testing was done by industry. Things would never have happened as fast as they did without the capacity of industry. But in retrospect, some of the marketing associated with the testing, particularly beginning when some of the companies said, 'This is as good as an amniocentesis,' led to the confusion that this was a diagnostic test. We've been trying to walk that back for many years now to say it's a screening test."*

A common theme among medical professionals was not the misconceptions among prospective parents, which they often felt could be easily addressed through time with a genetic counselor, but those of other medical professionals, which were perceived as more entrenched. For Theresa (prof.), who works as a medical liaison for a commercial company, the misconceptions that arise among clinicians come in part from the *"a little bit of heightened excitement and a little bit of, you know, that allure and that sexiness of DNA testing in general,"* leading to the perpetuation of misinformation in clinics. Sabrina (prof.) and Marcie (prof.) both argue that genetics needs to feature more prominently in medical school curricula. They note this is especially crucial given the increased routinization of genetic testing, as more and more prospective parents receive testing without ever interacting with a genetic counselor. Several professionals also noted a need to increase awareness and education among other medical and professional positions, especially clinic staff.

Triangulation with Documents

The majority of documents, regardless of source, suggested that Prenatal genetic screening and diagnosis provides knowledge that empowers prospective

parents to make decisions, resonating with the experiences of both interviewed prospective parents and medical professionals. Specifically, Prenatal genetic screening and diagnosis were presented as creating opportunities for "informed" decision-making, although in most cases failed to acknowledge that PGS/PGD creates new sets of decisions that otherwise would not otherwise need to be made. One professional society lists "empowerment" among the reasons people opt for genetic testing writ large, and commercial genetic testing companies pepper their websites and brochures with affirmations about the power of knowledge, such as "*before hello, it helps to know,*" "*the confidence you seek, with fewer risks*," and "*parents who know can make steps to prepare*." Very few address the anxiety of knowing "too much," as shown in the informant interviews above, although all resources heavily emphasize making decisions in concert with or at the recommendation of experts and professionals, suggesting that lay persons such as prospective parents need assistance in identifying what knowledge is appropriate for them to know. One professional society did allude to knowledge anxiety, noting *"some may choose not to get tested because they find the risk of getting a positive result too stressful, especially in cases when there is no treatment available."* However, there was very little in the documentation, especially from commercial manufacturers, to assist prospective parents in sorting through options, suggesting that decisions around what testing and screening to pursue were often made on their behalf in the clinic.

Uncertainty featured heavily in nearly all documentation reviewed. Often, this was in the form of liability statements from commercial companies. The phrase "*no test is perfect*," appeared verbatim on two commercial sites and one health system informational page, while others emphasized that screening and testing does not promise the "perfect" child. One reminds prospective parents that "*even when all the*

results of diagnostic testing are normal, all pregnancies still have approximately a 3-5% risk of birth defects." A professional society highlights uncertainty even further, emphasizing that genetics are not the only factor relevant in a fetus's health and development, stating "*It's also important to understand that genes don't determine everything."*

How and when knowledge was shared was obliquely referenced in the majority of documents, most of which emphasized the need for professional guidance or intervention when conducting PGS/PGD. As one hospital system stated, *"Talking to your doctor, a medical geneticist or a genetic counselor about what you will do with the results is an important step in the process of genetic testing."* Expert guidance, in this case, could also be read as gatekeeping: access to certain kinds of knowledge, including types of screening or testing and genetic counseling "*at your physician's direction*." The appearance of this gatekeeping in the documentation reaffirms the experiences of prospective parents, who felt inadequately informed about the screening and testing process. In terms of understanding and misunderstanding the technology itself, only a third of documents provided any detail on the processes and science behind PGS/PGD (and usually only in the context of non-invasive prenatal testing). Again, the importance of a clinical expert or guide was emphasized, with a professional society stating, *"Many couples do not realize what these tests may or may not tell them, so meeting with a genetic counselor prior to having cfDNA or other prenatal screening tests is highly recommended."* Overall, the documentation supported the interpretation of PGS/PGD as a provider of knowledge which served to empower prospective parents, as well as the experiences of prospective patients that the knowledge they have access to is filtered through the clinicians they encounter.

Table 2

Knowing and Not Knowing Theme Summary

Key Points: • Knowledge is simultaneously understood as both a pathway to empowerment and autonomous decision-making as well as potentially dangerous. Particularly, knowing too much about the genetic makeup of a potential child, or about one's own risk factors, may exacerbate anxiety and feelings of responsibility rather than mitigate them. • Prospective parents often asserted that they wished they had more information, or different information than what was being provided, while medical professionals often shared that they made assumptions about what type of knowledge was useful based on the kind of prospective parent they interpreted someone to be. • Understanding the purpose of testing, the meaning of results, and the technology itself emerged as a problem among users and professionals, often exacerbated by how and when communication happens or does not happen.

Subthemes (p. parent %/ prof. %):
• Knowledge as Empowerment (100%/75%)[6]
• Knowledge Anxiety (100%/50%)
  ○ Uncertainty (80%/50%)
• Transferring Knowledge (100%/50%)
  ○ (Mis)Understanding Technology (80%/88%)

Sample Quotes: "I just figured knowledge is power and we might as well know what we're dealing with." (Patsy, p. parent) "We can't predict what's going to happen to your child, we can't predict for any child." (Marcie, prof.) "I know they take your blood; I know they test your DNA. I have absolutely no idea of anything that's ... once the blood leaves my body, I have no idea what they do to it." (Abby, p. parent)

Theme 2: Responsible Parenthood

The second major theme that emerged from interviews with both prospective parents and medical professionals is the association between Prenatal genetic screening and diagnosis and the performance of responsible parenthood. Within this

[6] The first percentage is derived from the number of interviews with informants classified as *prospective parents* (Melanie, Rosalie, Patsy, Abby, and Gene) in which the theme appeared. The second percentage is derived from the number of interviews with *medical professionals* (Sabrina, Julia, Marcie, Pauline, Anton, Miriam, Carmen, and Theresa).

theme are several subthemes, including a perceived obligation to act, sometimes associated with perceptions of clinical authority, PGS/PGD as disrupting the joy of pregnancy, and blame and judgement of self and other prospective parents. Melanie (p. parent) exemplified the feelings of obligation she felt when presented with information about PGS/PGD. She felt that the imposition of PGS/PGD in her obstetrician appointments forced her into a position of responsibility that she anticipated having more time to prepare for:

> *"So, when they do all of this, are giving you so much risk stuff that it's like, as I'm about to be a new mom and you already make very tough decisions about your child when the child is just a fetus at that point. Like, I already had the maternal feelings, but I didn't have the feelings of like this as a child and this is what this means to make decisions. You think you're going to have to make those decisions when the baby is born. I had to making decisions when the baby was still in the womb."*

Some prospective parents, like Abby, explicitly discussed the often-conflicting pressure they felt to perform pregnancy – and neoliberal body management appropriately:

> *"I did feel kind of persuaded by what these people were saying,"* she shared, referring to the online pregnancy forums she participated in, *"But the people who were saying, 'Well, it doesn't matter,' I'm like, 'You're right. It doesn't matter to me either. And now I have to prove that.' …But then other people are saying, 'No, you have to prove that you want to be prepared for your baby and do everything you can before they get there.' And you're like, 'Oh yeah. I have to prove that I'm going to be the best mom and do everything I can.' So, it's all about proving how much you love your baby."*

Obligation to Act

For all prospective parents and half of medical clinicians, performing parenthood responsibly meant that because testing was available, they were obligated to pursue it. Not obtaining information, regardless of how it might or might not impact decision-making, was viewed as reckless. Abby (p. parent), whose religious beliefs initially dissuaded her from receiving NIPT, eventually changed her mind, stating, *"I had to prove that I'm going to do everything I can if it's going to be something wrong or whatever. Not wrong, that's a bad word, but you know what I mean."* She felt compelled to "prove" her fitness for motherhood, and implicitly linked preparedness with the knowledge accumulation that comes from genetic screening. Gene (p. parent) too felt an obligation to test, noting simply that *"Some stuff you want to take off the table. In terms of the ultimate goal of providing the start of a long, healthy, and happy life."* Interestingly, when pressed about what was screened for, he replied that he *"didn't know much of the ins and outs…you could test for other, more common issues. Down syndrome and the like."* His relative lack of knowledge about what it was that screening could "take off the table" reveals an implicit trust that clinical and commercial interests match his own and that there is no disagreement about what kinds of conditions or genetic anomalies interfere with a good quality of life. In all cases, prospective parents felt that if they decline testing, they would be jeopardizing the health of their future children.

Authority and Optionality

An additional dimension of the perceived obligation to pursue testing came from the authority or credibility of the medical professional recommending the procedure. While some prospective parents outright rejected the notion of feeling pressured to perform PGS/PGD – as Rosalie (p. parent) states, *"I didn't feel like it was a requirement"* – the majority of both prospective parents and professionals

alluded to the distinct power dynamic that emerges when a medical professional recommends a procedure. Marcie (prof.) most bluntly acknowledged this fact when discussing non-invasive prenatal testing specifically:

> *"It's coercive. 'Have this blood test done and it will tell you if your baby's okay.' Absolutely! They're not given a choice. No, that's not true, they do say, 'You can.' But without the explanation, it's your doctor saying, it's the authority saying. Why would you say no to your doctor?"*

Julia, Carmen, Miriam and Anton (all prof.) all felt their role as genetic counselors included reaffirming the optionality of screening and testing, as they all encountered prospective parents who interpreted their physician's recommendation as mandatory. As Carmen shared, prospective parents often enter into conversation with a genetic counselor suspiciously:

> *"I do think that there's a good number of people that just assume that if you talk to a genetic counselor, we're going to tell you to terminate your baby. You know, it's because there's something wrong and we're going to tell you to terminate."*

She later describes how she approaches these difficult interactions, noting that re-affirming the prospective parent's autonomy often serves to establish a working relationship: *"I've had other patients that seem like they've warmed up to me as soon as I told them that these testing options were, in fact, optional."* Importantly, informants who noted this phenomenon often suggested it was rooted in poor clinical communication from the clinician— such as an obstetrician— rather than a misunderstanding on the part of the prospective parent. In fact, in many instances, genetic counselors articulated a somewhat combative relationship with

other clinicians, aligning themselves both implicitly and explicitly with the desires and well-being of the prospective parent. Prospective parents, however, did not report this same relationship.

Disrupting Joy[7]

In addition to a sense of obligation to pursue screening in order to perform parenthood responsibly, the majority of prospective parents also noted that the imposition of screening and testing, a topic often broached during their first obstetrician appointment, created additional anxiety, disrupted their ability to celebrate their pregnancy, or alienated them from them from their pregnancy, creating a distinct "before" and "after" period when they could accept the reality of their future child. This latter experience is reminiscent of what Barbara Katz Rothman (1986) dubs a "tentative pregnancy," where pregnant people may have difficulty fully accepting their pregnancy until screening and testing results return. Rosalie's experience resonated with that of Rothman's prospective parents, despite over 30 years and rapid advancements in testing technologies between the two studies:

> *"The day that I got the genetic test results,"* she said, *"it sort of allowed me to own it. And really feel like a pregnant woman who is having a baby. Like a future mother. I hadn't really – I think I sort of didn't allow myself to integrate*

[7] While this theme was only identified in interviews with prospective parents, feedback from one genetic counselor informant suggests this theme resonates with professionals as well. She writes: "I very frequently share my experience (when educating other providers, usually) that giving a patient 'bad news' (at any point on the spectrum from there may be a problem/background risk to we know there is a problem/diagnosis) creates a tremendous disruption in the pregnancy experience. One that can really NEVER be resolved. That dose of reality (again, wherever it falls on the spectrum) against the expectation is shocking. I did this countless time to my patients. The best counselor in the world can't avoid the disruption, but there are certainly ways to do it better."

that identity because I was so afraid that something bad was going to happen that I was going to have to terminate or, you know, miscarry or something awful or some awful result. So, for me, just emotionally, that was sort of like a milestone."

Melanie (p. parent), who received a referral to a genetic counselor during her first obstetrician visit (and in fact had the topic broached in the middle of a pelvic exam). When I asked about that experience, she said:

"It doesn't feel good. It just got very clinical at that point. It wasn't like - I mean we kind of celebrated, you know, my husband and I like at the time like celebrating when we saw the positive but we're also like let's not get our hopes up...So we didn't really get to celebrate because all of us sudden all these questions got brought to us, you know, whatever."

As quoted earlier in this chapter, Melanie, who had previous reproductive issues that made her unsure she could even conceive, felt she was immediately thrust into this position to make life-altering decisions around her fetus's health before she even got an opportunity to celebrate its existence.

Rosalie, Melanie, and Abby (all p. parents) all also shared that they felt an obligation to shield others in their lives from the anxiety and stress they experienced during their pregnancy, leading to feelings of isolation. Only Rosalie suggested that her anxiety was directly related to genetic testing, however. *"I was afraid to tell anyone because if God forbid something awful were to come of it, I didn't want to have to explain to so many people that something terrible happened when they were so excited,"* she shared. Her feelings were also exacerbated by guilt and

responsibility, which she recognized emerged from her unique, gendered position as the carrier of the pregnancy.

> *"So, I was lonely, and it sucked and because my partner wasn't really worried about that kind of stuff, I kind of felt like I was on my own in it…Yeah, you know, I think people really want to be excited…it just felt like, you know, I don't want him to be super stoked that I'm having a baby and then me just rain on the whole parade and say that I'm so afraid of all these things."*

Part of this impulse to shield others from anxiety and stress seemed to emerge, at least for Melanie and Abby, from perceived judgement from others who suggested they were not sufficiently grateful for their pregnancies: *"I've been told that I need to be more grateful,"* Melanie recalled, referring to when she would express to others how difficult her pregnancy was, *"that it's not fair for me to be so upset when there's other people who can't have kids."* The implication that pregnant people may not feel welcome to express their concerns or anxieties suggests a form of epistemic invalidation that delegitimizes the experiences of pregnant people who have not fulfilled the impossible standard of an ideal pregnancy. When I asked Abby what a healthy pregnancy meant to her, she recounted the difficulty of comparing her own pregnancy, which involved fertility treatments prior to conception, with what she dubs a "healthy" pregnancy:

> *"I think of a healthy pregnancy is when you just get pregnant the way you're supposed to and then things develop how they're supposed to, and you never have complications…It's the dream world of having a baby."*

Here, she equates "healthy" as a nearly unattainable ideal, positioning not only her pregnancy but nearly every other pregnancy as pathologized. More broadly,

medical intervention of almost any kind is seen as disrupting the "naturalness" of pregnancy, equating its medicalization with "unhealthiness." Rosalie and Melanie also self-pathologized their pregnancies (Rosalie's as geriatric, Melanie's as marred by her own health complications). This pathologization reinforced feelings of guilt and shame as they fell short of an unattainable de-medicalized ideal.

Blame and Judgement

A common experience among prospective parents linked to their perceptions of responsible parenthood were feelings of blame, guilt, and judgement, either directed at themselves or other prospective parents. Rosalie, whose pregnancy was unplanned, admitted, *"I haven't always treated my body the best, and there was a lot of, you know, guilt that comes with, with worrying about what your life decisions might translate to your baby."* She was overwhelmed by a preemptive guilt as she waited for the results of her prenatal genetic testing:

> *"To think, okay now that I've treated my body so poorly for so long, if something is wrong with this baby it's my fault…that something that I had done in the past would already make this kid's life worse or harder or impossible, right?"*

Abby (p. parent) expressed judgement of other prospective parents who used access to the same information, PGS/PGD results, in ways that were vastly different to what she herself would have done. She recalled reading another prospective parent's decision to terminate a pregnancy that had a positive diagnosis for a genetic disorder on an online pregnancy forum while she was struggling to conceive:

> *"I guess it's hard when you see it. Because I'm like, 'I wanted that baby.' It's not even my baby…I think it's just hard for me, especially because of what I went through. I want these babies so badly, no matter what, that ... I don't*

want to say I feel judgmental, but I kind of do. I'm just angered by it, I guess, because I'm like, why would you be proud of [termination]?"

Julia, a genetic counselor, also struggled with recognizing and withholding judgement of others, particularly when her personal beliefs and her professional obligations to be a "non-directive counselor" were at odds:

"You have to buy into [non-directiveness]. You really do. But you really have to appreciate that you have to let people do what they're comfortable doing. And it really doesn't have anything to do with 'what you would do, if…' And over the years, people have made decisions that I would never do if it was me. Never, ever. But it's not me."

Taken together, these examples of judgement of others reveal that each informant is operating with an implicit framework about the "correct" use of the knowledge acquired from PGS/PGD, and that these frameworks are often at odds with one another.

Triangulation with Documents

All the reviewed documentation in some way touched on the responsibility of the prospective parent, whether that is in their responsibility to adequately prepare for pregnancy and child-rearing, their responsibility for communicating with their family members, or their responsibility to request a specific brand of PGS/PGD from their clinician. Primarily, PGS/PGD was figured as a necessary step for responsible parenthood. As one commercial manufacturer's website stated: *"Knowing the relevant genetic information about your pregnancy is one of the first steps in planning for a happy and healthy family."* Supporting the analysis of interviews, documentation was also embedded with rhetoric that prospective parents had an obligation to act in the pursuit of knowledge. Screening was almost universally

described in terms of providing knowledge to prepare for a child with a disability, with results being described as "*actionable*" or "*of clinical significance*," and next steps often described in terms of finding specialists and establishing a care plan. *"Having information about these chromosomal changes before birth,"* one commercial website reads, *"can help ensure your baby receives the proper and necessary support."* Only one third of the sources reviewed mentioned termination as an option following testing at all, and of those, it was often described obliquely as an *"irreversible"* pregnancy management decision. The emphasis on PGS/PGD as essential for preparing for the birth of a non-normative child encodes the responsibility of the parent – without testing, one is not providing appropriate care and support. Here, choice (including the choice to terminate) is minimized in favor of a discourse of personal responsibility toward a future child. It should be noted that the majority of documents were directed specifically at women, reinforcing a gendered dimension of responsible parenthood echoed in some interviews. Further, all sources used the term *"baby"* or *"unborn baby"* as opposed to fetus when discussing PGS/PGD, suggesting the existence of a parental relationship prior to birth, reaffirming parental responsibility.[8] The choice of this emotive language in official documents, especially those sources by prospective parents for decision-making, requires a deeper analysis.

[8] Feedback from one informant suggests the use of the terms "baby" and "child" rather than "fetus" may be less intentional than this analysis suggests. Her full comment reads: "I appreciate the observation of the use of 'baby' rather than 'fetus' in commercial materials and I would like to suggest that the choice is not thoughtful, but rather restricted given the language requirements for public information. 'Fetus' is considered too-advanced of a word for medical writing, and therefore is often changed to 'baby'. You will find this in many patient directed reading materials from non-industry organizations as well." She also notes these restrictions may limit the appearance of termination-related information as well, depending on location.

Elsewhere, however, the optionality of testing was emphasized, although the juxtaposition with the above framing should be noted. As one source's FAQs stated, *"All testing is optional. The decision to accept or decline screening is a personal choice and should be one you discuss with your healthcare provider."* The majority of documentation, particularly those coming from commercial testing companies, implied prospective parents have significant choice over the *types* of testing they have access to, often encouraging them to request one specific company's test over another's. However, the majority of prospective parents did not even know which company they were receiving testing from until after they received their results. Rather, tests were chosen by the clinics they attended, with little attention paid, in the clinical interaction, to the details of the private companies involved. Further, the routinization of PGS/PGD was mentioned in several sources, such as this professional society informational page, which reads *"Both screening and diagnostic testing are offered to all pregnant women."* As discussed above, the routinization of procedures such as PGS/PGD inherently impact their perceived optionality.

Another aspect of responsible parenthood that featured in much of the documentation was understanding and weighing the risks of prenatal genetic testing. Almost universally, commercial companies promoted non-invasive testing, emphasizing the physical risk of miscarriage with other testing methods (such as amniocentesis) and describing NIPT as *"simple"* and safe, with no physical risk to *"mother and child,"* to use the language from one source. Only two of the sources reviewed, a health system and a professional society, suggested there are non-physical risks associated with genetic testing that may need to be considered. As the health system's informational page noted, *"Genetic testing can have emotional, social and financial risks as well."* This source also briefly addressed discrimination

and stigma associated with genetic conditions, as well as legal recourse under the Genetic Information Non-Disclosure Act (GINA). While documentation addressed some of the elements of responsible parenthood addressed in the interviews, much of the personal and emotional difficulties experienced by prospective parents, including overwhelming clinical experiences, feelings of guilt and judgment, and testing disrupting their joy in pregnancy, were predictably absent from these documents.

Table 3

Responsible Parenthood Theme Summary

Key Points: • For many prospective parents, testing and screening was seen as an obligatory expression of responsibility. Professionals conceded that even though they insist testing in optional, many prospective parents feel coerced or beholden to the authority of their clinicians. • The introduction of the decision to screen and test for genetic anomalies and the often highly medicalized interactions with clinicians at the beginning of pregnancy are in some cases perceived as disrupting the prospective parents' joy. In other cases, the prospective parent shields their anxieties about testing from others in their lives, such as partners and family members, so as to not disrupt their joy in the pregnancy. • A common feeling among prospective parents was self-blame (often preemptive) that something would go wrong in the pregnancy, including genetic anomalies. Some further extended that blame of prospective parents onto others who made decisions that ran counter to their own schema.
Subthemes: • Obligation to Act (100%/50%)   ○ Authority and Optionality (60%/75%) • Disrupting Joy (80%/0%) • Blame and Judgement (80%/13%)
Sample Quotes: "Some stuff you want to take off the table. In terms of the ultimate goal of providing the start of a long healthy and happy life." (Gene, p. parent) "So, they're traveling far differences to get this quote-unquote better test that their, you know, doctors are recommending because they're over the age of 35, and so they feel obligated, because of course, you have to do what's best 'cause it's your unborn baby." (Theresa, prof.) "I was afraid to tell anyone because if God forbid something awful were to come of it, I didn't want to have to explain to so many people that something terrible

happened when they were so excited. So, I was lonely, and it sucked." (Rosalie, p. parent)

Theme 3: Defining Disability

The final theme that emerged in the vast majority of interviews involved how disability came to be understood and defined in the context of PGS/PGD. The meaning of disability was established along two binaries: medical/social and tragedy/inspiration. In the majority of professional interviews, there was a stark distinction made between the medical and social dimensions of disability, with the majority relying heavily on physiological and medicalized frameworks to discuss disabilities resulting from genetic abnormalities. Secondly, both parents and medical professionals discussed disability – particularly disabled children – in two specific and contrasting tenors: as tragedies or as valuable or inspirational lessons for able-bodied parents and societies. Finally, medical professionals also discussed a sometimes strained but critical relationship with disability advocacy communities, who were viewed as providing essential context to genetic diagnosis, even as there were very few formal pathways to connect prospective parents to them. Three prospective parents also discussed connections with disability communities (through personal connections rather than facilitated by medical professionals), which profoundly informed how they thought about disability and made decisions around screening and pregnancy management.

This theme also raised questions about *who* does the defining when discussing disability in these contexts, linking it in important ways to questions of knowledge production, autonomy, and authority. As Anton (prof.) questions when discussing whether to bring fetuses with life-threatening genetic conditions to term or to perform therapeutic treatments on such newborns, "*Well, a lot of people would say*

no, we shouldn't do that because these babies don't have a real high quality of life, but then who decides what's the quality of life?" How disability becomes defined, and who does the defining are essential questions to understanding how decisions get made about the worth and value of potential children with genetic conditions.

The Medical and Social

Both prospective parents and medical professionals made a distinction between medical information about disability – such as risks for and the presence of physiological differences – and social information about disability – such as a potential child's ability to learn, develop, and their potential for independence. In some cases, this latter category included potential mental health status, distinguishing it from physical health and removing it from the purview of medical professionals. Professionals almost universally noted that they tended to share the biological or physiological dimensions of disability, even as prospective parents sought information about the social dimensions when making their decisions. Julia (prof.) spoke directly to the desires of prospective parents, sharing,

> *"I think, you know, overall, the impression I get from patients is what they wanna hear is, you know, might the child be able to live and work on their own one day? Is the child going to need help long-term? Or, is the child that's not going to make it out of infancy."*

Abby (p. parent) had a different opinion regarding what prospective parents wanted to know or how they perceived their pregnancies, particularly in the context of genetic diagnoses:

> *"When you're pregnant, you don't know your baby as a person yet. So, when you get a diagnosis, it's easier, I think, to just think of them as just the diagnosis, because they're not people."*

Sabrina (prof.) also noted prospective parents' tendency or ability to abstract their pregnancy in a way they couldn't with a child. Rather than making it easier to terminate, as Abby was suggesting, Sabrina cites a study (de Wert, Dondorp, and Bianchi, 2017) suggesting that this abstraction will eventually enable prospective parents to make decisions about in utero therapeutic options:

> *"They [prospective parents in the study] stated that it was important that their unborn child didn't yet have a personality. Once a child was born, that child (he or she) existed as they were, and they loved them for who they were. But when the child was still in utero, they felt that treatment was OK. They wanted to do whatever they could to help the child because they really didn't know what the child would be like. I think that it was very interesting that that distinction was made."*

Regardless, medical professionals including Anton, Miriam, and Marcie all shared that they tended to primarily or exclusively present the physiological dimensions of a genetic diagnosis when speaking to prospective patients. Often, these explanations were justified by an assumption that the physiological dimensions of a genetic condition, even offered in the form of probabilities, were more certain or tangible than social outcomes. As Anton said,

> *"The hard thing is like, social context. It may [be] your baby's going to get a heart defect because this is a very tangible – this is the next thing; you do heart surgery. Versus, they might develop a mental health issue, schizophrenia, at some point, that's – then you're like on pins and needles, like, are they gonna get this, and when are they gonna get that? That's a lot harder to discuss prenatally because it's not tangible, there's not a next step, it's kind of a wait and see and hope that it doesn't happen type of thing."*

And yet, Anton simultaneously states a responsibility to share as much information as possible with prospective parents in the pursuit of informed decision-making. What information gets deemed essential for "informed decision-making" appears ad hoc and heavily favors medicalized understandings of disability.

Favoring medicalized understandings of disability may also emerge from a lack of interaction with disabled people, or interactions that primarily or solely take place in medicalized or institutionalized settings. Carmen revealed her orientation to disability was not rooted in extensive experience, stating

> *"I think talking to the genetic counselor, you know, me talking to the patient is – while I'm very experienced with what these conditions are, genetically and, you know, in a book. On paper. It's not the same as somebody who actually has it. A family who actually has it."*

She continued by sharing that a few personal and professional encounters with individuals with genetic conditions changed her perspective: *"You see the humanity in it a lot more than you do by just reading,"* she shared, *"You know, points in a book about what the features of the condition are."* Others shared that their understandings of disability often came from rotations in general genetics units, brief encounters in institutionalized settings like day services for disabled adults, or other situations in which disability is pathologized and treated as a medical condition.

Further, several medical professionals noted that they felt they had a professional obligation to share the biological or physiological risks associated with a genetic condition. Julia explicitly addressed this in her interview, noting that she sometimes is critiqued as primarily focusing on the health risks associated with a genetic condition:

"But, you know, some of the feedback I get as well, particularly with Down Syndrome is, It was all doom and gloom. And nobody told me how wonderful it could be to raise a child that has Down Syndrome.' And while I am empathetic to that, my professional opinion is if I don't tell you the worst of it, I have not done my job, and from a litigation perspective, it would be particularly dangerous for me. So, I try not to be all doom and gloom, I try to be balanced, but it is my personal and professional opinion that we've got to get some of the bad news out there in addition to some of the, you know, 'families can be happy with kids with this condition' stuff out there as well."

The privileging of the physiological conditions of disability at the expense of sharing knowledge about social and political realities ultimately undermines the rhetoric of autonomy and informed consent that undergirds PGS/PGD. Further, the frustration of prospective parents at this partial knowledge and the reliance on external sources such as online forums and parent support groups exposes a resistance to the assumptions of medical professionals about what information is most salient during pregnancy management.

Tragedy or Inspiration

The second binary that emerged regarding the meaning of disability was one that constructed disability as either a personal or familial tragedy, or an inspiration, lesson, or gift to an able-bodied family or community. The former rendering of disability was often found in negatively connotated language rather than outright statements of beliefs. For example, Rosalie, when discussing anxiety around her testing results, said, *"There is a definite before and after to me…because of the anxieties I had around all that kind of* ***high risk, horrible stuff****."* Gene describes feeling grateful upon learning the genetic screening did not raise any concerns for

genetic conditions, admitting *"The **devastation it can wreck on households** and oh I can't even... financial, emotional, I can't even fathom some of this."* Carmen, when discussing disability with prospective patients, noted *"I try obviously to be gentle with it [laughs], you know, when I'm talking the social aspects of it because they can be, depending on the condition**, very devastating**."* Miriam notes that while she often encounters prospective parents with a positive understanding of genetic conditions, especially Down syndrome, she feels it necessary to reorient them to recognize the potential negative outcomes:

> *"And I will say, 'Yeah, I'm glad to hear you had some pleasant interactions with people with Down syndrome, there are definitely lots of people with Down syndrome out there who have a great life. They are able to do these jobs that you see them doing, and I'm – they're smiling and whatnot.' And I say, 'But unfortunately that is not the case for everybody.'"*

As Julia expressed above, Miriam also felt a professional obligation to present disability as potentially difficult in the pursuit of a balanced presentation of facts.

Other professionals like Marcie recognized that historically medical professionals have been complicit in constructing a universally negative picture of disability, and she noted recent adjustments to training and practice, particularly in the rhetoric used to discuss disability. For example, she shared that she personally no longer offers condolences when offering a genetic diagnosis:

"I used to. I used to. And it – I would say it was culturally appropriate then. It's no longer appropriate. So, we don't. We don't say that anymore. We sometimes say, 'I'm sorry your test result didn't turn out the way you wanted,' because that is. But not, 'I'm sorry your baby has Down syndrome.'"

Even the above statement, however, assumes prospective parents' investment in able-bodiedness. The conscious recognition of how discourse shapes perceptions was not singular to Marcie but was not found in the majority of interviews.

On the opposite end of this constructed binary about the meaning of disability was the perception that disability was a valuable addition to a community. As Theresa (prof.) shared, when she encountered people resistant to genetic counseling because of its potentially eugenic applications, she frames the conversation this way:

> *"[Make] sure that people are on the same page about, right, children with Down Syndrome are enriching, they enrich our lives, and they are beautiful, and they, um, your life is better because of your loved one with a disability. And yes, there is value, there is not a burden, you know what I mean? You just want to clarify that*."

This statement and others are examples of what disability activist Stella Young dubbed "inspiration porn" (Young, 2012), a pervasive and objectifying perspective that disability exists to teach able-bodied people a lesson about gratitude, tenacity, or humanity. Disabled children's value, in this construction, come from their ability to enrich the lives of others, not from their intrinsic being. Anton (prof.) shared a similar perspective when discussing the potential of PGS/PGD to eliminate certain kinds of people from the world:

> *"Well, you might say that's a good thing, but what do you learn from someone with CF [cystic fibrosis]? You can learn a lot of things from them. You can learn a lot about human nature, and um, overcoming great obstacles and difficult things. I mean, they teach us a lot about who we are as – people who go through different struggles teach us a lot. So, I'm afraid we'll become boring."*

Again, the value of disability emerges from what a disabled person can teach able-bodied people, centering able-bodied rather than disabled experiences and desires.

Not all perspectives on disability as valuable were inflected with inspiration porn, however. As Patsy (p. parent) noted, she resented the implication that disability or ill health immediately invalidated someone's worth:

> *"I guess they don't like the connotation that if you're not healthy, you're not able to, you know, make a contribution to society or you know have a meaningful full life. I guess that's kind of the big picture."*

Patsy, Melanie, and Abby (all p. parents) all shared similar perspectives on the value of people with disabilities, in part because each had personal and professional relationships with disabled people. Abby, in particular, voiced an opinion about value that directly resists the idea revealed above that disabled people must somehow benefit able-bodied people in order to be valuable. She rejects the stark dichotomy drawn between disabled and able-bodied:

> *"It's still a human, it's still a person. Down syndrome, trisomy, whatever ... they're still a human person so why are you going to say they're now less important because they had that diagnosis? I think maybe that's an issue that I have with it, too."*

Disability Communities

Despite their role in identifying disability – and in some cases, assisting in bringing to term a pregnancy resulting in a disabled child – the interviewed professionals related complex orientations toward existing disability communities. Their linkages with such communities were often tenuous, as these communities are often both vocal criticizers of genetic counseling and the primary resource available

to prospective parents. The majority of clinical professionals interviewed claimed they refer patients to disability communities, though these were often informal recommendations that the counselors were not able to follow up with. Pauline, Marcie, Julia, and Theresa (all prof.) each also cited somewhat oppositional relationships with certain disability communities. As Julia said, there is a lot of *"animosity in feeling like there's seek-and-destroy."* All professional interviewees recognized and refuted this criticism, attempting to stabilize their position as patient advocates.

Sabrina (prof.) noted that a large part of her job, as director of a major research center, was to do advocacy work for (and with) disability communities, rebuffing the idea that scientists and medical professionals are not are not deeply engrained in disability communities. *"It's kind of the opposite of being detached,"* she shared, noting that a full third of her personal lab staff was the sibling of a person with Down syndrome.

Theresa (prof.) directly referenced the public's eugenic fears, a theme that occurred in the majority of interviews with medical professionals.

> *"I mean it's like a little dust storm, like it kind of gets unsettled, and then it settles, and then it comes unsettled. But the whole conversation about, 'what's the purpose of screening and is this, like, bordering on eugenics and is this going to eventually lead to the elimination of the disability community and what's so wrong with Down Syndrome? Cause why are you trying to get rid of us and why are you so focused on Down Syndrome, we're pretty great?'"*

She continues by acknowledging the importance of that conversation, but ultimately feeling at odds with the community:

> *"And I think the question, 'Why Down Syndrome?' is an important one. And I think that that's reasonable to have a conversation about. Um, and I am okay with the fact that people are talking about the impact to the community – the Down Syndrome community or the disability community – um, but I don't necessarily agree with their predictions. Um, and I don't think that those are coming to fruition. But you know what? Let's talk about it. I mean, it's a very good thing to talk about."*

This perceived or real hostility with disability communities threatens genetic counselors' and prospective parents' access to disability organizations, cited in several interviews as one of the few resources available to prospective patients outside of clinicians themselves. Therefore, this animosity risks further essentializing disability to its genetic components by cutting prospective parents from the embodied and experiential expertise of disabled communities in favor of medical expertise.

Triangulation with Documents

Disability, beyond lists of names of specific diagnosable conditions and brief descriptions of their physiological characteristics, was largely absent from the documentation. While preparation for a disabled child was often brandished as the justification for testing, not one of the stories of real users featured in the analyzed documents included the birth of a disabled child— or even the receipt of an abnormal testing result. Down syndrome was often presented as an example of a genetic condition, although very little information about what Down syndrome was, beyond trisomy of the 21st chromosome, was presented. Only one commercial company alluded to the fact that babies born with Down syndrome eventually become adults with Down syndrome, noting simply that *"babies with Down syndrome often lead*

healthy and productive lives." Others, however, specifically conflated health with genetic normalcy, noting *"healthy people usually have 23 pairs of chromosomes."* Such a framing immediately excludes anyone with aneuploidy from the category of "healthy." Some sources opted for more neutrally connoted terms, referring to differences in genetic makeup as *"variants"* or *"conditions"* as opposed to abnormalities or disabilities. One commercial site described Down syndrome as *"associated with differences in physical and intellectual development."* These descriptions varied widely in their connotative meanings, however. Another commercial site noted that *"chromosomal abnormalities can have profound consequences,"* while still a third used outdated and connotatively negative terminology such as *"mental retardation"* to describe genetic conditions. Unlike the interviews, there were no sources that presented disability as inspirational or valuable, in objectifying terms or otherwise.

There were scant references to disability communities in any of the sources. One commercial company, when providing an overview of the common conditions it screens for, provides a list of resources that included disability advocacy communities, but these were listed without distinction alongside medical resources. Others recommended seeking out support groups, advocacy organizations, or social workers upon diagnosis, but no further resources were provided. One a single resource, an informational page provided by the US federal government, acknowledged the tensions between clinicians providing genetic screening and testing and disability communities, a major theme among interviewed medical professionals. The site reads that *"some advocates…question whether conditions like Down syndrome might eventually be eliminated from the population or whether parents who choose to have children with trisomies will face future discrimination."* It

continues by acknowledging other potential ethical dilemmas, including sex-selective abortions. In general, there was a lack of acknowledgement among documentation of the existence of disability advocacy and support organizations. Instead, prospective parents were encouraged to seek out more information primarily from their physicians and genetic counselors, thus reinforcing their position of expertise and delegitimizing the expertise of disabled communities.

Table 4

Defining Disability Theme Summary

Key Points:

- Both prospective parents and medical professionals made a distinction between medical and social information about disability, with professionals sometimes suggesting that medical information was more tangible and predictable, and therefore more often what they presented, even though prospective parents often desired information about the social dimensions of disability.
- In some cases, despite explicit insistence on neutrality as clinicians, the medical professionals often described disability and/or genetic abnormality in negatively connotated terms. Prospective parents also often discussed disability in terms of tragedy or devastation.
- Some informants among both the prospective parents and professionals groups had awareness or experiences among disability communities, which impacted their perceptions of the potential for genetic anomalies. Several medical professionals also noted strained, but necessary relationships with disability communities, alluding to the knowledge and experience these groups can communicate with prospective parents.

Subthemes:

- Medical or Social (20%/88%)
- Tragedy or Inspiration (80%/100%)
- Disability Communities (60%/75%)

Sample Quotes:

"But when you're pregnant, you don't know your baby as a person yet. So, when you get a diagnosis, it's easier, I think, to just think of them as just the diagnosis, because they're not people." (Abby, p. parent)

"I'm familiar with that, you know, world of disabilities because I've worked with all of those. And so, it doesn't scare me, it doesn't change how I am going to feel about my kid. It just means that down the line I know there's other things that will come into play. So, to me that wasn't, that wasn't like a motivation to do anything, right?" (Melanie, p. parent)

"So, I have had numerous people say, 'Oh, people with Down syndrome are just so happy and they're smiling all the time, and I just think they're adorable.' And I will

say, 'Yeah, I'm glad to hear you had some pleasant interactions with people with Down syndrome, there are definitely lots of people with Down syndrome out there who have a great life. They are able to do these jobs that you see them doing, and I'm – they're smiling and whatnot.' And I say, 'But unfortunately that is not the case for everybody.'" (Miriam, prof.)

Conclusion

In this chapter, I have summarized the descriptive findings and inductive analysis of semi-structured qualitative interviews with prospective parents who have received Prenatal genetic screening and diagnosis, and medical professionals including genetic counselors and a medical geneticist. Findings were organized into three themes and nine subthemes broadly addressing the knowledge production, the construction of personal responsibility, and the meaning of disability in prenatal genetic testing and screening. The first theme, Knowing and Not Knowing addressed how knowledge was understood in the decision to pursue genetic testing as both a pathway to empowerment and a source of anxiety. Additionally, this theme addressed how knowledge was or wasn't transferred between prospective parents and clinicians, as well as how the technology itself was understood in clinical settings. The second theme, Responsible Parenthood, addressed feelings of obligation to pursue testing in order to make responsible, appropriate and "informed" decisions around pregnancy management. This theme also presented prospective parents' feelings of guilt, resentment, or blame when considering or pursuing testing. The final theme, the Meaning of Disability, broadly addressed two binaries present in interviews with both prospective parents and medical professionals. The first was the distinction between the medical and social dimensions of disability, with the majority of professionals preferring physiological descriptions as opposed to addressing the social aspects of living with disability. The second was the interpretation of a child with a disability as either a tragedy or an inspiration, both of which further the

objectification of disabled bodyminds. Finally, this theme touched on the strained but essential relationships between medical communities and disability organizations.

While medical professionals rely on biomedical or physiological definitions, obfuscating the social, embodied, and experiential dimensions of disability, prospective parents are expected to make "fully informed" autonomous decisions in contexts in which they express lacking crucial information. Further, the assumptions made about what knowledge is necessary or relevant for prospective parents to make decisions about pregnancy management represent a form of gatekeeping. Medical professionals have established an authority to determine what a person should know (and what is "too much" knowledge). This arrangement creates conditions under which undesirable pregnancy outcomes are naturalized. In other words, the conditions detected through recommended genetic screens and tests are assumed to be undesirable, regardless of the prospective parents actual understanding of the condition or the technology. Additionally, the complicated relationship between medical authority and perceptions of personal, parental, and social responsibility come to bear on the decision to pursue testing. Additional research is necessary to better understand the personal experience of screening and testing for prospective parents who receive abnormal results. Ultimately, these findings indicate several sites of tension in the PGS/PGD apparatus, from disjunctions in how, when, and to whom information is communicated, to the perceived obligatory nature of screening at odds with explicit statements of optionality and agency. These tensions will be explored in greater detail in the Chapter 7.

CHAPTER 5

"IT WAS LIKE HE HAD TO SOMEHOW CONQUER MY BRAIN:" DEEP BRAIN STIMULATION

Introduction

In this chapter, I will present descriptive findings and inductive analysis of interviews with users of deep brain stimulation and their families. I will also present findings from an analysis of user-directed guidance documents including FAQs, hospital guidance documents and informational brochures from hospital systems and neurological centers as a means of triangulation. I relate the design, use, and discourse around deep brain stimulation to individualized understandings of disability and neoliberal ableistic paradigms. The understanding and operationalization of disability as a purely physiological phenomenon also creates and exacerbates tensions between medical authority and experiential or embodied knowledge. Three major thematic areas, each with subthemes, are presented below. The first theme, Invasion and Control, directly addresses the first research question, drawing a distinct connection between the technology and experience and understanding of disability. The remaining themes, Self-Responsibility and Epistemic Authority and (In)Validation both primarily speak to the second research question about the construction and enactment of accountability. Themes and subthemes are summarized in tables at the end of each thematic section.

A deep brain stimulator is a surgical implant that delivers electrical impulses to targeted areas of the brain to manage symptoms of neurological and psychiatric conditions including Parkinson's disease, dystonia, epilepsy, essential tremor, major depressive disorder, and chronic pain, among others. The process by which DBS is implanted includes the creation of a 3-dimensional image, CT, or MRI so that the placement of the electrodes can be decided. A small hole is then drilled in the skull

and the electrodes, also known as leads, placed. During surgery, the user is typically awake, and the electrodes may be tested through a series of exercises or questions posed to users to confirm placement (Pluta, Perazza and Golub, 2011). The leads are then connected to wires which run to an internal pulse generator (IPG) implanted in the chest (AANS, 2019). For Parkinson's disease, the electrodes are most often placed in the subthalamic nucleus or the globus pallidus, while in the essential tremor and epilepsy, they are most often placed in the thalamus (Pluta, Perazza and Golub, 2011). Some people implant electrodes on one side of the brain, while others receive two implants (powered by either one or two IPG). While the exact mechanism by which DBS impacts neurological function is not known, the American Association of Neurological Surgeons (AANS) states "DBS is presumed to help modulate dysfunctional circuits in the brain so that the brain can function more effectively. This is accomplished by sending continuous electrical signals to specific target areas of the brain, which block impulses that cause neurological dysfunctions" (AANS, 2019, para 2). The rather unclear mechanism by which DBS works contributes to some uncertainty about whether DBS will improve target symptoms in any given person. Following implantation, the user then works with a care team to program the device, a process that ranges from several months to much longer. Throughout this chapter, both the *process* of implanting and programming the deep brain stimulator and the stimulator itself will be referred to as DBS.

The majority of available research on DBS has been conducted with people with Parkinson's disease. In a recent metanalysis of eight studies conducted in the United Kingdom with 1,189 participants, DBS for advanced Parkinson's disease was reported to provide improved outcomes in terms of "mental status, behavior, mood (UPDRS-I), ADLs [activities of daily living] (UPDRS-II), motor function (UPDRS-III),

and complications from therapy (UPDRS-IV) in PD users" as compared to the best available medical therapy (Brastos, Karponis and Saleh, 2018, 15). Hitti and colleagues (2019) found during a retrospective analysis of 320 users that while DBS does not halt the progression of Parkinson's, for many it provides symptomatic relief (and user satisfaction) for at least 10 years. Other recent research with 611 people with DBS and 611 people with medically-managed Parkinson's suggests DBS may be linked to longer survival rates as compared to those who did not receive it (Weaver et al, 2017).

There is relatively little information available about the potential side effects of DBS, in part because they are extremely difficult to predict from user to user. Additionally, Christen and colleagues (2012) reported side effects from DBS may be similar to those experienced when taking alternative therapeutic approaches such as medication and "the evaluation of some side effects differs significantly between patients, their relatives, and physicians" (37). Nonetheless, the AANS reports various potential side effects, ranging from those encountered due to the invasive surgical nature of the implant to those emerging from the placement of the leads themselves. Regarding the former, the AANS reports there is a 2-3% chance of brain hemorrhage (potentially leading to paralysis, stroke, or speech impairment), a 15% chance of a temporary minor implantation problem such as infection, which may result in the removal of the leads, and a very small risk of cerebrospinal fluid leakage resulting in meningitis or headaches (AANS, 2019). According to Cyron (2016), other side effects related to the surgery itself include temporary swelling at the implantation site, tingling in the face or limbs, and allergic reaction to the implant. Stimulation or lead-related effects may include confusion, hallucinations, risk-seeking behavior, and aggression. Additional side effects include speech and vision problems, shocking

sensation, loss of balance, difficulty with concentration, and dizziness (ibid). According to AANS, most of these side effects are both mild and reversible. Brastos, Karponis, and Saleh (2018) report in their meta-analysis of DBS for advanced Parkinson's in the UK that the risk of a "serious adverse event" (SAE) with DBS, however, is more than double the risk of an SAE when using the best medical therapy. They caution, however, that while adverse events such as infection can be tied directly to the device, in the case of suicide or psychosis, it is not clear whether the event can be directly linked to the device, to the disease, to medication, or external factors (ibid).

Gilbert and colleagues (2017), when conducting a small set of semi-structured interviews with 17 recipients of DBS with Parkinson's, noted that while neuropsychiatric changes caused by implants are increasingly detected and reversible, phenomenological effects – or how the recipient views and understands themselves – are relatively little understood. In their Australian study, their informants nearly all experienced a shift in how they perceived themselves following their implants. This included both a deterioration in their sense of self, often linked to a perceived loss of control, and feelings of restoration linked to their perception of their capacities following implantation. They note that some recipients felt a sense of empowerment, which seems to be linked to if they perceive their DBS as an integrated part of themselves versus an invasive technology taking control (Gilbert, et al, citing Amadio and Boulis, 2015). Saliently, Gilbert and colleagues call for continued qualitative work and user-perspectives when considering implants' impacts on autonomy and identity. While the study presented here does not take up issues self-estrangement directly, it does consider perceptions of the self, autonomy, and agency in the context of DBS, following Gilbert and colleagues call.

Deep brain stimulation was chosen as a case for this study for several reasons. First, DBS has a wide range of applications, but in all cases serves as a means of symptom-management rather than treatment of the underlying condition. Therefore, this case provides an interesting site to understand how certain symptoms emerge as important and in need of management, which is linked more broadly to how disability becomes understood and operationalized. Secondly, deep brain stimulation, as a complex biotechnological intervention, exemplifies a class of medical technologies that typically do not prioritize user engagement and participation in decision-making (e.g. Gagliardi, et al, 2017). Therefore, understanding how responsibility, accountability, and autonomy get articulated in the context of DBS yields crucial insight into complex biotechnologies more generally.

In this case, only interviews with DBS users and their partners were analyzed. While several professionals, including a neurosurgeon and a biomedical engineer, were interviewed about this study, they were not consented into it. Therefore, their interviews serve only to build context. Thirteen informants were interviewed, nine DBS users and four partners, during eleven interview sessions. One person requested a written interview, but the remainder were conducted verbally, recorded, and transcribed. Interviews ranged from fifty minutes to two hours and fifteen minutes, averaging eighty minutes. One informant requested a follow up interview, but otherwise each interview was conducted in a single session. Informants and the method of recruitment are briefly described below. Pseudonyms were assigned using a random name generator.

John. John is a 75-year-old man living in northern California. He was diagnosed with Parkinson's disease between 10 and 12 years ago. Prior to receiving DBS in 2016, he

was on a medication regimen that resulted in compulsive side effects. He was recruited through a Parkinson's support network.

Rachel. Rachel is John's wife. She was interviewed at the same time John was interviewed.

Mary. Mary is a Parkinson's blogger and author, diagnosed with early-onset Parkinson's in 2007, although she experienced symptoms for many years prior. She lives in the southwest United States and runs a local Parkinson's support group. She received DBS in 2012. Mary was recruited through a request to her blog.

Barry. Barry is Mary's husband. He was interviewed at the same time Mary was interviewed.

Carol. Carol is a woman living in the southwest United States. She was diagnosed with early onset Parkinson's around 2000 and received DBS in 2011. In 2014, she had her DBS removed and replaced. Carol was recruited via an online interest form.

Marty. Marty lives in the southeastern United States, where he relocated from the Mid-Atlantic region after retiring. He was diagnosed with early onset Parkinson's disease in 2012 and received DBS in 2017. He was recruited via an invitation through his support group.

Hilary. Hilary is Marty's partner. Hilary has worked as a mental health professional and with individuals with Parkinson's disease professionally. She was interviewed during a separate session from Marty.

Carl. Carl is a 39-year-old living in the Midwest United States. He was diagnosed with acute cervical dystonia, also known as torticollis, in 2010 and received DBS in

2015. He was hospitalized several times following his DBS implantation for mental health issues. Carl was recruited via snowball sampling.

Bradley. Bradley is a 34-year-old living in the Southeast United States. Following a 2013 stroke, he received DBS and a motor cortex stimulation in 2016 for the treatment of chronic pain. He was recruited via an online interest form.

Freddie. Freddie was diagnosed with Parkinson's disease in 2004, although symptoms appeared much earlier. He received a DBS in 2014 and experienced seizures afterward. He is living in the southwest United States. While replacing his battery in 2017, he developed an infection and had to have the device removed and replaced. He was recruited via my professional network.

Nora. Nora is Freddie's wife and an academic living in the southwest United States. She was interviewed at the same time as Freddie.

Vickie. Vickie is a 60-year-old woman living in the Mid-Atlantic region. She received DBS in 2014 for inherited torsion dystonia. Following her implant, she experienced multiple side effects including memory loss and physical symptoms. She turned her DBS off and has since had it removed. She was recruited via social media.

George. George is a 70-year-old living in the Mid-Atlantic region of the United States. He was diagnosed with Parkinson's disease in 2012, which he suspects is related to his exposure to Agent Orange during the Vietnam War. He received DBS in 2017. He was recruited via an online interest form.

For this case, more than 175 pages of documentation from 16 hospital systems and neurological clinics were reviewed. These included FAQs, fact sheets about DBS and the procedure, media publications, patient stories, and more.

Theme 1: Invasion and Control

The decision to pursue DBS is in many ways influenced by the experience and understanding of disability. For many who have pursued DBS, their disability was perceived as a loss of control and DBS as a method to regain it. For some, their disabled bodies become figured as enemies, with DBS as a powerful weapon in their arsenal against it. Both their health status and their choice of intervention triggered shifting relationships with their bodies. This differential understanding of self and embodiment influenced an understanding of invasiveness and risk that is in tension with the typical clinical understanding. Tensions in how clinicians view potential DBS users and how they view themselves manifested in mismatched expectations, poor or combative clinical communication, and perceived under preparedness for the physical and emotional experience of both their diagnosed condition and the DBS procedure.

The Meaning of Disability

For all user informants with the exception of Vickie, the condition that precipitated their adoption of DBS was something that was acquired over the course of their lives, rather than a condition existing since birth. Their descriptions of their current state often contained an understanding of disability that was directly related to a loss of function, control or movement away from an idealized body or self. As George states, Parkinson's meant, "*your life changes in ways which you have no control over*." The inevitability of decline or impotence to prevent disease progression is exemplified in John's statement, in which he quotes a former health provider who also had Parkinson's: "*It's like my old psychiatrist says, 'You know we're screwed, don't you? Grow a beard to cover the drooling*.'" These statements, which perceive the disabled bodymind as out of control, contribute to a desire to regain or enact control through technological intervention. In Bradley's experience, the DBS returned

him to a baseline of human: "*…now I actually feel like I felt before I had my stroke. I just feel human. So, it's just the overall comfort of it all*." This statement reveals an orientation to disability that perceives it as dehumanizing: when he is experiencing chronic pain or feeling cognitively affected by pain medication, he is no longer human. This perception aligns with a desire for control or intervention to re-achieve humanity.

Further, the declining or debilitated body was perceived by others as an opponent or host to an invading force. As Freddie expressed,

> "*I still see my body quite often as the enemy because Parkinson's is still there. And what's worse, my body's never going to improve, year-after-year, it's only going to get worse*."

Freddie's adversarial relationship with his body exemplifies a common perception amongst informants, in which the *person* was viewed as distinct, separate from, and in combat with the *disabled body,* figuring DBS as a weapon in the arsenal to fight disability.

Social and Observable Dimensions of Disability

Perceived loss of control extended not only into bodily function, but into control of one's self-image. The appearance of difference, weakness, or disability as it was perceived by others was threaded throughout many of the conversations. The recognition of the unaccommodating attitudes and infrastructures that peppered the daily experiences of informants seemed to in some cases influence the decision to pursue deep brain stimulation.

For some, the difference produced through disability came to the fore when encountering inaccessible infrastructure. For example, Marty recounted an incident at

a local shopping center where he started having difficulty walking, eventually realizing he would not be able to ambulate back to the parking lot on his own:

> *"And you know, when you have that - like I'm not very self-conscious person, but like now I feel it makes me more upset when it happens because I feel like, you know, people are looking at me, I feel like, you know. So, you almost become agitated like, you know, why is there no chair? Why is there no where for me to sit down? You know, those kinds of things are racing through your mind."*

In this quote, he is confronted by the construction of a material world that is not accommodating to his bodymind while simultaneously experiencing embarrassment that he is being identified by others as differentially experiencing the world.

Freddie, who is highly involved as a disability advocate in his community, shared both his experience with attitudinal barriers arising from visual differences he has experienced as a person with Parkinson's, as well as the work he does to educate others to address those barriers.

> "*One thing I'll say in educational talks about Parkinson's: What you see is the first thing about yourself that someone else in public notice. But what you see with Parkinson's is not what you get. What someone looks like when they have Parkinson's is not necessarily how they feel. I can't express myself the way a normal person normally does. Visual cues are off-limits with Parkinson's.*"

When I inquired about examples, he shared several anecdotes of people misinterpreting his body language and assuming that he needed assistance in public settings. Both Marty and Freddie emphasize that others perceiving them differently due to disability or illness has impacted their lives. I was struck that informants

made sure to emphasize that this stigmatization is *distinct* and *separate* from the embodied experience of disease. Deep brain stimulation primarily addresses the outwardly observable symptoms of conditions like Parkinson's (tremor, gait, etc.), which, given the impact of perceptions of others and inaccessible infrastructure, may be viewed as significantly improving quality of life.

Invasive Medication

Deep brain stimulation, deployed as a metaphoric weapon against invading disability, is not the only possible intervention. As Freddie states, "*it's not as if the DBS is a substitute for anything, it's an additional tool in play against the formidable enemy of the multi-symptoms of Parkinson's*." All informants shared wide-ranging strategies for medical and non-medical treatments, ranging from Botox injections to exercise classes, diet changes to medication. According to many, clinicians often present DBS as a last resort in the hierarchy of interventions due to the surgical nature of the implant, and for Parkinson's disease, poor management of symptoms through medication is often a precondition for surgery. As Marty noted, when his neurologist first broached the subject, it was couched in a promise to trial various medications prior to considering surgery: "*He didn't jump into it, he just said, 'You would be a candidate, you know. But I think right now let's just try some different medications and see where you go with it.'*" Of those trialed medications, however, Marty noted they made him feel less cognitively present – which was particularly meaningful to him as he felt less in control of his body. John experienced compulsive gambling as a side effect of medication, although it took several years to recognize it as related to his medication. This fact that left him with an enormous feeling of guilt and shame. Mary shared that the mixture of her medications prior to her DBS resulted in cognitive side effects that her clinician initially misidentified and she

corrected. When I asked Carol if she felt she had options other than DBS, she replied simply, *"No. Not to control the tremors."*

Bradley, who received DBS for chronic nerve pain, expressed that his options were DBS or narcotics; the latter of which he viewed as significantly more invasive.

> *"So, yeah, it was definitely a feeling of control much more so than any medication that I'd been taking, just because medication has so very specific time frames, you know, especially with narcotics, they only give you a certain amount, so if I'm having a particularly bad pain episode, there is that rationale: 'Well, I could try to take another pill, but I only have X amount and I'll have to justify it to a doctor or I may run out.'"*

His concerns about the surveillance that accompanies the use of narcotics was supplemented by the disruption they caused in his life due to the effects they had on him: "*While I was taking all these medications, I gained 50 pounds. I was just incredibly lethargic, I mean, I felt like a zombie*."

These experiences expose a differential understanding of embodiment. Medication regimens— especially surveillance from healthcare practitioners and unanticipated side effects— were perceived as *more* invasive and made informants feel *less* in control than surgical implants. Invasiveness becomes not about transgressing the physical boundaries of the body, as assumed by able-bodied clinicians, and more about the social stigma, surveillance, and side effects.

Under Preparedness for Affective and Physical Changes

For many with DBS, tensions arose between how clinicians think about their condition and technology and how they think about themselves. In some cases, this meant their experiences with DBS and disability were surprising because they received no information about what it is to live with a chronic condition or to be

implanted. The information provided by clinicians or found through independent research rarely addressed the embodied experience of either condition or treatment. As Marty shared, recounting his first visit to a support group,

> "*One thing that nobody ever mentioned, not once since I had this is, you know, it actually hurts sometimes…the disease brings pain and, you know, nobody is really talking about that part of it…So, there are things that you experience through the disease that you know – I don't know if it's just by chance or by, you know, the doctors I had, but, you know, there are things that nobody told me I might feel or experience later on*."

The lack of information about embodied and affective experiences extended into receiving DBS as well. When asked what he knew about surgery prior to receiving it, John expressed that while he attended a program at the hospital to learn about DBS, "*I walked into it pretty blind. Pretty naïve. You know, when you sit down and find out you're going to have your implant done and a hole drilled in your head, it's like, wow*."

Trauma and Anxiety of Surgery

Resultant from this perceived lack of preparation for the physical and affective dimensions of surgery came a great degree of trauma and anxiety arising from surgery. Descriptions of the surgery, which typically involves being awake to respond to lead placement while held still by a metal device that attaches to the skull, include "*a very barbaric situation*" (Carl), and "*like throwing a bunch of walnuts in a blender with the shells on the walnuts*" (John). Bradley expressed jokingly that "*I think I probably have some minor PTSD from it*," sharing that while the drilling itself was notable, he was more anxious about his involvement in ensuring proper lead placement:

> *"It is kind of like a bizarre thing. Because you're not quite sure what you're going to feel, you know, is going to be painful? They're like, you know, it's a slight buzz, maybe, like I said, like a pins and needles feeling. So, there's a little bit of anxiety there of like you know waiting for it to happen and you don't know where it's going to be. Yeah, a little bit, but it wasn't an unpleasant sensation by any stretch of the imagination. And yeah, the first thought is, "Oh my god, I hope I don't mess this up." You know. I hope I don't imagine myself feeling it somewhere and they put it in the wrong spot. But it was very obvious once it started happening. It was very obvious where it was. So those fears and that anxiety quickly washed away. Yeah. So, it wasn't really too bad."*

Common in all of these descriptions is a lack of awareness of what the condition or intervention should feel like. An inattention to the bodily experience of DBS from clinicians may be linked to the dearth of people who have experienced it in positions of authority in medical settings. This is one way in which the lived experience of disability and biotechnology becomes discounted or invalidated. This will be discussed in greater detail in Theme Three: Epistemic Authority and (In)Validation.

DBS As Control

As mentioned above, as disability comes to be defined as a lack of bodily control, DBS becomes configured as a method of re-establishing order. This is achieved not only through the use of the device itself, which for some enables control of symptoms they deemed as interfering with their quality of life, but through an acquisition of scientific and medical knowledge about their bodyminds. Bradley, who received DBS for chronic pain following a stroke, notes that "*seeing the post-surgery or post-implant MRI and seeing exactly where it's placed compared to the actual*

specific damaged spot was in the brain," was "*eye-opening*" and "*kind of comforting, knowing that I have control over it.*" The identification of a physiological locus of his pain, which previously felt unknowable, factored into his understanding of control, linking it, in part, to knowledge acquisition.

For others like Carl, the control enabled by the DBS felt precarious, and he expressed a discomfort in knowing that he was beholden to a piece of technology to subdue the pain he was feeling due to torticollis: *"I mean, that's the scary thing too is that I'm relying on this device. It's not a cure, it helps you get through the day."* Therefore, DBS represented a newfound control over an unruly body, but not one that originated from he himself. He had to trust this technology to behave an intended; unlike Bradley, he viewed the device, not himself, as in control of his symptoms. While the control was displaced to the device, however, the responsibility for management was not. In other words, while he had to trust the technology to control his symptoms, he still felt personally responsible for the outcome. This will be discussed in greater detail in Theme Two: Personal Responsibility.

Losing DBS

The element of control enabled by DBS was acutely felt by Carol and Freddie, who each developed infections that required removal and replacement of their devices. Vickie, conversely, had her DBS voluntarily removed after determining it reduced her quality of life. These three informants provided a unique perspective on the sociological and psychological impacts of the perceived gain and loss of control enabled through DBS. Freddie shared the distress he experienced without his device, even as his wife Nora reported that the visible symptoms of his Parkinson's did not re-emerge as strongly as they expected: *"I guess the simple fact is, it was terrible*

without it. It was a tremendous daily impact on all my life. I felt like I was circling the drain, if I'm honest."

Carol's experience of her body without her DBS was magnified through the judgement she anticipated from others. She notes that "*…when we took out the wires, I discovered how much I tremored. And I had dyskinesia and freezing, and everything I hated about it*." Later, while stating that should she experience an issue with her current device that she would have it replaced, she elaborated, "*I hated tremoring. I hated shaking. That's obvious to people."* Therefore, the control she experienced was not simply control over her body, but control over the self-image she presents to the world. With the implant, she was able to navigate interactions without an obligation to disclose her disability through its visual dimensions, re-establishing some authority over her self-presentation.

Triangulation with Documents

For this case, more than 175 pages of documentation from about 15 hospital systems and neurological clinics were reviewed. Nearly all of these materials featured language that figured disability or disease as an invasion, loss of control, or deviation from an ideal self, simultaneously figuring DBS as a means of control or return to able-bodiedness. For example, one success story on the use of DBS for dystonia published by a children's hospital described the person who received treatment as having to "*fight his own limbs*," thus reinforcing the paradigm that the disabled body is separate and in conflict with the person. Other documents use a framing that suggests a struggle for control. "*Don't let tremors control your life*," reads the title of a university hospital's information page on DBS, while another hospital's interview with a neurosurgeon suggests "*Patients are freed from the tremors with the flip of a switch."* Additionally, several documents emphasized the

social and observable dimensions of disability prior to implantation, noting those differences may "*embarrass*" (children's hospital information page), or even leave someone "*emotionally traumatized*" (hospital system patient story).

Further, while not featured in the majority of the materials, several documents corroborated informants' perceptions of medications as significantly invasive or disruptive. One university hospital's news story promoted DBS as an option when medication regimens became unpredictable, while a children's hospital FAQ page on treating dystonia suggested that medications "*do not benefit all children and can have unwanted side effects*," making DBS a more attractive option. More commonly, DBS was presented as invasive, with one university hospital's information sheet allowing that DBS may seem "*overly aggressive and unnecessary*" during the early stages of Parkinson's disease. That same information sheet continues by arguing for the control enabled by DBS, noting that "*Rather than letting patients adapt to their worsening symptoms as the disease progresses, DBS is adjustable to treat symptoms as they change over time."* Further, just as Bradley connected knowledge about the physiological locus of his pain to his sense of control, some documentation also linked knowledge acquisition to control. A brochure from a university hospital's movement disorder clinic most explicitly made this connection when inviting patients to attend conferences, stating "*When it comes to the fight against Parkinson's disease, knowledge is power*." Not only does this statement reiterate the perceived combative relationship between disabled bodyminds and the people who occupy them but emphasizes that medical knowledge is a crucial "weapon" in that battle.

Table 5

Invasion and Control Theme Summary

Key Points: • Disability is sometimes perceived as invasion, loss of control, or movement away from an idealized self. The socially observable dimensions of disability feature in how informants perceive themselves and how others observe them. • Invasiveness is differentially understood by users and clinicians, meaning that for some, the surveillance, stigma, and side effects of medication are more invasive than implantation surgery, despite clinical insistence. • Deep brain stimulation and knowledge acquisition are means of control, although whether the individual or technology is in control differs.

Subthemes:
• The Meaning of Disability (100%)[9]
  ○ Social and Visual Dimensions of Disability (82%)
• Invasive Medication (90%)
• Under Preparedness for Affective and Physical Changes (73%)
  ○ Trauma and Anxiety of Surgery (55%)
• DBS as Control (82%)
  ○ Losing DBS (27%)

Sample Quotes: "It's like my old psychiatrist says, 'You know we're screwed, don't you? Grow a beard to cover the drooling.'" (John) "…now I actually feel like I felt before I had my stroke. I just feel human. So, it's just the overall comfort of it all." (Bradley)

Theme 2: Self-Responsibility

Informants overwhelmingly reported feelings of self-responsibility in both their decision to pursue deep brain stimulation and their role in the procedure, aftercare, and programming the device. For some, DBS was explicitly viewed as necessary to re-emerge as a productive and independent member of society, and as such, the decision was often couched in moralizing rhetoric. For others, perceptions of personal accountability appeared in their judgement of others who had not pursued DBS or

[9] Percentages derived from number of *interviews conducted* rather than number of interviewees, since several informants were interviewed together.

who had what informants perceived as poor outcomes from the procedure, suggesting that these outcomes often went hand-in-hand with poor self-management or self-advocacy.

Independence and Autonomy

The following section highlights the role that neoliberal values including independence and autonomy play in perceptions of the self for many informants. Dan Goodley (2014)'s theory of neoliberal ableism suggests there are "increased expectations placed on the autonomy of self-responsible individual citizens to care, educate and govern themselves" (p.63). People become responsible for their own health and welfare. Interventions on non-normative bodyminds are individualized and privatized – such as medical interventions – but are understood as being for the public good. For informants, values including independence, autonomy, and a return to financial productivity at times drove the decision to receive an implant.

John noted he decided to pursue DBS because

> *"I needed to lighten the load, which has not been terribly lightened, but I needed to lighten the load of my lovely caregiver wife, who I owe everything to…it's one of those difficult things, where you know you're a burden, but you don't know what to do about it."*

He goes on to emphasize his personal agency by saying *"It's kind of like, you die and go to heaven and you're all upset at God and you tell him and he's like, 'Well, what do you mean? I gave you DBS, why didn't you try it?'"* John's feelings of responsibility toward his family drove his decision to intervene. In this statement, and in the rest of the interview, it was clear that John felt doing nothing to medically intervene on his Parkinson's, when medical intervention was available and possible, was not a responsible option given his familial obligations.

The ability to work independently was also a strongly held value for several informants. Carl shared that his drive to return to work, which strongly motivated his decision to pursue DBS, was linked in part to proving himself a productive member of society:

> "*Currently I am looking for a job and I'm going to be studying, and hopefully I'll find something that's part-time that just helps me show parental guidance that I'm doing my best to try to function as a normal human being, if you will.*"

Hilary, when discussing the period of time prior to her partner Marty disclosing his Parkinson's disease, remarked, *"I mean, initially, you know, it really was very normal. We were both working. Marty was still working."* The equating of "normal human being," with one that is gainfully employed reinscribes neoliberal ideals of individual accountability and responsibility, especially as it is linked to economic productivity, which in turn influence decision to pursue individualized interventions for bodily non-normativity.

Choosing DBS

As Mary stated on the decision to pursue DBS,

> *"The reality is there's probably not going to be a magic pill ever and certainly not in our lifetime. So, you better do all you can do now to have the best quality of life. And that to me was the DBS - it was a quality of life decision. Because otherwise no one would elect to have elective brain surgery. There is no other elective brain surgery."*

The stated reasons for deciding to receive DBS were highly personal, variable, and contextual, and there is no one unified path users follow prior to or after implantation. However, there were several common characteristics that appeared

throughout the decision process, including many instances of independent research, differential understandings of how and when the surgery becomes a worthwhile risk, and moralizing the decision. Crucially impacting the decision to pursue deep brain stimulation for some was a sense of a lack of other viable options. For more than half of all informants, DBS seemed inevitable in the progression of care. When asked if he considered not receiving DBS, George simply stated, *"I never considered not pursuing it."* Marty notes that he had reached the end of his knowledge of viable alternatives before turning to DBS:

> *"I mean, you know, my other options were essentially like I could I could pick up the pace of, you know, exercise in different ways you know. But you know, the reality was I didn't feel like I - I just - you know, I felt like I covered kind of most of those bases and I didn't really, you know, I researched as much as I could, like, for new things out on the horizon."*

Carol shared that there were simply no other options to control her tremor as much as she would like it controlled.

Independent Research

Nearly all informants expressed their knowledge of DBS emerged largely from independent research conducted outside of the clinic. Sources of information commonly included the internet, device manufacturers, academic papers, television, and online communities. Rarely, however, were people able to meet someone with a device prior to receiving the implant.

Mary and Marty both noted feeling very alienated from much of the information available about DBS, especially that coming from commercial device manufacturers, because they did not see themselves, as people with early-onset

Parkinson's, represented in the materials. Mary eventually produced her own videos and a blog sharing her experiences receiving DBS, asserting that

> *"I wanted someone to be able to see, because I didn't have the typical resting tremor and a lot of times in the, um, commercially produced one, the people don't look like a young onset. They've already got gray hair. They're 65, 70 years old, and they don't look like someone who's only in their 40s or 30s."*

Carl and Hilary both expressed regret in not having the opportunity to do more research: for Hilary, whose partner Marty did not experience the significant improvement to his quality of life that they had hoped for, she wished she had known that more than one type of implantable produced by more than one manufacturer was available. She only learned of different device manufacturers when she and Marty connected with other DBS recipients following his surgery. For Carl, who experienced significant tensions with the care team as well as poor outcomes following the surgery, he regretted not exploring additional hospitals to receive treatment. He said:

> *"My best advice is for anybody that wants to get deep brain stimulation is to really do your research with the hospitals that are available in your area or what your insurance can cover, and really extensively take your time with the neurologist and really heavily discuss everything from A to Z, meaning side effects that people have experienced during the surgery, such as infection, which has been a lot of the bigger issues, a lot of people are getting infections after the surgery, and also sharing any other side effects that people have been experiencing later down the road from deep brain stimulation so that they know what they are getting into. And that's my best, final statement to*

say about deep brain stimulation. I'm not dissing deep brain stimulation, but I just feel people should be on the up and up 100%."

The prevalence of independent research may be linked in important ways to the sense of personal responsibility many felt when pursuing DBS. This responsibility does not only extend into receiving the implant itself, but in being informed users. It also may reveal a sense of inadequate information shared in the clinic. Given the experiences summarized in Theme 1, in which people felt underprepared for both their conditions and DBS, it is perhaps unsurprising that people felt the need to seek information elsewhere.

Weighing the Risk

The decision to pursue DBS was also influenced by a contextual and personal risk calculus. Freddie, who had originally planned to have DBS in the summer of 2014, pushed the date up by about six months when he felt the benefits had started to outweigh the risks: *"…the reason I made that decision that I had to do it now was it's not going to get any better if I wait. If I wait six months, it's not getting any better. I'll be in worse shape if anything, because I can't exercise."* For Marty, the decision was made after one specific incident where he felt himself *"run out of gas"* during an exercise class, which indicated for him that the risks of surgery where now more in balance with the possible benefits. For more than half of the informants, that risk calculus was influenced by the closing time window articulated by their clinicians, whether that be an age cut-off or other criteria. "*There's a window of opportunity there*," as Mary said, "*where you get to the point where you're not eligible anymore.*" This time crunch weighed heavily in the decision-making process for some people, while others were more motivated by their perceived decline in function.

For Vickie, in retrospect the risk of the implant ultimately was not worth the benefits. Even as she experienced some improvements in her quality of life, the cognitive affects she experienced post-implant counteracted any potential benefit, leading to her eventually turning off the device and seeking its removal. She warns others to carefully develop their own risk analysis:

> "*So, I mean, it was kind of nice having the relief, a little bit of relief, but not at the expense of me being totally out of it. And not at the expense of my mind or my, you know, my brain…I don't feel it was worth it and I would not do it again. And I would not advise anyone to do it without being fully informed and they do not fully inform you*."

Moralization

The moralization of the decision to pursue biomedical interventions, which includes placing a value judgement on intervention, is tightly wound up in the societal judgement placed on dis/abled and ill bodyminds. Body management in neoliberalism suggests that people are held personally responsible for dis/ability and illness. John, for example, felt an obligation to pursue DBS in order to "*be a better person*" for his family, especially his wife and current caregiver. He said:

> "*It's just a mindset. Get your shit together, John. Quit feeling sorry for yourself. What are you doing? You know? You have to take care of [indecipherable] yourself. You know? It's kind of like my children - I don't want them thinking, 'Why isn't dad doing something? He's just sitting there.'*"

His decision to pursue DBS is then couched in a morality lesson to his children about responsibility and familial obligation, which ascribes a value judgment not only to himself, but to others who do or do not pursue intervention. This was reinforced by several anecdotes he shared about acquaintances with Parkinson's (one of whom had

recently been institutionalized after threatening his wife and another whose wife had told him she would no longer be his caregiver). Each of these cautionary stories ended with an assertion that people with Parkinson's needed to *"share the burden"* of management and *"Just keep your mouth shut and be a good person. Work hard and be a good person."*

Pride and Guilt

Both positive and negative outcomes following implantation were accompanied by feelings of individual responsibility, either pride in success or guilt at failure. Barry, Mary's husband expresses a pride in Mary's relationship with her clinicians and the device manufacturers, which has enabled an enhanced level of care: *"It's because of the advocacy work that she does that she gets a special bond. That's what it is. She earns it. I shouldn't say she's lucky. She earns it."* This statement, through its framing, suggests that the extra work she puts in developing relationships, including teaching medical students and developing a telemedicine service in her area, enables her to receive better care than someone who is simply the recipient of medical services. Her actions are in this sense directly responsible for her care, which is in turned linked to her perceived outcomes. Mary supports this perspective, noting that *"Their [the neurologist and neurosurgeon] job is to fix the problem in your brain. It's your job to learn everything else."*

Conversely, Carl links his poor outcomes to taking action outside of his role as passive recipient of technology. He shares that he believes one of the reasons that he hears voices, which he perceives as the care team at the hospital where he received his implant, is because he used the patient remote to adjust his stimulator's settings. Despite the fact that the patient remote is designed to provide some latitude to adjust the stimulator settings within certain parameters, Carl felt in doing

so he had transgressed a boundary between patient and clinician. He asserted that he shouldn't be "*making my own adjustments, because I'm not a neurologist.*" His subsequent difficulties stemming from the voices were, in his view, directly related to that transgression.

Additionally, the majority of interviews also contained themes around gratitude and positivity as key to successful implantation outcomes. Rachel, John's wife, notes that "*John is, and always has been, just very positive, very appreciative, very helpful. He doesn't feel sorry for himself.*"

Judgement and Altruism

Further, neoliberal-ableism (and body management in neoliberalism) can also be found in perceptions of others who either experienced poor outcomes with DBS or did not pursue it at all. As Mary notes: *"If you don't do self-management, you're not going to have a good outcome."* This view is further defined by delineating requirements for technical expertise as a DBS recipient. "*You know, in fact I have often even said if you couldn't program your VCR you probably have no business getting DBS unless you're going to take some responsibility for – be your own advocate.*" Through such statements, there emerges a picture of a "worthy" biotech recipient as outspoken, educated, and self-motivated. For Carol, with DBS comes the ability to make downward social comparisons against those with similar dis/abilities who have not been implanted. *"I think that I'm kind of a step ahead of everybody else because I've had DBS. Most people have not had it. I'm shocked…Nobody has DBS. I think, 'Why not? Look at you.'"*

For the majority of informants, this judgement of others manifested in a desire to share resources, information, and experiences with others who shared their conditions or disabilities. Often, as was the case for Mary, this desire emerged in part

because no such peer-to-peer resources existed in her area when she was considering DBS. For John, his desire to share his experiences with his Parkinson's support group came about because he was not receiving support from them for the issues he brought to the sessions and planned to stop attending. *"But then I started looking a little different,"* he said, *"How can I help these people? I need to give a little bit. Open my heart. Give a little bit. Help try to bring these guys up to speed."* This statement is embedded with judgement about the kinds of people who attended the support group. They are not his peers with whom he can empathize; they are people in need of assistance that he figures himself as capable of providing. This reframing allowed him to continue attending, albeit with altered expectations.

In the majority of cases in which informants reported altruistic activities such as volunteering to speak to other potential DBS users, educating clinicians, or sharing their experiences in online and in-person support groups, it often stemmed from a perceived lack of knowledge about the technology itself or the experience of receiving it. Mary educated medical students so that people with DBS admitted to hospitals didn't have to. Bradley spoke to other people who have had strokes to advocate for the use of DBS during recovery since it is a relatively new treatment. As Bradley states,

> "*I think honestly one of the coolest things that come from all of this is that I get to be - become an advocate for it and that's one of the things that I've honestly tried to do the most since having the stroke and especially since having the surgery and having the DBS and everything is just trying to reach out to other people that are going through this in any way*."

Overall, informants felt a draw or responsibility to fill the knowledge gap they themselves had experienced when receiving DBS, which often translated into establishing themselves as embodied experts for other potential users.

Triangulation with Documents

Personal responsibility was a common theme in much of the documentation available from hospital systems and clinics. One university hospital released an informational sheet on facts and myths about Parkinson's disease, stating flatly that "*This 'it is what it is; there's nothing I can do to help myself' myth is counterproductive*," connoting an assumption that many people are not experiencing good quality of life due to an unwillingness to take responsibility for their well-being. Other documents also shared this paternalistic tone, such as this informational sheet from a neurological center, which suggests that potential users must "*have realistic expectations…patients should not expect a miracle cure.*" Such statements may serve to preempt dissatisfied users' experiences by suggesting that unhappiness with quality of life may arise from unrealistic hopes or an unwillingness to be accountable for their health. More often, however, themes of personal responsibility were couched in rhetoric of empowerment. For example, an informational news story published by a university hospital closes by quoting a neurosurgeon who advises, "*it's up to the patients to decide whether the problems are significant enough to take the small but present risks of the procedure in order to achieve those results*." Such a statement is outwardly empowering, yet simultaneously shifts the onus of responsibility away from the clinicians and onto the individual to do the complicated risk calculus articulated by informants above.

Additionally, themes of altruism toward others who may seek treatment emerged in several human interest or patient success stories shared by hospital

systems. In one such story, published by a university hospital, the person who received DBS is dubbed a "*a familiar face at [university hospital], where she serves as a cheerleader for DBS and the [university's] efforts to help Parkinson's patients live better lives.*" The article reports she volunteers for both medical courses and to speak with potential DBS users, noting "*you have to have that kind of support*," when deciding to pursue DBS. As is echoed in the interviews, this example displays users identifying a gap in support, whether that be in clinician education or in the communities receiving DBS and feeling compelled to fill it with their own knowledge, often pro bono. Ultimately, the documents resonated with the interviews regarding feelings of personal responsibility and accountability toward others.

Table 6

Self-Responsibility Theme Summary

Key Points: • Neoliberal values including independence and productivity motivate biomedical interventions for some people who view the adoption of DBS as a moral responsibility. • Users experience both pride and guilt related to the success or lack thereof of deep brain stimulation, often influenced by perceptions of disability as a personal responsibility. • Expectations of self-responsibility also impact how others with and without DBS are perceived. Expressions of acts of altruism toward other DBS users position them as embodied experts.

Subthemes
• Independence and Autonomy (90%)
• Choosing DBS (100%)
  ○ Independent Research (90%)
  ○ Weighing the Risk (73%)
  ○ Moralization (27%)
• Pride and Guilt (100%)
• Judgement and Altruism (82%)

Sample Quotes: "Their [the clinician's] job is to fix the problem in your brain. It's your job to learn everything else." (Mary) "I think that I'm kind of a step ahead of everybody else because I've had DBS. Most people have not had it. I'm shocked…Nobody has DBS. I think, 'Why not? Look at you.'" (Carol)

Theme 3: Epistemic Authority and (In)Validation

A third common experience among informants was the experience of epistemic invalidation by clinicians or other authorities, particularly as it related to experiencing physical, neurological, or psychiatric symptoms relating to either their diagnosed conditions or the implant. Epistemic invalidation often occurred prior to clinical diagnosis, and experiential symptoms, as opposed to those measured through laboratory processes, were often dismissed. Epistemic invalidation was paired with an assertion of the medical authority as credible and trustworthy, an argument raised in much of the documentation as well. This perception of medical authority appeared throughout interviews, with several informants undermining their own experiential knowledge in favor or medical expertise. In many instances, invalidation occurred specifically when the line between the neurological and the psychological was blurred, such as the experience of mental health issues attributed to an implant for movement disorders. In some instances, where a person's self-knowledge was invalidated by a medical authority, they instead turned to informal user or patient communities such as support groups and online forums for validation and resources.

Clinical Authority

The authority of clinicians, including neurosurgeons, neurologists, primary care physicians, and other medical professionals, was articulated through credibility-building practices to establish trust with informants and through stable and open communication. As Marty states, when he was deciding to pursue DBS, these were both crucial factors: *"Okay, if I'm going to do this…" he shared, "this is a good surgeon, he's got a good reputation, you know. I felt like he was honest with me and answered the questions."* Where either of these elements broke down, informants lost trust in their clinicians, sometimes developing resentment and perceiving their authority to make decisions on the informants' behalf as a form of control. As Vickie

shared, when she felt her clinician was focusing all his attention on her tremors and ignoring both the symptoms, she was most concerned with (difficulty breathing) and the side effects she was experiencing, she expressed her resentment: *"His ego was in the way. It was like he had to somehow conquer my brain. And conquer these tremors and make them go away."* Clinical authority quickly shifted from being a source of comfort to being a source of control when the perceived priorities of the clinician do not match the priorities of the person receiving treatment.

Trust

Trust in clinicians performing DBS was established through a series of factors, including through the clinician or clinic's status or reputation, through a pre-established relationship, and through the scientific or technical naming, classification, and/or visualization of the person's condition.

Marty, who expressed some trepidation prior receiving DBS and some doubts that it had been effective at the time of his interview, stated that the procedure must have some value, or the doctors he received it from would not have suggested it.

> *"You know, I guess one thing in my brain is I will tell myself that I find it hard to believe that, you know, two doctors, both with very good reputations, you know, they're both like the big man on campus in the area. I find it hard to believe that the two of them would conspire to trick all these people into having brain surgery that isn't actually doing anything. You know, I know that sounds kind of crude and a stupid way of thinking, but in reality, like, I would hate to think that two people would be that money-driven or that ego driven to believe or project that it does more than it does. I mean, do they sell it? Do they encourage people to do it? Probably. I'm sure they do. I'm sure they believe in it you know. And I*

know it's not going to have the same effect on every single person. Clearly. But you know, I believe, I believe to some degree that it has to work [that] way..."

He ultimately decides to trust his clinicians because he believes their status and reputation would not be possible if they were untrustworthy. This statement, however, is made in retrospect, and signals some of the doubt he feels now that he did not achieve the outcomes he was expecting. He acknowledges the marketing aspect of DBS, but ultimately reaffirms that he trusts his clinicians' intentions.

To others like Vickie, their trust came from a long-standing relationship with their care team. When I asked as to whether she had felt any concerns prior to surgery, she noted:

"I can't really say that I felt suspicious. I asked my doctor about it. He said definitely there will be none. And I'd gone there for 25 years, so I was inclined to believe him…I actually was very relaxed during a surgery. I believed them, that was the only place I trusted. They were the ones who first diagnosed me."

As mentioned above, her trust in her clinicians was eventually eroded due to tensions created through a mismatch of expectations and priorities, but initially, she was confident in her team due to their previously established relationship.

Bradley's trust in his clinicians was established in part through their thorough explanations of the technical aspects of the surgery. He was reassured when his clinician "*actually showed me the exact spot on my brain that was literally the size of a pin tip that was causing all of these problems and had all of this data."* His clinician established credibility through his seeming abundance of "data," concretizing the ambiguous nature of Bradley's pain through visualization and technical explanations.

Communication and Education

Communication was also key to establishing or eroding clinical authority during surgery and programming. Freddie and Nora found the holistic communication they received, including from social workers, nurses, the neurosurgeon, their neurologist, and the Medtronic representatives, was crucial to their perception of the procedure and outcomes. For them and several others, the willingness of their care team to openly discuss the possible negative outcomes cemented their trust in clinical authority, in part because it was an admission of uncertainty. As Nora says, these conversations assisted in the processes of "*trying to balance all that*" in Freddie's decision to pursue DBS. Communication also became key for the surgery process itself. Bradley suggests that his clinician talking through all the steps of the surgery aloud, which he was doing for the benefit of a medical student in the room, had a calming affect for him. Further, "*he was constantly checking on me, and it was just so reassuring laying out all the steps*."

Communication, however, was sometimes perceived as a one-way channel, to the frustration of several informants. Mary, who herself has been engaged in education and advocacy projects bluntly stated *"I believe as I said it would be nice if you could get several Parkinson's folks to speak to a lot of doctors. But the reality is that it's doctors speaking to folks with Parkinson's."* This statement suggests a rigidness to this relationship, which both Mary and Barry often reiterated throughout their interview. As Barry commented when Mary suggested she would like to see a room full of clinicians listening to a panel of people with Parkinson's: "*You couldn't arrange that. They [Clinicians] wouldn't come*." In their estimation, clinicians do not have the time or ability to learn from users, which further contributes to the shifting of the onus of responsibility onto users to be self-motivated and self-responsible. That onus, as alluded to by several interviewees, included educating physicians who

were not experts on DBS. John noted he was the first person with DBS that his general practitioner had ever encountered, forcing John into an educator role: "*This is the curve, you know?*" He shared, "*And so when I go in and talk to him, I tell him - I enlighten him a bit every time I can*." His embodied and experiential knowledge suddenly becomes an asset in this situation, and his responsibility for his care takes on an additional dimension.

Embodied and Experiential Knowledge

Informants expressed the value of their embodied and experiential knowledge in their day-to-day care practices, the setting of priorities for their treatment plans, and the interactions they have with both clinicians and others. The knowledge that arises from occupying a non-normative bodyminds is essential and under-recognized in clinical settings, in part due to the relegation to a one-dimensional and passive patient role. As Freddie asserts, "*We're not a patient, we're not a client, we're a person*." He continues by sharing the advice he provides whenever he speaks about disability to able-bodied people, demanding

> "*When you ask somebody with Parkinson's - or other disorders, other disabilities as well - If they say they're okay, well, believe them. So, if the person says they're alright, believe them. That's one thing you need to do.*"

He and others expressed that there is no one who knows more about themselves than they do, and yet that knowledge is constantly dismissed or invalidated in public and clinical settings.

Mary argues that she, as a person with Parkinson's, knows much more about the condition than her clinicians, even just by virtue of the time she spends thinking about it.

> *"So actually, it will end up being 15 months between appointments and I'll probably have a half hour appointment with her [neurologist]…but the rest of those bazillion hours and minutes, guess who manages my Parkinson's? Me."*

Just as John's knowledge about DBS became an important element to his care with his general practitioner, informants often argued that more attentiveness to what they know could transform their care. For example, Mary notes that one type of pulse generator (implanted in the chest during surgery) has a squared edge. This shape makes it impossible for her to shave her armpits, which impacts her quality of life and self-image. She also mentioned a patient remote in development that was operated by touch screen rather than analog buttons. While this design might ostensibly seem more convenient, Mary suggested that people with dexterity issues – which can be caused by many of the conditions intervened on by DBS – are often not able to use touch screens effectively, thus limiting the usefulness of this design. Barry, Mary's husband, asserts "*If they had talked to the patient first, they would've pointed that out right away. You're going in the wrong direction here."* He continues by arguing that "*People with Parkinson's should be the ones who are designing these things."*

Epistemic Invalidation

Despite the value of embodied and experiential expertise as articulated by interviewees, the majority also experienced invalidation of their experiences, knowledge, and personhood from their clinicians. This was particularly prevalent when their experiences of DBS blurred the lines between the neurological and the psychological. Not only was their self-knowledge delegitimized, but in doing so, they were recast as passive or helpless. Patients, rather than people. Mary and Freddie, for example, both shared that their initial diagnosis of Parkinson's was delayed by

several years when the symptoms they shared with clinicians were dismissed out of hand. In some instances, when a person's embodied experience was invalidated by a clinician, they turned instead to informal patient communities for validation and resources.

For example, when Mary began experiencing depression and suicidal thoughts and suspected her DBS to be contributing, she was rebuffed by several clinicians before eventually having her experience corroborated by a DBS recipient online:

> "*I reached out to the local doctor and said, "Is there any chance my settings can be causing my depression?" No. And I went to the movement disorder specialist in [City], "Is there any chance that my settings could be causing my depression?" No. And all they want to do is put me on antidepressant, which just made me feel even worse…so then I reached out to my online community via Facebook and I said, "Is there any chance that my settings can cause depression?" And within minutes I got a reply back…so she actually called me and said yes.*"

Mary, through her connection with another DBS user who had been part of a clinical trial interrogating the effect DBS had on mood, was able to find supports to reprogram her device.

Psychological Impacts

Carl shared his experiences being involuntarily institutionalized after developing hallucinations following his DBS implantation. He experienced a significant amount of trauma he was told again and again that what he was experiencing was either impossible or in no way linked to his DBS:

> *"And what really made me mad…I was having side effects and…I should be seeing my neurologist. And not be, you know, sentenced to an area as a guinea pig where they just, in my opinion, dope you up on pills to see if it would help your issues, like mental issues that you're having when I knew inside that this was a side effect from the deep brain stimulation…Well, when I did bring it to my neurologist and told her that, she said quote-unquote, 'That's impossible.'"*

He suggested that the invalidation he experienced made him feel isolated:

> *"Because that's all I wanted to hear from them was why wasn't anything said that, 'Hey by the way…you know what, Carl? After you had the surgery you might have some side effects, but that's just the trade off and there's nothing we can do about it.' I probably would have been totally cool about it. You know, I would've been much more ready for it. So, I didn't feel like I was alienated and losing my mind*."

He and others expressed that rather than having their mental health treated as linked to (and in fact inseparable from) their neurological and physical health, psychological symptoms were treated with condescension and blame. Marty noted that his anxiety was dismissed out of hand, despite that fact that he felt it was exacerbated by poor clinical communication:

> *"That's an excuse to say, "Well, the reason why you're acting this way is because you just, you just get too anxious about what setting you should be on." And that's not really, that's not why – I'm anxious or I'm getting anxious because, you know, you're not telling me the right information or, you know,*

I can't sleep and you're giving me this kind of medication [anxiolytics] instead of a medication that will help me sleep."

George shared experiencing anxiety following his DBS, but admitted his uncertainty as to its source, noting: *"I don't know if there is a connection or if perhaps it is just age-related."* Overall, these experiences of epistemic invalidation exemplify a forced distinction between the neurological and psychological— the brain versus the mind— in the clinic. Additionally, this privileging of clinical or medical authority over self-knowledge, which has been demonstrated throughout this chapter, creates scenarios in which users look for validation from their clinicians and experience distress when they do not receive it. Carl shared his distress when visiting his neurologist, "*She ... [crying]. She doesn't believe me. It's very upsetting. She thinks I'm crazy..."* Through these examples, it is clear that epistemic invalidation has significant impacts on DBS users, and appears especially prevalent when users bring forward psychological, affective, or psychiatric concerns.

Triangulation with Documents

Resonating with the elements of clinical interactions that established clinical authority in the interviews, the majority of documents engaged in credibility-building discourses by providing information about clinicians' credentials, hospital rankings, and other elements to reaffirm the expertise and credibility of the hospital to perform successful DBS intervention. Often, these credibility statements included information about the historical or unique role the hospital or a clinician therein played in DBS research and development. For example, a neurological center frames its informational page about DBS with the following: *"[Center's] neurosurgeons and neurologists were involved in early clinical trials of the therapy and have developed expertise that is hard to find in this emerging field."* Additionally, statistics and

technical explanations are also embedded in many of the materials, as was reflected in the interviews as strategies for building trust and credibility.

As in the interviews, the importance of clinical communication was highlighted in the documentation, often used to build trust in clinicians and establish user autonomy and empowerment. One health service system makes the following recommendation on their informational page: "*You and your neurologist should discuss the role of DBS in your long-term treatment plan early after your diagnosis with Parkinson's disease*." This statement is embedded with assumptions about bi-directional communication, user engagement in decision-making, and transparency by suggesting opportunities to make decisions collaboratively about future courses of action. Another simply assumes trust has been established, stating simply at the top of their DBS informational page, "*thank you for trusting us with your care*."

In contrast to the some of the experiences of epistemic invalidation around psychological or affective experiences following DBS, several of the materials produced by hospital systems acknowledge the potential of DBS to impact mood or personality. One hospital system lists potential side effects as DBS to include "*changes in personality, behavior, memory, thinking or language skills (including confusion)*," while another states that "*DBS does not help improve the cognitive and emotional symptoms of Parkinson's disease, such as depression or memory loss. In fact, it can make these symptoms worse."* The disconnect between the written communications and in situ experiences of the people interviewed in this study raises concerns about mixed messages and variable standards of care. Very few documents addressed the experiential knowledge of DBS users, with the exception of those that simultaneously reinforced the need for users to serve as educators for non-expert such as emergency room attendants or general practitioners. In the documents

examined, there were no suggestions of or allusions to the incorporation of DBS users into the design and implementation of DBS.

Table 7

Epistemic Authority and (In)Validation Theme Summary

Key Points: • Clinical authority is established (or eroded) through credibility- and trust-building activities. • When trust is eroded or priorities differ, clinical authority is viewed with suspicion or resentment. • Embodied and experiential expertise is important in day-to-day practices, but often unrecognized in clinical settings. • Epistemic invalidation occurs when experiential knowledge resist, opposes, or exposes gaps in clinical knowledge.

Subthemes:
• Clinical Authority (82%)
  ○ Trust (73%)
  ○ Communication and Education (64%)
• Embodied and Experiential Knowledge (82%)
• Epistemic Invalidation (73%)
  ○ Psychological Impacts (64%)

Sample Quotes: "His ego was in the way. It was like he had to somehow conquer my brain. And conquer these tremors and make them go away." (Vickie) "She doesn't believe me. It's very upsetting. She thinks I'm crazy..." (Carl)

Conclusion

In this chapter, I have summarized the descriptive findings emerging from an inductive analysis of semi-structured, qualitative interviews with DBS users and their families. Findings were organized into three themes and eleven subthemes broadly addressing the construction and operationalization of disability and the enactment of accountability and responsibility in receiving deep brain stimulation. The first theme, Invasion and Control, addressed the articulation of disability as attack or movement away from the idealized self, differential understanding of invasiveness which included aspects of healthcare not typically considered in clinical settings such as stigma and surveillance, and perceptions of deep brain stimulation and knowledge

acquisition as a means of regaining or retaining control over unruly bodies. The second theme, Self-Responsibility, discusses the prevalence of neoliberal values such as independence and productivity in the desire to pursue biomedical interventions for disability. Additionally, this section discussed how perceptions of self-responsibility and body management were reflected onto others who either had not pursued DBS or experienced poor outcomes. The third theme, Epistemic Authority and (In)Validation addressed the methods by which clinical authority and trust was established or eroded, the perceived importance of embodied and experiential knowledge, and experiences of epistemic invalidation by clinicians.

It is clear from these findings that there are significant tensions between clinical and embodied experiences of deep brain stimulation. These include differential understandings of invasiveness and repression of experiential knowledge. Informants often fill these knowledge gaps themselves, positioning themselves as embodied experts in support groups and to others considering deep brain stimulation. Further, people who are deemed eligible candidates may feel obligated to pursue DBS due to the social and political pressures of neoliberal ableism. People considering DBS are then caught in the double bind of the expectation of personal accountability and the invalidation of their embodied expertise or self-knowledge. One additional notable experience was the shifting perception of clinical and medical authority. Credibility and authority from clinicians and device manufacturers were a source of comfort and trust in some situations, often contributing to the eventual decision to pursue DBS. However, in instances where embodied experience challenged that authority— such as through the experience of psychological side effects— that trust quickly soured and authority was deemed more as a source of social control. The individual experience of medicalization as social control bolsters the theoretical arguments that

animate sociological scholarship on the subject and opens up additional research questions about the fluid nature of clinical relationships. These tensions will be explored in greater detail in Chapter 7.

CHAPTER 6

"IT COULD BE A DIFFERENT WAY:" DIY ARTIFICIAL PANCREAS SYSTEMS

Introduction

In this chapter, I will present the descriptive findings and inductive analysis of interviews with users and developers of do-it-yourself artificial pancreas systems (DIY APS). I will also present findings from an analysis of user-directed guidance documents, including collaboratively-produced directions for DIY systems, informational blog posts, and regulatory warnings about the use of off-label systems such as DIY technologies. I relate feelings of difference and guilt about disability to perceptions of personal and community responsibility to pursue off-label or non-sanctioned treatments, challenging perceptions of clinical or professional authority through an emphasis on experiential expertise and self-taught or community-based knowledge. Four major thematic areas, each with subthemes, are presented below. The first two themes, Insufficiency and Invalidation and Embodied Resistance, both address both research questions, respectively explicating the meaning and experience of disability and difference in a medical paradigm that does not value or respond to individual experience and the development of a community built on mutual priorities and experiences. The remaining two themes, Risk and Responsibility and the Profile of a DIYer primarily address questions of personal responsibility and accountability, correlating with the second research question. Themes and subthemes are summarized in tables at the end of each thematic section.

DIY APS, otherwise known as hybrid closed loops or automated insulin delivery systems, are systems that integrate continuous glucose monitors, insulin pumps, and smart phone or smart watch technologies with open source algorithms in order to

control insulin delivery for people with type-one diabetes (T1D) with limited user engagement. There are currently three DIY APS variants in regular use:

OpenAPS. This system was the first widely reproducible DIY hybrid closed loop, developed originally by Dana Lewis, Ben West, and Scott Leibrand in the United States in 2015 (Crabtree, McLay, and Wilmost, 2019). It was based in part on the design created by Lewis and Leibrand started in 2013. It is compatible with some Medtronic pumps (older pumps with a security feature that allows communication with other devices), uses a Pebble watch and a microcomputer, and recommends changes in insulin delivery by referring to trends in data such as insulin sensitivity factor (ISF), basal rates, and carb ratios (most often through another open source program called Autotune, which iteratively adjusts basals, ISF, and carb ratios by drawing on data over several weeks) (Lewis, 2017)

Loop. Developed in 2015 by Nate Racklyeft and Pete Schwamb in the United States, Loop uses a different algorithm and hardware than OpenAPS and is compatible with both the Medtronic pumps used in OpenAPS as well as the tubeless pump Omnipod. It utilizes an iPhone, Apple Watch and a specially designed communication component called a RileyLink (Crabtree, McLay and Wilmot, 2019).

AndroidAPS. Developed by Milos Kozak and Adrian Tappe in the Czech Republic and Austria respectively, Android APS was designed to serve a large European community. It utilizes an Android phone and smart watch and is compatible with a large selection of pumps (including Dana R, Dana RS, Roche Combo, Roche Insight, and Virtual Pump) that all can communicate with the other system components without additional hardware components (Crabtree, McLay and Wilmot, 2019).

As of January 2020, there are over 1,700 DIY closed loop users around the world, with more than 20 million "loop hours," according to the OpenAPS community (OpenAPS, 2020). A 2018 retrospective study conducted by OpenAPS community members in the United States with 20 users found that blood glucose, hbA1c (or average blood glucose level over time), glucose "time in range" (or number of hours when their blood glucose is within the clinically defined range of 70-180 mg/dl) all improved through the use of OpenAPS (Lewis, Swain, and Donner, 2018). Similarly, a study in Italy in 2018 with 30 participants (Provenzano et al, 2018), showed statistically significant changes in A1c and percentage of time in hypoglycemia through the use of OpenAPS. A study conducted in South Korea with 20 children also showed significant benefits from OpenAPS, including decreased A1c, increase in time in range, and decrease in time in hypo- or hyperglycemia (Choi, Hong and Noh, 2018). In a self-reported survey, users also report better quality of life through "increased time in range, uninterrupted sleep, and peace of mind" (Lewis, Leibrand and #OpenAPS Community, 2016, 1). However, in each of these cases samples were small, and may represent a subset of people with diabetes who are especially tech-savvy or engaged in their management (Lewis, Leibrand and #OpenAPS Community, 2016; Crabtree, McLay, and Wilmot, 2019). Further, while these systems automate some care delivery, Lewis (2018) notes there are misconceptions among many stakeholders that artificial pancreas systems will be a technological cure rather than a tool that requires active attention and engagement. Similarly, people within the DIY community and clinicians have expressed concerns that DIY APS systems will result in deskilling of newly diagnosed people with diabetes, who will not be able to manage using more traditional insulin pump setups or multiple daily injections (MDI) (ibid). To counteract the myth of full automation, the term "hybrid closed loop" is often used to clarify user engagement as crucial to effective use of DIY APS systems.

By having "hybrid" qualify "closed," this term suggests a less autonomous technology. An example of continued user engagement would be manually doing meal boluses as you would do with a traditional commercially available pump. As the OpenAPS site states, "OpenAPS is not a 'set and forget' type of system. You'll still be actively managing your diabetes and doing basic self-care as you were before – this includes everything from meal boluses, checking BG and calibrating the CGM, changing out pump sites, etc." (OpenAPS, ND, FAQ 4). While one commercially-available hybrid loop is currently on the market (Medtronic 670G), it has been criticized for its lack of customizability and has high abandonment rates in situ (Goodwin, et al, 2019). Several other closed loop or automated insulin delivery systems are currently in development, often based on DIY algorithms and systems (e.g. Tidepool Loop, Bigfoot Loop, Beta Bionics ILet).

This case provides a particularly interesting site to examine the relationship between the construction of disability and individual responsibility and agency. Responsibility emerges in part from the failure of the medical establishment to respond to the needs and desires of people with T1D, and as a result expertise in this community emerges directly from embodiment and/or experience. Further, an emphasis on decentralization, transparency, and collaboration create different conditions for the production and sharing of knowledge than that found in traditional medical professional-patient relationships, creating a distinct connection between agency and personal responsibility.

Sixteen informants were interviewed, ten people using DIY artificial pancreas systems on themselves, and six guardians of children using DIY APS. One informant is heavily involved in the development of DIY technologies, and three are employed by companies attempting to formalize and gain regulatory approval for technologies

emerging from DIY spaces. All but one informant use one of three DIY APS systems: AndroidAPS, OpenAPS, or Loop. The remaining informant was interviewed immediately prior to beginning OpenAPS. Nine informants were living in the United States at the time of their interview, and the remaining seven were living in Europe. Countries represented include the United Kingdom (2), Romania (1), Austria (1), Spain (1), and Czech Republic (2). Interviews were conducted verbally, either in person, over the phone, or via a video conferencing service and ranged from forty to one hundred minutes, averaging seventy minutes. In two cases, written correspondence was also included in the data analysis with permission. In one case, an informant requested a follow up interview, but otherwise each interview was conducted in a single session. Informants and method of recruitment are briefly described below. Pseudonyms were assigned using a random name generator.

Benjamin. Benjamin is a 30-year-old software engineer living in the United States. He was diagnosed with diabetes at the age of three and began using an insulin pump at nine. He began using OpenAPS in 2017 before switching to Loop. He was recruited via an online DIY forum.

Abene. Abene is a 35-year-old PhD student living in an autonomous region in Spain. She has been diabetic for 20 years. She had been using a pump for 2 months at the time of the interview and planning to begin OpenAPS shortly. She was recruited via an online DIY forum.

Nikol. Nikol is a 40-year-old mother of two living in the Czech Republic. Her eldest son **Adam** is seven-years-old and was diagnosed with T1D at the age of two. Adam began using an insulin pump 8 months after he was diagnosed and has been using AndroidAPS for the better part of a year. She was recruited via an online DIY forum.

Jonas. Jonas is a 45-year-old father of two and husband of Nikol living in the Czech Republic. He was primarily responsible for building AndroidAPS and NightScout for their son, Adam. He was recruited via an online DIY forum. He and Nikol were interviewed together.

Aditi. Aditi is a primary care physician and mother living in the United Kingdom. She is a mother of three, and one of her children, now eight-years-old, was diagnosed with type one diabetes last year. They started using a continuous glucose monitor shortly after diagnosis and started using a pump and AndroidAPS last summer. She was recruited via online DIY forum.

Carolyn. Carolyn is a type one diabetic living in California. She has had diabetes for almost 55 years and has been using Loop for the past two years. She is also an active diabetes blogger and runs a diabetes support group. She was recruited via targeted communication.

Ramona. Ramona is a 25-year-old medical student living in Romania. She was diagnosed with type one diabetes when she was 10 years old and has been using an insulin pump since she was 14. Last year, she began using a continuous glucose monitor, and began using AndroidAPS shortly after. According to her, she is the first person in Romania to use an artificial pancreas system. She was recruited via an online DIY forum.

Marianne. Marianne is a mother of a seven-year-old son with type one diabetes living in Austria. Her son was diagnosed in 2015 who began using NightScout in 2016 before beginning using AndroidAPS in 2018. She was recruited via an online DIY forum.

Erica. Erica is a 28-year-old nursing student living in California. She has had diabetes for 26 years. She began using an insulin pump and continuous glucose monitor in 2015 and began using Loop in 2018. She was recruited via snowballing.

James. James is a 58-year-old retiree living in the United Kingdom. He was diagnosed with diabetes in 1968 and used many different diabetes technologies throughout his life. He started using a continuous glucose monitor and an insulin pump several years ago before building his rig for AndroidAPS in the summer of 2018. He was recruited via an online DIY forum.

Evelyn. Evelyn is a pharmacist and citizen scientist living in the southwest United States. She was diagnosed with type one diabetes 32 years ago. She has been an active member of the DIY community and used NightScout before eventually building an OpenAPS rig. At the time of the interview, she was planning on transitioning to Loop. She was recruited via an online DIY forum.

Amy. Amy is a mother and employee of a diabetes technology company with a background in first aid and biology, living in California. She has a 12-year-old daughter who was diagnosed with type one diabetes at age 8. She started using an insulin pump shortly after diagnosis and transitioned to a commercially available hybrid closed loop system. They eventually switched to Loop when the commercial system did not provide the functionality they were hoping for. She was recruited via email request.

Joel. Joel is a 24-year-old PhD student currently working with a diabetes technology company and living in California. He was diagnosed with type one diabetes when he was 11. He has been using Loop since winter of 2019. He was recruited via email request.

Gordon. Gordon is a father of two and designer for a diabetes technology company living in California. His daughter was diagnosed with type one diabetes when she was 1 and a half years old. He was recruited via email request.

Gary. Gary is a 35-year-old man with a computer science background living in the Midwest. He identifies as Asian and has been living in the United States for four and a half years. He was diagnosed with type one diabetes in July 2017 and starting using Loop in September of that year. Gary also mentors healthcare professionals with diabetes to use DIY systems. He was recruited via an online DIY forum.

Melody. Melody is a woman in her mid-30s living in the Northwest United States. She was diagnosed with type one diabetes when she was 14. Since 2013, she and her partners have developed several DIY diabetes technologies, including the first public example of a closed loop system. She has been using some version of a hybrid loop system since 2013 as well as other DIY diabetes technologies, and is an active leader, researcher, educator, and user in the DIY community. She was recruited via my personal network.

For this case, more than 260 pages of documentation were reviewed, ranging from guidance documents created and shared in DIY communities to FDA regulatory warnings and media publications. In direct opposition to the other cases in this study, it is likely that much of this documentation was written by users themselves, including some of those interviewed in this study. Therefore, it is unsurprising that themes in the documentation aligned with themes in the interviews.

Theme 1: Insufficiency and Invalidation

When deciding to build and use DIY technologies to manage diabetes, many informants cited a dearth of resources, support, and technologies available to them via sanctioned routes of care. For many, a primary motivator was that available

technology could not provide the features they needed, and clinicians failed to provide support or information that could be meaningfully applied to their lives. Further, in traditional care pathways, they noted that despite insufficient technologies and clinical support, they were still often blamed for their poor outcomes. Often, discontent stemmed from perceived invalidation of their experiences and disjunctions between their lived realities and the priorities of clinicians and device manufacturers.

Difference and Blame

Two interlinked experiences, perceived difference from others without T1D and blame from clinicians or other authority figures for poor health outcomes, appeared in the majority of interviews. For several informants, including Ramona, Joel, Carolyn, Benjamin, Melody, and Erica, they grew up feeling isolated or stigmatized because of their diabetes, which in turn caused them to distance themselves from it and its management at some point in their lives. Benjamin noted he avoided forums to communicated with other people with T1D because *"I didn't want to define myself by diabetes."* Joel expressed a similar position prior to starting DIY tech, *"I think I was always more or less trying to minimize the amount of time that I ... I didn't really identify having diabetes as part of my identity."* Nikol noted that her young son is currently experiencing the realization of difference that many of the adults with T1D recounted in their interviews: *"So, I think for him it was a very big moment when he was thinking that, 'I am a bit different than the others.' I don't think he was thinking any of that before."* Often, what exacerbated or accompanied feelings of difference was resentment about the constant burden of management or judgement and blame about perceived failures to manage or control diabetes adequately. Carolyn discussed her frustration with the blame experienced by many people with

T1D, which she suggested often fails to account for the cognitive, physical, and emotional toll constant management can take on a person:

> *"And, yes, they are blamed. And even if they're not doing everything they should and could be doing, they're not evil people. They're just burned out. They're tired. They're overwhelmed by it. And how do you keep doing the same thing, and not getting good results, and keep caring to do it?"*

Gary also expressed exasperation at the blame that gets off-loaded onto people with T1D from clinicians, noting that current on-label treatments – even when people with T1D can access them and knowledgeable clinicians – make it nearly impossible to achieve those results:

> *"And also, there's a lot of blaming patients for not getting desirable results. So basically, if your A1c percentage is too high, [inaudible], because the normal level is about 5-6%, under 6%, and you want to get as close to 6% as you can, whereas the average patient is about 9-10%. And right now if you are sticking to the book, I don't think it's possible to get anywhere near the desirable temp 7% target that all the professional associations want."*

For many, their introduction into DIY communities altered their relationship both to diabetes and to each other. Melody articulates this transition in her interview, stating:

> *"I do consider diabetes to be a chronic disease, and that is something that, like, yes, I would say I have a chronic disease. It has always been a part of my identity, that's actually something I was very concerned about when I was diagnosed. I didn't want it to be part of my identity, I didn't want to be thought of as a person with diabetes, um, but I just feel so differently now. I don't want*

to be cliched like 'I feel so empowered now' – it's not like I wasn't empowered before, but I just feel more confident, is probably the right word, in terms of living life with diabetes and figuring things out and going with the flow and having the tools to support me to do all those things."

Access to both people and resources that redefine diabetes, control, and community reconfigure attitudes toward themselves and others.

Clinical Relationships

When I asked about the experience of broaching the topic of alternatives interventions like DIY technology with their clinicians, informants shared memories of a range of clinician responses, from disinterested to enthusiastic. Anecdotally, informants suggested that specialists like endocrinologists often displayed disinterest or reluctance, while generalists, including general practitioners, displayed interest and even support. Clinicians or medical professionals such as certified diabetes educators (CDE) who had diabetes themselves often were especially supportive of DIY technologies. For some, like Evelyn, her poor clinical interactions, especially those that blamed her for her poor quality of life managing her diabetes, encouraged her to pursue DIY options:

"They just didn't have a level of knowledge, I guess is what I would say. I just didn't feel like I was getting anything at all from them. And I was still trying to get something from them…And so, I kept trying to find somebody with the knowledge I needed to make things better, and there was nobody."

Joel echoed this sentiment, having found DIY APS following a chastising from his endocrinologist about his health. *"He didn't seem very interested in discussing advanced moves in diabetes management,"* he shared. *"I don't know what he expected me to do."*

Informants also shared stories of a variety of clinical responses when they brought in DIY technologies and management tools. Many, like Ramona, Erica, Abene, and James have been met with enthusiasm and encouragement from their clinicians, even if they are legally not able to provide much support. Nikol and Jonas recalled being asked if they were crazy by a clinician when they requested a loopable pump for their son. They, Marianne (also a parent), and Evelyn (diabetic herself) all also recounted being told by clinicians that their DIY technologies amount to micromanaging their diabetes and their clinicians cannot or will not provide support if they won't follow clinical recommendations. *"I can't help you with settings if you keep doing that,"* Marianne recalled being told directly by her endocrinologist. More often, however, informants were met with disinterest from their clinicians. Melody, who was on the leading edge of DIY closed loop technology development, shared her endocrinologist's response when she first showed him an early iteration of a DIY alarm (a precursor to APS):

> *"And I went to the endo's office and I was like 'Hey, I built this thing, it makes the alarm louder, it tells me what to do, it wakes me up at night, it's fabulous!' and I was so excited. And he looked at me and said 'Okay, do you get less lows?' And I said 'Uh, yeah.' And he said, 'Okay, what prescriptions do you need?' Like, I built this thing, and it's amazing, and you're not interested at all. It's very deflating and disappointing."*

The tensions that arise from people with T1D and their families being held responsible for poor health outcomes, but receiving little to no support, and sometimes outright resistance, to pursue new types of off-label management plans like DIY APS creates a bind in which they are configured as both accountable and impotent in clinical settings. The DIY community provides an alternative set of power

dynamics, which still configure them as responsible, but also enable them to make meaningful decisions about how they manage their diabetes.

Mismatched Priorities

A theme that nearly all informants addressed was an experience of mismatched priorities between those living with T1D (as diabetics or as guardians), and everyone else, whether that be clinicians, device manufacturers, or paid caregivers such as teachers and school staff. For some, especially guardians, this manifested in distrust and a desire for control. Marianne, for example, wanted to fully manage her son's diabetes remotely through AndroidAPS, as she felt his teacher operated with a different set of priorities than she did, due to her liability when administering insulin:

> *"One advantage that me taking care of my son's management 24 hours a day is definitely a good thing for my son's management because I make decisions differently than the teacher does. The teacher's main concern is for my son to not have low blood sugar in school. So, she will be biased. Her decision will be biased to keep him higher so that there's no low blood sugar. Right? And I have a different mindset because fair enough, I don't want him to go low, but I also don't want him to stay high. Right? And I bring, so to speak, this philosophy in my decision making on what I pump and when and how all the time."*

Others noticed and chafed against the mismatched priorities that resulted in sanctioned technologies and treatments that did not work as desired. Prior to beginning to use a DIY APS, Benjamin had avoided news about diabetes technology, feeling it had all stagnated. *"I think it's that we were, that it wasn't – I don't want to say hopeless, but it was a fixed set of options…this is what it is to have diabetes."* Evelyn was explicit in her reluctance to return to sanctioned medical devices:

> *"My motivation and the motivation of people in the DIY community is parallel. My motivation and the motivation of Dexcom [manufacturer of a popular continuous glucose monitor] are not, because they are a publicly traded company, so automatically our interests are not the same."*

Perhaps most explicitly, Gordon brought into focus that limited engagement with diabetic people in the design process has resulted in a stagnated view of the world which does not acknowledge different ways on knowing can be directly built into medical technologies. *"I think, arguably the most important ingredient in these communities is an unwillingness or just a recognition that so much of this is the built world. These are human choices that humans made, and it's changeable,"* he said, referring to communities with authority to change design and practice on a large scale. *"The disease state, maybe not, but everything that we build around it is. We made it this way and it doesn't have to be this way. It could be a different way."* These mismatched priorities and motivations were brought into acute focus when considering the curative rhetoric adopted by clinicians and device manufacturers.

Curative Promise

An essential tension roughly half of informants highlighted was their desire for better quality of life – which many asserted they achieved through DIY looping technologies – and clinical and device manufacturers' preoccupation with a curative promise. In other words, while diabetics and their families looked for strategies, practices and technologies to improve their quality of life, they instead received promises of an imminent cure. Many, like Evelyn, remarked on the humor of being told over their entire lifetimes that a cure was coming: *"everything's always five years away."* Carolyn, however, was adamant about the danger of a curative

promise. She recalls her diagnosis over 50 years ago, which was accompanied by her physician's promise of a forthcoming cure:

> *"My doctor was world-famous, and he said, 'There will be a cure in two years.' A lot of us were told that. And after two years, he goes, 'No, it'll be five. Don't worry about it.' And I started to kind of give up on that after about 10 years. I thought, 'Well, he's lying.'"*

She continued with her fears for people offered the same kind of technological optimism: *"What I hear a lot now in young people, is they don't feel they have to control things, because there will be a cure. So, they'll just run wild until then."* In her estimation, a technological savior is particularly attractive in diabetes, which requires a significant amount of physical and cognitive work.

> *"Control your portions, and do this and do that, and take shots, and stick things in you, for the benefit of not dying. It's not like, for the benefit of making a million dollars. Or benefit of, you get to eat cookies. You don't. The benefit is, you don't die, and you don't get miserable complications. It's a negative."*

Further, Gordon asserted that the movement away from a curative promise and toward attentiveness to quality of life enabled participation from people previously excluded from design and care:

> *"I mean, even just this insight of like, the shift from quality of life to cure, I think is really critical. Because cure is so inaccessible, like it's the specialized guild and priesthood of medicine that has all these boundaries around it that you can't cross."*

In his estimation, this curative promise keeps control and authority firmly in the hands of clinicians and researchers, while quality of life thinking delegates agency back onto individuals whose lived experience is essential for meaningful design and practice.

Regulation and Formalization

Informants often held multiple, sometimes conflicting, perspectives on the design and regulation of medical devices like insulin pumps and CGMs, which are key components to DIY APS as well as more traditional diabetes management. While several informants expressed frustration at the slow and rigid approval processes that prevent medical devices and processes like DIY APS from being commercially available, the majority of informants also expressed trust in FDA safety approval processes. Benjamin and Nikol directly expressed an interest in adopting commercial devices once they become available and approved by regulatory bodies, in part to mitigate the responsibility on themselves that DIY solutions demands. Joel struggled to balance the tradeoff between safety and customizability, noting:

> *"I guess that is my fear, because I do feel like obviously you can iterate a lot faster and make more individualized solutions when you have more control like with the DIY stuff. I expect a lot of that to go away, and that is a trade-off because supposedly the solutions coming out will be broadly safer, but they won't be as customizable, I assume."*

Others fears of regulatory bodies were more immediate: Amy mentioned she initially feared adopting a DIY system for her daughter because she did not want to be accused of negligence for using an off-label treatment. Carolyn revealed that she no longer shared public information online about looping because she feared it would impact her Medicare benefits. Evelyn feared the regulatory community could partner

with device manufacturers to further limit access to DIY materials. According to Evelyn, those fears of regulatory gatekeeping were bolstered by the 2019 US recall of Medtronic MiniMed 508 and Paradigm series insulin pumps due to a security flaw in its wireless communications; a flaw that enabled it to be used in DIY closed loop systems (Cybersecurity and Infrastructure Security Agency, 2019). However, not all communications from regulators regarding DIY systems were deemed threatening. Melody shared her thoughts on another 2019 FDA statement warning about the use of DIY systems and devices, noting she viewed it not as a threat to DIY communities, but an affirmation of their commitment to safety:

> *"We care about safety, and so we absolutely support people reporting to the community or FDA if they have problems. (Interestingly, a lot of people learned through this communication that you can/should report commercial adverse events, too - many people don't know that! So adverse events go under-reported even for commercial devices)."*

Such statements, along with those hoping for (or working toward) regulatory approval for DIY systems do not configure DIY communities as radically opposed to regulatory and authority bodies, as they've sometimes been presented in media, but as responsible users equally invested in regulatory approval as a means to expand the reach of DIY solutions.

Additionally, calls for additional regulation and formalization of resources appeared throughout the interviews, especially in terms of providing formal networks of support, akin to customer service, for emerging management solutions like DIY APS. As Gary shared, this need for more support does not only apply to DIY systems, but more broadly as more complex medical devices come to market:

> *"And I think as these systems become more and more complex, the FDA needs to look whether it is realistic for someone of average intelligence and self-awareness - whether the amount of training materials provided is sufficient, only relying on those materials. I think it is too much to ask a patient to have to rely on unofficial sources to get the most out of these systems."*

Here, regulation was not seen as an impediment to innovation, but an essential component to making these innovations accessible to a wide audience.

Triangulation with Documents

The documents that emerged from the DIY community itself unsurprisingly resonated with the perception that currently available commercial technologies were insufficient. For example, one blog that supplements documentation for a DIY APS system describes the frustration of non-communicativity between devices, lamenting that *"When you go to your endocrinology office, you probably start the process by dropping many of those devices at the front desk to be individually downloaded and then having to pack all them away 20 minutes later."* While experiences of difference and blame were not directly addressed, potentially tense relationships with clinicians were alluded to in several documents. All three documentation sites for the major DIY systems currently in use provided additional information for clinicians, including professionals such as school nurses, to try to bolster clinical support and communication. *"As with all things health care related,"* one blog read, *"honesty with your health care provider is paramount so that the best decisions can be made."*

While less explicitly stated than in the interviews, the documentation from the DIY community also contained excerpts that suggested frustration with the mismatched priorities of commercial manufacturers. For example, one DIY system's

documentation addresses the lack of support from commercial manufacturers to allow for communication between devices, stating

> *"Until and unless companies elect to provide such access, the open source community will continue reverse engineering additional insulin pumps wherever possible to make APS technology as widely available as possible until all individuals living with Type 1 Diabetes have the opportunity to sleep safely every night."*

Although, like several interviews, this same document grants the benefit of the doubt, later stating, *"We support all of the companies working to commercialize a closed loop system. We just wish they would each get their solution(s) to market more quickly!"*

Regulation also emerged as a major theme in the documentation. As with the interviews, regulation was sometimes regarded as an essential safeguard – such as when documentation asserts *"It is critically important that you only use a tested, fully functioning FDA or CE approved insulin pump and CGM for closing an automated insulin dosing loop."* The FDA itself released a warning about off-label devices and treatment plans, using similar language relating FDA-approval to safety: *"These unauthorized diabetes management devices have not been reviewed by the FDA to ensure they provide a reasonable assurance of safety and effectiveness for their intended use."* In other cases, as with the interviews, it was viewed as an impediment to access. One blog accompanying a DIY system's documentation addressed this when justifying DIY, claiming

> *"We believe that we can make safe and effective APS technology available more quickly, to more people, rather than just waiting for current APS efforts to*

complete clinical trials and be FDA-approved and commercialized through traditional processes."

This ambivalent and precarious relationship with manufacturers and regulators, acknowledging both their value and shortcomings, characterizes the attitudes of many in the DIY community.

Table 8

Insufficiency and Invalidation Theme Summary

Key Points: • Much of what is available to people with T1D, from technology to clinical support, is insufficient, which compels people to pursue off-label treatments. • In spite of people's expressions of insufficient support, they are still often blamed for poor outcomes • Much of the discontent people have with the technologies and treatments available to them stems from a recognition that neither clinicians nor device manufacturers have the same priorities as they do. • Regulators such as the FDA are perceived as limiting innovation and options in some regards, while in other regards are held up as protecting users.
Subthemes: • Difference and Blame (81%)[10] • Clinical Relationships (94%) • Mismatched Priorities (94%)   ○ Curative Promise (44%) • Regulation and Formalization (75%)
Sample Quotes: "I didn't want it. I didn't want to be different. I just like said, 'Okay, I don't want to do this anymore.' So, for a while, diabetes was the worst enemy in the world to me and I was struggling, struggling, struggling with trying to deal with why [inaudible] - why I had to deal with this thing and other people didn't." (Erica) "I hate to say yes because that's like a terrible soundbite [laughs], but I think any provider that is threatened by a patient doing things on their own would likely be equally threatened by them choosing a technology like this, whether commercial or DIY, that truly puts the power and the flexibility back into the patients' hands." (Melody) "We're Not Waiting, came about because ultimately, we're a community that felt like the people who had the power to make devices that we needed and solutions that we needed, weren't listening to us." (Gordon)

[10] Percentages are derived from number of *interviews conducted* rather than number of interviewees, as several informants were interviewed together, and one informant was interviewed twice.

Theme 2: Embodied Resistance

The second major theme, often motivated by the first theme, was the ways in which embodied and experiential knowledge are leveraged in the DIY community to resist and transform the invalidating and insufficient paradigms in the traditional medical paradigm. Informants expressed trust and affinity for DIY communities in part because of their shared experiences and motivations, and in part because of the allure and excitement of creating, collaborating on, and experimenting with off-label treatments. Additionally, informants described the value of these DIY technologies in terms of quality of life and reduction of cognitive burden, two elements of living with diabetes that are often unacknowledged or undervalued in traditional clinical communities.

Community Ethos

"That's part of the blessing of the do-it-yourself community, is it's impatient," Carolyn shared during her interview. *"And it's not ... I don't know if I'd say it's angry, but it's just impatient. It's like, 'Okay, don't tell us to wait.' So, I like that."* This statement, which suggests empowerment, collective motivation, and an action-oriented ethos summarized much of what all informants found appealing about DIY APS. For many, the technology itself was only one benefit; involvement in a like-minded community offered was in some cases an equally valuable benefit to pursing DIY APS.

Shared Experiences and Priorities

In direct opposition to perceptions of distrust and mismatched priorities with commercial device manufacturers and clinicians, the majority of informants explicitly stated that their trust in DIY communities emerged from their shared experiences and priorities. *"I think that the shared experiences bring us together and we have to*

be compassionate for one another," Amy stated, *"because we're not always compassionate to ourselves."* Further, as Gordon shared, because this community has experienced technological black-boxing, losing access to their health data, and being relegated to passive "patient" roles, the technology *and* the community have been developed to intentionally push back against that experience and reclaim agency. When speaking about the company he works for, which is formalizing DIY technology for regulatory approval, he noted the values they strove to maintain:

> *"Of being radically open and transparent, that people own their own data and should be able to both understand how it's being used and controlled. And those are not common values in technology. I think that comes from this lived experience and intentionally shaping the company to exist to serve these values and these goals, as opposed to get acquired or ship a product real fast."*

He continued by expressing that his engagement with DIY communities has personally altered his perception of himself in relation to his daughter's diabetes, stating:

> *"I can tell you, like We're Not Waiting and finding that group of people that's transformative for my own sense of agency and wellbeing and of not just giving up and moving beyond victimhood and back into agency. And even if it's not effective for anything else, that's really valuable."*

Much of the trust that informants expressed feeling for DIY technologies emerged from a recognition of the knowledge that arises from living with and managing diabetes on a daily basis. This aligned with distrust or dismissal of clinical and manufacturer knowledge as being incomplete. Gary shared:

> *"And a lot of healthcare providers don't have diabetes themselves, so they don't understand what it's like living with it…Because all physicians can learn through word of mouth and studies, but if you're not living - diabetes is about the most intensive, hands-on disease there is. You have to so much self-care."*

He continued by asserting that people must rely on informal communities of people with diabetes in part because traditional medical training makes it very difficult for people with T1D to become clinicians. In the DIY community, however, the expertise of everyday practice is highlighted and celebrated. Being built on a foundation of flexibility and individual customizability, DIY APS communities adhere to the basic principle that, as Benjamin said, *"I know my body. And I know what works for me."* In many instances, building and using DIY technologies was an opportunity to assert the embodied and practical knowledge that had been invalidated or minimized in clinical settings, resisting a passive patient narrative.

It is important to note here the distinction between the embodied knowledge of people with T1D and the experiential knowledge of guardians of children with T1D, a division acutely felt by several guardians who were interviewed. *"There's even a sheer between my experience as a parent caring for a child and the experience of somebody who actually lives with the disease,"* Gordon noted when discussing his involvement with a design project centering the experiences of a teen with T1D. He continues:

> *"And I think it's an important distinction to hold. I consider myself a part of the Type 1 community, but I do not carry the disease in my body. I carry the burden of that disease for my daughter but one day she's going to take it and be the primary one carrying it. It's a bit of an insider-outsider perspective."*

Marianne and Amy both also addressed their role as parents as one distinct from people managing their own diabetes. Marianne shared that while her young son was currently using DIY technologies and starting to become involved in his management, he had the right to choose what he wanted to do in the future. Amy acknowledged her daughter's frustration at times, admitting, *"As much as I want to be there for my daughter, I'm not the one going through it."* This distinction highlights the recognition and respect for embodied knowledge of people with T1D while also acknowledging the practical and experiential knowledge of guardians and caretakers of children with T1D.

In addition to feelings of community and trust with others with diabetes, Melody, Amy, and Gordon also discussed feeling compelled to bring this community ethos to other disability communities, suggesting an affinity for a broader disabled community rather than viewing people with T1D as singular and exceptional. Melody suggested that the support and attention given to the DIY APS community can be leveraged *"into a broader conversation around the broader principles of patient driven innovation and research."* Gordon was slightly more reserved in his opinion on whether the possibilities of DIY APS could be generalized to other disability communities, *"But I've wanted to try, because I think that there has been so much good about it."* The identification with and affinity for broader disability communities signals a movement away from adherence to medical categorization and toward a political and social disability identity, a move that further resists medicalization and clinical authority.

"Rogue Cowboy Hackers"

"Rogue cowboy hackers…" Evelyn laughed, *"that's what Dexcom called us, back in the beginning."* While Dexcom apparently leveraged the term "hacker"

derogatorily, informants explicitly or implicitly all advocated for principles often related to the "hacker ethic," including collaboration, experimentation, altruism, and radical transparency (Keulartz & van den Belt, 2016). Others found the allure of building and creating new technologies exciting. *"It got my "gadget-drive" going,"* Benjamin said, *"It felt like a new toy, in a lot of ways, but so much more."* Ramona expressed the process was *"like an adventure."*

The iterative, organic, and experimental elements of DIY APS also featured in many interviews. James found the playfulness of DIY appealing, stating that whenever he had a question about what DIY APS could do and he couldn't find a readily available answer, he thought to himself, *"'Okay, nobody knows about this.' And, you know, I'm techy, I play. I go, 'What happens if I do this? Or what happens if I do that?'"* Melody, who was engaged at the earliest stage of DIY APS development acknowledged that a tolerance for experimentation was necessary to make it work.

> *"So, it wasn't so much that I knew a solution, like 'Oh, we're going to do x and y and z' and you know, be really straightforward and easy. It was experimentation by both of us [her collaborator and herself] …and just chipping away until we figured out how to do it."*

The experimental and self-reliant elements of the DIY community also creates an investment in both the technology and in the individual success of others in the community. As Gordon says,

> *"I call it out as the Ikea effect: where you spend time making that awful shelf. Even if it's falling apart and has real problems, you love it because you put*

time and blood, sweat, and tears into it. It's something I think about a great deal as we watch the community online grow."

This collective buy-in creates a culture that is committed to iterative improvements, knowledge- and resource-sharing, and mutual encouragement. As Erica expressed, *"Everyone is with you to have the best management possible."*

Inherent in conversations about experimentation with DIY APS were acknowledgements of collaboration, both in the DIY community itself and with other stakeholders such as commercial device manufacturers and researchers. Informants expressed a sense of openness, transparency, and knowledge-sharing as vital for both the development of the DIY community and increasing accessibility to others through regulatory approval and commercialization, even while recognizing the shortcomings in commercial device design and clinical care. *"I believe the technology people actually are trying to develop something that helps diabetics,"* Carolyn shared while explaining why she continually engages with commercial device manufacturers, *"so I want to give them access. I want them to be able to talk to me. I want to be able to give them input. And I just, somehow, plow forward."* In her estimation, she views commercial manufacturers as well-intentioned but uninformed, and so makes a concerted effort to develop collaborations, injecting herself into the process often without invitation. Melody also articulated the importance of collaboration across stakeholders, advocating for radical transparency and the centering of the experiences of users with T1D as crucial to meaningful technological development:

"We don't necessarily have to work with companies, though we'd like to. We don't have to work with researchers, though we'd like to, but it's like how do we get everybody all together? So social media and kind of the open source diabetes community has played an interesting role in all these areas, including

research of how to bring people together instead of talking over each other's heads or duplicating work or you know focusing on credentials or whatever. We can actually say 'What are the unsolved problems that are actually meaningful to the community and let's go tackle those.' Because that's good for the diabetes community, it's great for the researchers and their careers, it's great for medical literature in the long term. So how do we combine all these things to be a win-win-win all around."

Control and Quality of Life

"The word control is so significant in the diabetes world," Carolyn stated, and nearly all of the interviews featured themes around control: over diabetes, over management plans, over biometric data. Many interviews directly connected control to quality of life and quality of life to the adoption of DIY technologies. As discussed above, the distinction between tools and technologies that support quality of life and those deployed for curative purposes is acutely felt by many with T1D, with the latter being positioned as an elusive but alluring promise in the medical establishment. For some, control over their management plan translated into freedom. As Abene states, upon beginning to use DIY remote monitoring of her blood sugar levels, *"I felt more independent than I used to be."* For parents like Nikol and Jonas, *"the remote control, it is again a big step because when our son wants to go with his friends, for example, we have him under control, so we don't have to be on the phone with the parents of the friends every 5 minutes."* The visibility of data enabled by DIY APS meant a perceived feeling of control by virtue of the transparency of the decisions the APS algorithm makes. By taking diabetes management out of the black box of commercial devices (or out of the guesswork out of analog interventions such as multiple daily injections), *"I think about my blood sugar more, and yet I think about it less,"* as Benjamin said.

Erica recalled of her time prior to using a DIY APS:

> *"There was a little bit of a cloud over my potential and then all of a sudden it was like the clouds broke apart and moved and I really feel like I'm fully living my life. My brain and my body and my energy. Everything's very clear, very definitive now. Like there's nothing that I feel like I can't do because I actually am in it."*

Beyond the immediate and tangible control over diabetes management that many acknowledged DIY APS enabled them, Gordon articulated a different, more metaphysical control enabled by engaging with DIY technologies. *"I was mad,"* he expressed, recalling his young daughter's diagnosis:

> *"I still am and constructing something positive is one of the only ways I know to use anger. One of the only ways that I know to use anger, to make something out of it, to use that energy to fuel creative work. Whether it's expressive and artistic, or whether it's constructive, or whether it moves the needle on quality of life."*

Creating DIY technologies enabled not only resistance to the passive patient role allocated to him and his family by the medical establishment, but also the passive "sufferer" identity socially thrusted on disabled people and their families. DIY APS was not just a technological solution, but a social and political act to reclaim agency.

Triangulation with Documents

The community ethos espoused in the interviews, which involves sharing resources, experiences and data for the benefit of the community as well as trusting DIY developers on account of their shared priorities and experiences was found

throughout the documentation. *"Developers are parents, caregivers, loved ones and people with diabetes,"* one set of guidance documents reads, *"working together to development and improve a solution to a very common want."* In addition, in contrast to the dry and clinical language found in most medical guidance documents, the documentation emerging from the DIY community, while containing important and technical information, was often humorous, welcoming, and conversational in tone. For example, when discussing the benefits of one particular type of insulin pump that can be used for looping, one document stated, *"And the battery is a default one you can buy at any gas station, 24 hour convenience store and if you really need one, you can steal/borrow it from the remote control in the hotel room ;-)."* This conversational tone, which suggests a familiarity with the practical aspects of living with diabetes, contributes to the community ethos that was a strong theme throughout the interviews. Many also provided resources for developing community, such as online forums.

While much of the documentation was written in an informal tone that cultivated a sense of community, there were several instances that distinguished "developers" from "users," creating a sense of a hierarchical community. One set of documentation continually distinguished between "you" (the end user) and "we" (the developers), despite an invitation to edit the documentation, while another requested donations to go *"towards the developers costs to leave their darkened rooms and meet each other at conferences and events to let their creative and analytical brains bounce off each other."* The distinction in the documentation hints at fissures within the community, which were also hinted at in some of the judgement toward who can and should participate in DIY, a topic discussed in more detail below.

The hacker ethic that infused interviews was also present in much of the documentation, primarily through references to collaboration, transparency, and iteration. *"Using [DIY System] is essentially carrying out a medical experiment on yourself,"* one guidance document reads, while another states, *"Individuals…are essentially doing an (n=1) experiment, which they have a right to do by themselves."* Transparency in what the system was, who contributed to creating it (one site featured a long list of names that ran several pages), how the algorithm worked, and more created a sense of trustworthiness: there was no black-boxing the technological processes because the user needed to build it themselves. *"[DIY APS] system is open and transparent in how it works,"* one document reads, qualifying that transparency to move beyond traditional expertise by noting it is designed to be *"understandable not just by experts, but also by clinicians and end users (patients)."* People with T1D are recognized as users of this technology first and foremost, rather than immediately slotted into passive patient roles. Further, collaborative efforts – between other open source projects, traditional researchers, manufacturers, or other users – are highlighted and encouraged throughout many of the documents. At the end of the documentation for building all three DIY APS systems (Loop, OpenAPS, and AndroidAPS), each contains examples of how one might contribute to the broader DIY community. Options range from providing language translations to donating money, supplies, or data to contributing to software development. Each emphasizes that everyone has a place and something to contribute.

Table 9

Embodied Resistance Theme Summary

Key Points: • People who have adopted DIY technologies identify characteristics of the DIY community that attract them to it and establish trust, including an assumption about shared motivations, experiences, and priorities, trust in the embodied and experiential expertise of the DIY community and generosity among DIY community members. • Informants also note an affinity for the exciting, experimental, and collaborative nature of "hacking," which requires collective buy in and reinforces the community nature of the on- and offline DIY world. • Finally, informants discuss the technological appeal of DIY APS, including a focus on quality of life rather than cure, individualization, and control over both diabetes and their treatment plan.
Subthemes: • Community Ethos (100%)   ○ Shared Experiences and Priorities (94%) • "Rogue Cowboy Hackers" (100%) • Control and Quality of Life (100%)
Sample Quotes: "The best community you never want to join." (Evelyn) "I'm not just beholden to whatever the medical companies say is appropriate, and whatever my endocrinologist who doesn't actually want to get in depth with me tells me to do, because I have this wealth of community knowledge that I can contribute to and draw from." (Joel) And, you know, I'm techy, I play. I go, "What happens if I do this? Or what happens if I do that?" Yeah, it's just me. Sometimes it works, sometimes it goes massively wrong and I'll have a hypo. It happens. It happens a lot less than it used to." (James)

Theme 3: Risk and Responsibility

The burden of decision-making in the daily management of diabetes and feelings of guilt and shame at "failing" to manage appropriately figured heavily in the decision to adopt the DIY algorithm. By displacing immediate decision-making to the system, many people perceived a lessening of that emotional feeling of accountability in addition to reduction in cognitive burden. Secondly, in many cases, people managing T1D were discouraged from pursuing DIY options due to the fears and concerns of clinicians, manufacturers, regulators, and family members. These

moments brought into focus how different lived experiences produce difference conceptions of risk.

Burden of Management

> *"There's really very few, if any, other diseases that are this user-intensive and complicated. And no matter what you do, you're not going to get the same results. So, it's terribly frustrating… When I talked to the researchers, I said, "I want you to understand. This is hard. This isn't like, what pen or pencil am I going to buy? It's life and death decisions that normal people are making. And they're making it every day, and they're choosing to keep involved. It's exhausting.'"*

Carolyn's statement above reveals two themes that emerged from the majority of interviews. First, the constant decision-making required in basic diabetes management served as a motivator for many to pursue DIY APS. This was in part due to a desire to lessen cognitive burden and in part because of the emotional impact of being solely responsible for every minute decision made around management, which often involve mathematical calculations and guesswork. Second, people not engaged in the day-to-day work of T1D do not have the same framework to understand diabetes management choices. Gordon recalled:

> *"What we found to my great frustration and anger was that when we tried to talk about the actual burden of care, people denied it. People who had no engagement with us said that can't be…It was very, very upsetting. Basically, within the first month we just learned to stop talking about it in public because we didn't have the emotional capacity to not lose it on these people who were denying our experience from nothing."*

As noted above, however, a distinction must be made between the experience of guardians and that of people with T1D, especially in regard to the lived experience of disease. While parents overwhelmingly shared feeling an immense responsibility for their child's management, they themselves don't physically experience *"the extreme rollercoaster that diabetes can be sometimes,"* as Erica dubs it. It is unclear from this research whether fissures have formed between guardians of children with T1D and adults with T1D, although other research addressing disability advocacy more broadly suggests tensions between parent-led and advocate-led social movements can be significant, particularly when priorities and experiences diverge (Carey, Block & Scotch, 2019). This distinction will be discussed further in Chapter 7, although more research is needed in this area.

Displacing Decisions

DIY systems not only enabled better management of diabetes for most people, but also lifted "*the burden of it,"* in Aditi's words, "*the constant decision-making."* She continues:

> "*I would take away the burden rather than the blood glucose levels. Yes, It's nice to be in range. Yes, It's nice to be range more and more, but my worry about diabetes management in the long run is the burden of diabetes management, not the actual levels of glucose."*

The displacing of the everyday decision-making of diabetes management to the DIY algorithm was, to many, equally if not more important than perceptible differences in the clinical measurements of diabetes, such as A1C levels. *"A big reason why people, me included, want to do looping,"* Gary stated flatly, *"is to think less about staying alive. The direct adjustments necessary to keep yourself alive."* This motivation for

adopting DIY technologies should be distinguished from the quality of life dimensions enabled by better management, such as sleep quality. Here, the desirable element of DIY technologies is not that they work significantly better than commercially available management options in terms of clinically-relevant measurements such as A1C (although preliminary research suggests this may be the case), but that they reduce the cognitive burden of constant decision-making. As articulated above, this burden of decision-making is not limited only to the in-the-moment cognitive processes, but the guilt and blame associated with what clinicians perceive as poor outcomes. By displacing the responsibility of immediate management decisions to the algorithm and shifting focus to oversight of the technology, they are distanced from those decisions in a way that reduces the emotional impacts of less-than-desirable outcomes. *"It takes those decisions that you would make minute by minute, it takes out the emotional payload from that decision, and it does it."* Evelyn said, exemplifying this rearticulation of roles and responsibilities in day-to-day management.

Responsibility

"It's like the Matrix," Joel expressed, referring to balancing the benefits of the DIY community with the responsibilities he takes on when pursuing off-label treatments:

> *"When you take the pill and now you see how the world is, and you can do something about it, or you can just sit with it and not do anything with it. I guess it's not really, I can't take away my knowledge and also take away my responsibility, I guess."*

Many other interviews also touched on the individual responsibilities that arise from pursuing DIY technologies, which were distinct from the more general responsibilities

felt about diabetes management. Much of this new dimension of responsibility comes from the lack of a formal support network noted in other sections. As Melody recalled thinking when creating documentation for one DIY system, *"If you do use it, know that if it breaks, you'll have to fix it. You can ask for help, but sometimes people are living their lives."* Nikol and Jonas expressed this perception of personal responsibility as tangibly different from their experience of commercial products, where a customer service representative or clinician could provide guidance and direction at any time:

> Nikol: *"Everyone has a different experience, and no one is a responsible person."*
>
> Jonas: *"Only we are responsible because we have decided to use the application."*

Like Joel, however, these acknowledgements of responsibility were accompanied by emphatic assertions of the benefits provided by taking that responsibility. Knowledge and responsibility become entangled in important and intractable ways.

Determining Risk

In each interview, I asked informants if building and using DIY technology ever felt risky. What emerged from this question in many instances was a sense that people who were not engaging with diabetes in a sustained way had more fears and concerns about DIY technologies, in part because of a general lack of awareness of the risks inherent in daily management. *"So that's why… [my doctor]'s afraid,"* Abene recounted, *"We're relying on old pumps, so it could happen that they are broken, that the rig will not be working okay. Who knows? It could happen. Of course, it might also happen with my actual pump."* Her "actual" pump, in this quote, refers to the pump allocated to her by through the Spanish government, and the "old pump" refers to the OpenAPS-compatible pump she had purchased online to start

looping. While Abene's statement may at first appear blasé, it resonates with the uncertainty in daily diabetes management felt by many informants. Carolyn shared a very similar conversation with her husband when she first started looping, asserting:

> *"I didn't have any anxiety or any fear. My husband did. 'How do you know this isn't going to kill you?' And I think my answer might have been, 'Well, the disease is going to kill me if I don't do something.'"*

For many, like Melody and Erica, trusting the DIY algorithm was *less* risky than trusting themselves to make the correct management decisions and calculations the many times a day they were needed. *"This is actually safer than me making the decisions when I'm sleep deprived or when I'm not paying attention,"* Melody said. Erica concurred, stating, *"It is proving itself to be a better decision maker than I am."* How risk becomes understood is deeply contextual, and the lived experience of diabetes management (and mismanagement) when one is tired, sick, or otherwise distracted shifts that risk calculus toward trusting the DIY technology to take on some of that everyday decision-making.

Triangulation with Documents

Responsibility and risk were highlighted in many forms in all documentation. These varied from statements designed to force one to consider the work of DIY ("*If you're ready for the challenge, please read on*;" "*You really need to figure this out yourself*") to those that read like boilerplate liability statements ("*Any person choosing to use these tools is solely responsible for testing and implementing these tools independently or together as a system*"). Responsibility also appeared throughout the documents in terms of oversight and management of the DIY system. Several times throughout the guidance documents, authors emphasized that the algorithm could not learn and relied on accurate input and attention from the user.

The user, then, must understand both the inputs and what expected outcomes should be, situating them as an overseer responsible for the choices made by the system. As one read:

> *"Please ask questions at this point about why [DIY APS] is making the recommendations it does. It should be similar to the therapy decisions you would make yourself. If the recommendations it makes are different than you would make, try to figure out why."*

Risk, especially the differential and contextual risk calculus that accompanies living with a chronic disease, appeared in the documentation alongside the interviews. In the formal guidance from the FDA, *"new risks…not evaluated by the FDA for safety or effectiveness"* were cited as a warning against DIY systems (particularly those that use modified or hacked hardware – an approach not typically encouraged by the broader DIY APS community). From within the DIY community, however, individual choice was emphasized: *"The ultimate answer to 'is it safe,'"* one set of guidance documents reads, *"will be something each individual decides for themselves."* This approach to risk differs significantly from traditional healthcare regulation, in which safety and risk are exclusively adjudicated by government bodies as opposed to individuals (including clinicians and manufacturers). While both formal and informal guidance documents recognize the potential risks of DIY APS, only the informal documents assert the individual agency of the user to determine whether those risks are worth it. Here also, the difference between "patient" and "individual" should be noted. In the formal documents, the "patient" (usually addressed in the second person "you") is encouraged to take a passive role and rely on clinical and regulatory guidance, while the "individual" in the informal documentation has the right to decide what risks are allowable for themselves. The

latter also recognizes individual experience, meaning there is no one right answer for the community at large, diverging again from the homogenous and universal "patient" of the formal documentation.

Table 10

Risk and Responsibility Theme Summary

Key Points: • Users with T1D (and their family members) have a different conception of risk than clinicians and manufacturers, in part because they live with the responsibility of constant decision-making around diabetes management, which is transformed using DIY systems. • The burden of decision-making and daily management figures largely into many decisions to pursue DIY solutions, as does perceived responsibility for management (and guilt at failure).
Subthemes: • Burden of Management (63%)   ○ Displacing Decisions (50%) • Responsibility (94%) • Determining Risk (100%)
Sample Quotes: "It's life and death decisions that normal people are making. And they're making it every day, and they're choosing to keep involved. It's exhausting." (Carolyn) "And those of us who have to live with them because we've been diagnosed with them or because our family members have, people we love have, we cannot escape it. And so it just totally changes the calculus of risk." (Gordon)

Theme 4: The Profile of a DIYer

The final major theme that ran throughout all informant interviews involved who pursues DIY. Informants suggested that access to materials, support, and information serves as a substantial barrier to DIY. The vast majority of informants in this study identified as white college graduates, and several suggested this was likely reflective of the broader DIY community[11]. Several also acknowledged they were

[11] It should be noted that DIY technology is also being used in non-European/North American contexts and interviews with users from these areas may substantially shift this perception.

recognized by medical professionals as "super users" capable of advanced management strategies, although rejected the idea that this was mandatory for DIY adoption. Suggested technological and diabetes knowledge requirements also featured in many interviews, although there was little agreement on what those thresholds should look like or who might enforce them.

The Issue of Access

"The big elephant in the room is access," Gary stated, qualifying that this did not just refer to the financial ability to obtain materials like pumps and sensors, but *"competent educators that can teach you basic things."* Access to pumps, insulin, CGMs, information, and community were all posited as barriers for others to participate in DIY communities. Erica shared her difficulty accessing CGM sensors, noting she'd been relying on donated and expired materials even though they could jeopardize her system's accuracy:

> *"If you talk about things that are tough in the realm of do-it-yourself, it's not so much the do-it-yourself from a technology perspective, it's do-it-yourselfing from a supplies perspective. For me that's really hard because I go in using expired sensors knowing full well that the sensor data is the crux of the algorithm working."*

For others, finding an affordable and loopable pump has posed a challenge, since many of the pumps necessary to run certain versions of DIY systems are no longer available from manufacturers. Many informants self-funded their medical devices – from out-of-warranty pumps to CGMs – and all had to pay out of pocket for the other hardware necessary to build their DIY rig, although few mentioned the financial barriers to entry for others. Instead, they referred to the "pay-it-forward" nature of the community, recounting stories of loaned and returned materials circulating

through the community. However, there was very little reference to who constitutes the community or barriers to entry such as geographic location, socioeconomic status, or language.

Who DIYs?

Many informants acknowledged positions of privilege that allowed them to seek out, build, and maintain DIY systems. From relative financial stability to education to community connections to having the confidence to challenge clinicians, all informants noted characteristics about themselves and their positions that allowed them to pursue DIY. *"We're privileged in that we had full time jobs, we were able to spend our nights and weekends on this as a passion project,"* Melody immediately acknowledged when asked about the financial and emotional costs of pursing DIY. *"Not everybody in these kinds of communities can do that. So, we started from a position of privilege in being able to dedicate our time to do that."* For some, like Ramona, Carolyn, Benjamin, and Evelyn, being an early adopter of diabetes technology predisposed them to be curious about DIY APS. *"I've always been a little ahead of the game,"* Benjamin joked, sharing that he'd first started using an insulin pump in the 1990s as a 10-year-old, much to the surprise of his endocrinologist. For others, a technological background made them feel comfortable building and using DIY systems.

Super Users

"You're the kind of patient we like to have," Benjamin recalled being told by an endocrinologist, guessing it was, *"Because I'm knowledgeable about care and I'm active in the process. As opposed to saying, 'Hey, this is what's wrong with me, what do I do?'"* Being perceived as a "super user," or a person with advanced knowledge and skills about diabetes management, by professionals enabled many informants to

pursue DIY options. Nikol and Jonas, who were initially discouraged and scolded by their clinician for requesting an insulin pump for their young son whose diabetes was not well-controlled, were eventually told by a clinician, *"I will give it to you because I can see that you are smart enough to operate it and to have it under control."* Ramona shared that her clinician approved of her curiosity around other management options, recalling that *"She was very excited and happy and she's like, 'Oh my God, you are the ideal patient.'"* Being "advanced," "active," or "engaged" with care was a common theme among informants, creating a sense that they recognized themselves as different from others managing diabetes, which imparted a confidence to explore DIY options and challenge clinicians.

The appearance of the super user narrative raises questions about the treatment of people not deemed super users by the medical establishment. Questions of access should not only center on the ability to obtain materials, but who is encouraged and supported to pursue technological treatment options, and who is not. As Gordon noted:

> *"There is this myth among clinicians that pumps and CGMs are for advanced users, that you really should prove that you can do it the hard way first, before we can trust you with a pump. And that's like saying, you got to learn how to drive a stick shift before I let you drive a car. We might have a better time if we gave people easier to drive cars that they need to live."*

Despite this assertion to reject the arbitrary distinction between average and super users, all informants spoke not to just their experience with DIY, but their perceptions about who *should* or *can* DIY responsibly, a topic explored in more detail below.

Who *Should* DIY?

When I asked James if there were people who could benefit from DIY APS who felt intimidated or unable to access it due to technical or knowledge requirements, he answered bluntly, *"I think there are, yes. But hey, which way do you go? Stupid dead people or alive people who may not have as good control?"* This perception, which in some ways runs counter to the affirmation that the benefits of DIY should be available to all people, was often inflected with assumptions about motivations, engagement levels, and attention to detail which were deemed necessary to successfully DIY. Nikol suggested that there are many people who could benefit from DIY, but their passivity and unwillingness to seek out different support prevents them from achieving what she and her family have achieved*:*

> *"But there are people are in the same situation we were five years ago, and they don't have enough energy, or they are not such person, so they are afraid to go somewhere and ask someone for help or something. They are just living with what the city is giving to them. What the place and the situation is giving to them. And they are afraid to ask to ask for more. So, our advantage is we are not so afraid."*

Gordon also noted a passivity in mainstream diabetes communities which typically mobilized around fundraising for cures and medical research rather than around action-oriented solutions such as DIY. *"Yeah, it feels like church,"* He joked, referring to fundraising events common in diabetes communities.

> *"I mean, I grew up in church and I still go to church. And it feels like this is what we're supposed to do. Like the families with type 1, you go to type 1 runs and you build a team and you raise the money. This is what we all do*

together. And that's not bad…[but] I found patterns of passivity and acceptance and consolation and community."

Gary, who didn't receive a T1D diagnosis until adulthood, also suggested that many people are passive about their treatment plans or content with suboptimal outcomes, particularly those who have been managing their diabetes for a long time: *"The strange paradox is that often people who have had diabetes for a very long time, they fall into very old habits that are not optimal."* While many informants mentioned that DIY systems are, in Carolyn's words *"not the appropriate forum"* for everyone, their judgements of passivity and lack of self-motivation were often tempered with an understanding about the difficulties of day-to-day diabetes management. Often, these were not harsh dismissals of people without ability to understand DIY, but a recognition that not all people managing T1D have the bandwidth, time, or energy to pursue DIY technologies. As Melody noted, *"For the most part it's not a knowledge gap so much as an experience gap and that people will choose to close [the loop] at different times."*

Technical Requirements

Erica, when recalling her first impressions of DIY APS, stated:

"I was super intimidated by it. I was so intimidated 'cause I was like, "yeah, I've just been HTML coding for like, a hot second in my life, but what does it mean…" The way that I think about DIY technology is I fully in my brain, the only way I make it make sense is to say that you're "hacking" into the medical devices. And that's such a scary thing to say, even now, and I'm wearing them all over me."

Her initial impressions, which presumed a technical competence beyond her experience, was common among informants, although nearly all expressed that the

technical competence needed to actually pursue DIY systems is not a significant barrier to entry, despite assumptions. Later in our conversation, Erica continued, *"And I think the biggest misnomers of do-it-yourself is that you have to have any knowledge of coding. Because what you need to be able to do is copy and paste. And everyone, except for maybe my dad, can do."* Others concurred. Melody, who has been instrumental in the development of one DIY APS system and its accompanying documentation, noted that she and others in the community intentionally removed technical-savvy as a barrier to access:

> *"But we also started having lots of conversations around access. I wasn't comfortable with – and other people weren't either – that only technical people could figure out how to do it. And so, we started writing some documentation. And we constantly over the last 3 and a half years have really had a conversation around – and it's evolved, like from even our set of documentation."*

Others noted that the documentation for all systems was imperative to increasing access. James found the conversational and welcoming nature of the documentation appealing, sharing *"They were obviously written from somebody who was type 1, rather than somebody who was a techy."* For others like Aditi, however, simply having the documentation was not sufficient for removing the barrier to entry, and she found members of the community to be quite resistant to providing assistance to those perceived as "non-techy."

> *"I can see the frustration where a lot of the techy people are just saying, 'Read the docs, read the docs, read the docs,' as answers to questions,"* she said. *"And some of the questions, okay, could have been answered from the*

first few lines of the documents. But actually, the documents are not well written for a non-techy people."

So while generally informants agreed that technical ability was not the barrier to entry it was perceived to be by many, there was still an implicit expectation in the community that members enter with a basic understanding of the technologies, which may inadvertently bar some with little to no technological experience from entry or from feeling welcomed. Such assumptions also do not take into account people without access to desktop computers or regular internet access. Additionally, no interviews broached the topic of access for diabetics with other disabilities such as vision impairments or fine motor skill issues. Such consideration is imperative, given the prevalence of these secondary conditions in people with T1D. Regarding vision impairments, 2015 meta-analysis found that diabetic retinopathy, a leading cause of vision loss, was present in between 36-94% of people with T1D in the United States and Europe. Anywhere from 7-35% of people with T1D in these regions experience vision-threatening diabetic retinopathy (Lee, Wong & Sabanayagam, 2015). In terms of motor skills that could impact participation in DIY communities or in building their rigs, diabetic cheiroarthropathy (a condition that can limit one's ability to flex or extend one's fingers) occurs in between 8-50% of people with diabetes (type 1 and 2) (Cherqaoui, McKenzie & Nunlee-Bland, 2013). That these issues were not raised in this set of interviews, however, does not mean it is not a concern in the DIY community, but a lack of attention to these impacts may inadvertently reinforce the boundaries of DIY to exclude certain geographies, socio-economic statuses and bodyminds that disallow regular computer use.

Knowledge Threshold

While informants were generally in agreement that technical competence was not required in order to DIY, there was a different knowledge threshold that others must meet to be successful with DIY— knowledge about diabetes. When asked if the technical competency was prohibitive, Melody simply stated*, "the more important knowledge is your diabetes."* Several informants, like Erica, James, and Gordon, worried that people who adopted DIY APS too quickly following diagnosis failed to learn what they considered to be critical skills about diabetes management. These skills were both necessary for setting up their DIY system appropriately and to treat their diabetes should their system fail*. "I've seen that in diabetics who go on technologies super early,"* Erica said, comparing to her own confidence in managing her diabetes through low-tech treatments like multiple daily injections*:*

> *"Like they have a CGM failure or their insulin pump will break, and they're lost. They don't know how to do a conversion back to like long and fast insulin, right? They don't know how to do those things mathematically or even conceptually. They can't wrap their mind around it, and that to me, is terrifying."*

She continued by hypothesizing that one reason some people who try DIY technologies did poorly was because they didn't have the requisite knowledge to get their settings correct. Gary, Erica, Melody, James, and Aditi all suggested that fundamental diabetes education, such as understanding carb counting and absorption, was significantly lacking for many people and presented a substantial impediment to DIYing as well as day-to-day management. As Ramona noted, to engage with DIY systems, "*You need to have time to study, to understand where the information in the system how it works."* So even while "*the diversity has absolutely*

expanded" in terms of users according to Melody, and DIYers have worked to fill diabetes education gaps, access to knowledge and time remains a significant barrier to entry. While commercialization of DIY systems may in some way mitigate this barrier, lack of support and resources on the individual user level means the continuation of disparities between who can and cannot DIY.

Triangulation with Documents

Access to supplies, resources, and support was a common theme in documentation as it was among interviews. Several justified the existence of DIY APS in arguments couched in rhetorics of access, stating that DIY APS more quickly and widely provides access to artificial pancreas systems than commercial manufacturers. Others acknowledged the financial costs of DIY systems, although almost none of the documentation addressed who is currently excluded from DIY communities (although one document did suggest making a donation to the International Diabetes Federation to support diabetes treatment across the globe, asserting, *"If you've been helped by the generosity of others, please pay it forward by helping those less fortunate than any of us."* This statement makes a clear, if implicit, delineation between who can currently access DIY APS and who cannot and creates a distinct audience of DIY users who can distinguish themselves from the "less fortunate." In terms of access to devices, several documents also addressed the practicality of DIY, with one educational blog stating, *"The key question [when choosing a DIY system] is generally 'What pump is available to you?'"* Links and suggestions of "pay-it-forward' communities, forums to purchase or trade supplies, and other resources meant to increase access to devices were common throughout the documentation.

Like many of the interviews, documentation consistently emphasized the work of DIY. For example, one educational article flatly stated "*'Looping' doesn't stand for 'not doing anything.'*" Another set of guidance documents elaborated on this idea, reading "*Implementation requires diligent and consistent testing and monitoring to ensure each piece of the system is monitoring, predicting, and controlling as desired. The performance and quality of your system lies solely with you.*" Self-motivation, knowledge of diabetes, and work ethic were emphasized throughout, constructing a DIY user as curious, hardworking, and self-responsible. Knowledge about diabetes management (including the diabetes math that is core to the DIY APS algorithms) was deemed essential. As with the interviews, however, technical competency was not. As one set of guidance documents reads, "*It is totally understandable to be intimidated and worried that this will be too technical...but please realize that this is actually as simple as reading, copying a few lines and clicking a few buttons...REALLY.*" As with the interviews, writers of the documentation seem aware that presumptions about technical prowess may serve as an impediment to some potential DIY users, and work to counteract that fact through such welcoming statements. Such statements serve to counteract the super user myth, while emphasis on self-motivation and responsibility may feed it.

Table 11

The Profile of a DIYer Theme Summary

Key Points: • Access to what one needs to pursue DIY, whether that is materials, support, or information, is a significant barrier to including more diverse populations in the DIY community • While there is no one profile among the DIYers interviewed in this project, many shared common characteristics, including higher education, a tolerance for increased accountability, and other elements that often get them labeled as "super users" – a term many reject as mandatory for pursuing DIY • When discussing who *should* have access to DIY technologies, answers varied widely, but many agreed that technical knowledge was much less of a requirement than knowledge about diabetes and its management and an understanding of the cognitive work required to build and manage DIY systems, running in some ways antithetical to the statements of universal access.

Subthemes:
• Access (81%)
• Who DIYs?
  ○ "Super Users" (75%)
• Who *Can* DIY?
  ○ Technical Requirements (82%)
  ○ Knowledge Threshold (50%)

Sample Quotes: "And so, I think there is a little bit of, well it's a system that you need to work with, and it takes work to make it work. So, if you're not willing to put the work in at the beginning, then maybe it's not for you." (Aditi) "The big elephant in the room that is access." (Gary)

Conclusion

In this chapter, I have presented an inductive analysis of semi-structured qualitative interviews with DIY APS users and developers. Findings were organized broadly into four themes and thirteen subthemes. I have related the decision to pursue DIY technologies with the invalidation of user experience in traditional medical paradigms. In DIY communities, the celebration of individual experience as well as perceived shared priorities creates a culture of trust that is bolstered by a "hacker ethic" promoting transparency, collaboration, and mutual support. DIY APS also offers a means of control over both diabetes and diabetes management –

control that was often stripped away in more traditional settings. Interviewees also highlight a differential risk calculus that makes DIY an allowable risk to them as opposed to those who are not engaged in day-to-day management, calling for greater attentiveness to embodied and experiential expertise in the design of diabetes technologies and management practices. Finally, despite ostensible calls for universal access and acceptance, interviews bring into focus a particular kind of person with T1D as the optimal user for DIY technologies, raising questions about who can and cannot contribute to and benefit from DIY systems.

There remain tensions between messages of universal access and selective profiles of successful DIYers. Additionally, by reviewing only documents meant for potential DIY users and interviewing those who have opted into the community, this sample is biased toward a positive representation of DIY communities. Future work should include gathering the experiences of people who have opted out of DIY communities or otherwise do not have access to them. Additionally, as found throughout this dissertation, tensions between clinical and embodied expertise and authority rise to the fore, as do issues of personal accountability, responsibility, and a differential understanding of risk. Unlike the "double bind" of personal accountability and epistemic invalidation found in other chapters, the DIY APS community has emerged as a rejection of the passive patient role thrust on many with diabetes. Personal responsibility becomes communal responsibility to, in Carolyn's words, *"guard our own communities."* The development of a coherent DIY community creates opportunities for alternative cultural imaginings about health, disability, and well-being. While DIY APS critically disrupts the hegemonic paradigm by shifting authority and credibility away from commercial medical devices manufacturers and clinicians and onto people managing diabetes, DIY APS also in

some ways reinforces the neoliberal ableist paradigms of self-responsibility and body management. The next chapter (Chapter 7) will present a detailed discussion between the three case studies and the literature.

CHAPTER 7

TRANSGRESSIVE RESPONSIBILITY AND TECHNOLOGICAL AMBIVALENCE

Introduction

The purpose of this multiple case study was to begin to understand the construction of dis/ability, agency, and accountability through the experience of using three biomedical technologies – prenatal genetic screening and diagnosis, deep brain stimulation, and DIY artificial pancreas systems. The decision to pursue biomedical technology is a complex one, influenced by myriad factors ranging from feelings of personal responsibility to manage or mitigate dis/ability to perceived authority and credibility of medical professionals. Conclusions from this study, following the research questions and drawing from informant interviews and document analyses, find that users of these technologies are often confronted with a double bind: they are held personally and individually accountable for their non-normative bodyminds (or that of their prospective children in the case of pregnancy) while simultaneously having their embodied or experiential knowledge invalidated or dismissed in favor of medical authority. Further, these experiences expose that often that clinical authority is mobilized by assumptions, expectations, and understandings of dis/ability that are in tension with that of the users. This creates systems of strained communication, dissatisfaction, and at times, traumatic clinical experiences. Outside of these often troubling clinical experiences, people seek and develop communities outside of medical jurisdiction, often taking the form of online or in-person knowledge exchanges. In these alternative spaces, the desire for technology becomes not about the elimination or mitigation of disability, but about individualized approaches for improving one's quality of life (however that becomes defined). Here technology often represents a displacement of the emotional or cognitive burden of navigating the world with a non-normative bodymind (or with the potential for

producing one) by either making decisions on behalf of the user or reducing the observable signifiers of difference.

While the three cases examined in this project vary greatly in terms of their methods, subject, and findings, there are several overlapping interpretations that unite these cases, suggesting a potential generalizability to other experiences of biomedical technologies. A summary of all themes can be found in Figure 4 below. Five major conclusions will be discussed in depth in this chapter, relating them to the study findings as well as to the previous literature:

Ableism and the Neoliberal "Patient." Findings across cases that suggest the decision to pursue biomedical interventions is motivated by feelings of personal responsibility, exposing an interpretation of disability as detrimental to social value. Therefore, assumptions about human value arising from the ableism and disablism that permeate the culture significantly impact how and when people decide to medically intervene on disability (including the prevention of it through genetic screening and testing).

Boundaries and Transgressions. Throughout all three cases, contrasting understandings of risk, bodily integrity, and need create tensions between clinicians, technology manufacturers, and users, suggesting a distance between the lived experience of a user and that of the authorities dictating interventions. Therefore, it appears clinical and technological authorities assume what is desired or needed based on their own understanding of disability, producing tensions, dissatisfaction, and conflict.

Relocating Disability and Authority. Out of this analysis emerges a third major interpretation, which draws on tensions between the understanding of disability

through the medical means to intervene on it and the assertion of embodied and experiential knowledge about disability. Perceived transgressions of authority and knowledge most often occur when disabled people attempt to disrupt disability as a biologically discrete phenomenon and relocate it to social, practical, and experiential contexts.

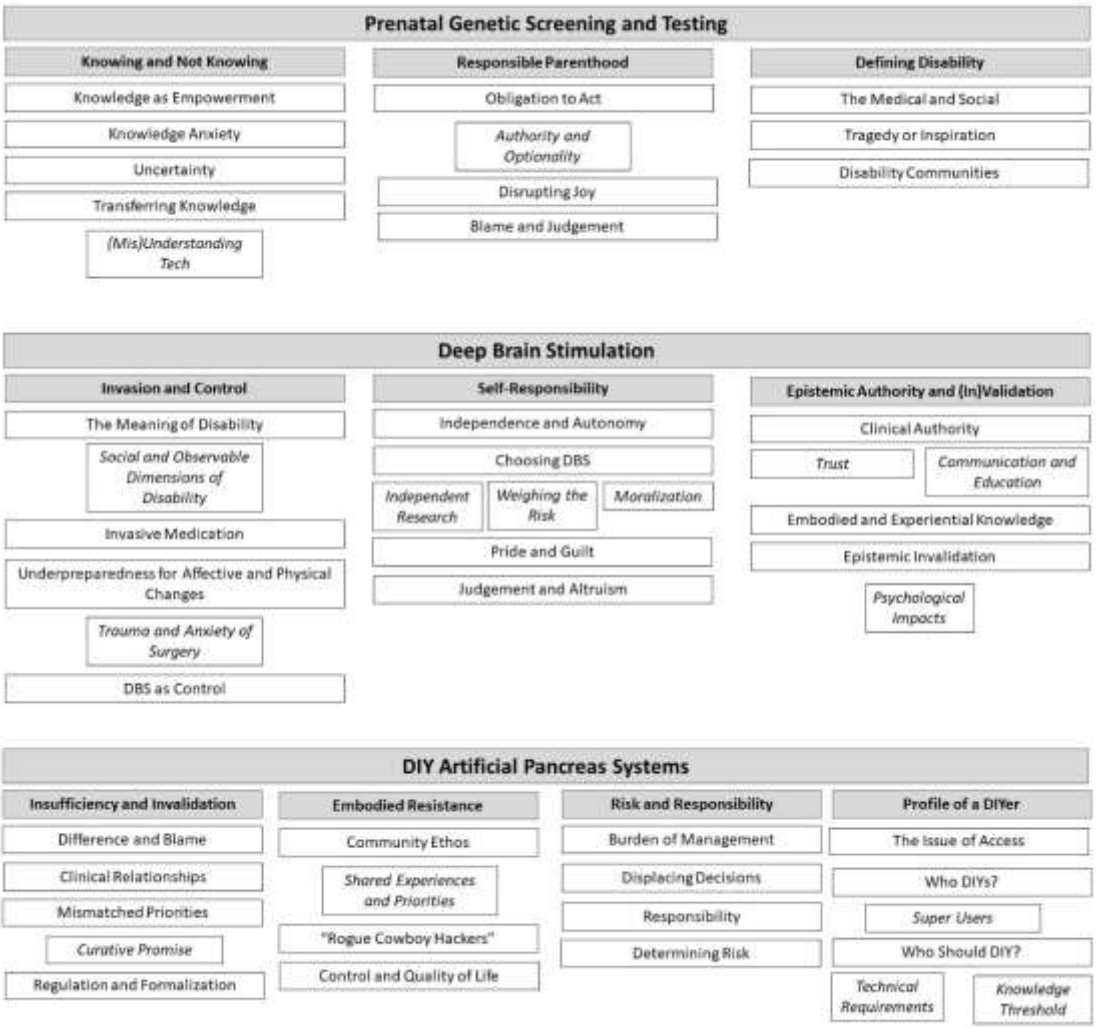
The Technological Fix. Drawing on findings about the perception of these technological interventions as in many ways improving quality of life, often through a displacement of the cognitive and/or emotional burden of navigating an ableist world, technology is seen not as a curative promise (a framing favored in many design contexts), but as a method of displacing the immense personal accountability placed on disabled bodyminds to self-manage.

Asking the Other Question. Finally, an interpretation of the intersectional dimensions of this study focuses on not only what was found, but on what was absent. I will heed Matsuda's (1991) call to "ask the other question," in order to emphasize where and when class, gender, race, and other dimensions of being intersect with the subordination of disabled people in medical care and practice.

This chapter will close with the theoretical and practical implications of this work, an analysis of its trustworthiness using Lincoln and Guba's (1985) four-part definition, limitations, and recommendations for research and practice.

Figure 4

Theme Summary



Ableism and the Neoliberal "Patient"

Personal responsibility, in many forms, appears across all three cases as meaningful in the decision to pursue biomedical interventions. While responsibility takes on many different tenors across cases and individuals, the perception of the amelioration of dis/ability, whatever that may mean in a specific context, as an individual responsibility resonates throughout the study. The interpretation of

dis/ability as personal responsibility, as opposed to collective phenomenon, inherently favors individual interventions such as biomedical technology as a means to address the misfit between disabled bodymind and social, political, and material context. Under neoliberalism, individuals are expected to be autonomous, self-regulating, and economically productive, a context that immediately subjects disabled people to scrutiny, judgement, and discrimination (Goodley, 2014). Potential parents of disabled children are subject to the same level of judgement and surveillance (Kerr and Shakespeare, 2002), as the management of pregnancy is assumed an extension of body management. Dis/ability becomes intrinsically linked to non-productivity, which in turn becomes linked to discitizenship (Devlin and Pothier, 2006). As I (along with Mateo Pimentel) have written elsewhere, the ability/disability binary in contemporary Western societies is articulated through productivity: "What an 'able bodymind' is *able* to do is implicit; such a bodymind is capable of joining the labor market, capable of being efficient, productive work, capable of turning a profit for themselves, or more likely, for their employer. Any bodymind that does not meet such criteria is thus considered 'disabled'" (Pimentel & Monteleone, 2018, 71). This relationship produces feelings of guilt and shame at difference and dis/ability. This guilt, in concert with the demands on the neoliberal subject to self-manage, creates a context in which biomedical intervention to identify and eliminate dis/ability seem both natural and necessary.

Throughout all three cases, informants expressed feeling guilt, shame, and self-blame for signifiers of difference. These experiences were corroborated in the documents, likely associated with the perceived inferiority of disabled bodyminds that pervades social and political life. In the PGS/PGD case, this is observed in the subthemes Blame and Judgement (under the thematic category of Responsible

Parenthood) and Tragedy or Inspiration (under the thematic category Defining Disability). In the DBS case, these perceptions are observed in the subthemes Social and Visual Dimensions of Disability (under the theme Invasion and Control) and Pride and Guilt (under the theme Self-Responsibility). In the DIY APS case, this is observed in the subtheme Difference and Blame (under Insufficiency and Invalidation) and Burden of Management (under Risk and Responsibility). For some receiving Prenatal genetic screening and diagnosis, there was pre-emptive guilt at the thought of birthing a disabled child, as voiced by a pregnant Rosalie: *"If something is wrong with this baby it's my fault."* For both APS and DBS, feelings of shame often arose from the observable difference caused by their disabilities. For some receiving deep brain stimulation, the signifiers of their disability that were observable, or in Carol's words, *"obvious to people,"* yielded a lot of shame that could be alleviated through technological intervention. In the DIY APS case, the recognition of difference from one's non-diabetic peers was almost viewed as an unwanted rite of passage experienced during youth. As Erica recalled thinking in her teens, *"I didn't want to be different."* It becomes obvious from the attention to the experience of alienation, isolation, or judgement from strangers that this is a significant aspect of the experience of disability. This is relevant both in terms of motivations to pursue medical interventions and in expanding the clinical understanding of disability beyond discrete, measurable physiological symptoms. By relating disability to difference and difference to shame, an ideal normate (Garland-Thomson, 1997) becomes reinscribed as the only desirable or valuable person. Shame at difference becomes internalized, making interventions to ameliorate difference through biomedical interventions seems both logical and appealing.

In the context of neoliberal body management and individualization, the individual medical decisions one makes to intervene on their disabled bodymind (or to detect future disability through genetic screening and testing) are perceived as benefiting not the individual, but the public. By preventing or ameliorating dis/ability, the individual becomes a productive, responsible citizen (Devlin and Pothier, 2006; Goodley, 2014). Throughout the cases examined in this study, responsibility, productivity, and independence were espoused as virtues that were enabled through access to biomedical technologies. For those receiving Prenatal genetic screening and diagnosis, technological intervention on their pregnancy was a signifier of responsible parenthood, and by extension, responsible citizenship. For those receiving DBS, the procedure was figured as enabling a return to previous economic productivity and reliability, regardless of whether or not that came to fruition. In some regards, the case of deep brain stimulation most acutely provides an example of what McRuer (2006) refers to as "compulsory able-bodiedness," in which a normative bodymind is both a naturalized assumption and a moral obligation. Intervention, particularly curative intervention where possible, becomes an expectation in pursuit of good citizenship. This pressure to perform citizenship through an approximation of able-bodiedness cannot be discounted when examining the individual decision to pursue biomedical intervention. As Kafer (2019) writes, "Understanding technology as something that everyone is equally empowered to accept or reject, as something that operates within the privatized realm of individual choice, obscures the complex histories, webs, and attachments of technoscience" (4). Failure to address the ableism and disablism that pervades medical and social cultures, especially the inequitable pressures that come to bear on non-normative bodyminds, risks perpetuating them in design and practice.

Despite the proliferation of perceptions around personal responsibility throughout the cases, the exact substance of responsibility, and therefore how it is responded to by the individual, is deeply contextual. In some, responsibility means feelings of shame and guilt associated with suboptimal clinical outcomes. This occurred in people with T1D who were chastised for poor diabetes management, pregnant persons anticipating genetic testing results, and people whose DBS did not match their expectations. In this particular iteration of responsibility, a clinician or other medical professional determines both the measurement and the standard outcome by which one is judged before shifting responsibility onto the individual. People become standardized in such a way that fails to reflect the messiness and uncertainty of lived reality, and then are expected to bear the weight of failing to meet idealistic standards.

Responsibility, particularly in the DBS subtheme Independence and Autonomy (under Self-Responsibility), also means maintaining or establishing a certain level of productivity. This particular facet of responsibility appeared gendered, with male-identifying informants more likely to speak to their desire to remain or re-engage with employment, support their families, and lessen the care burden on loved ones. As John stated, his decision to pursue DBS was informed by his desire to have *"less dependence on others."* For others in both the DBS and APS cases, responsibility was less about economic productivity as it was about the autonomy and independence that could be gained through technological intervention. For example, Abene discussed a newfound independence that allowed her to travel without her spouse since adopting new diabetes technology. Benjamin reflected on what his recent honeymoon would have been like without his DIY APS: *"It would have been so much more stress and worry, and so much more 'I can't' instead of 'I can.'"* The specter of

the independent individual subject as free and endlessly autonomous, particularly one that conflates freedom with independence, haunts these perceptions (Bostad and Hanisch, 2016). By both valuing individual freedom and equating such freedom with independence, the interdependence or dependence that arises from being disabled is interpreted as a shortcoming and impediment to full autonomy, agency, and freedom. As Bostad and Hanisch argue, however, reconceptualizing not only freedom to include interdependence and dependence, but also reconceptualizing the individual subject to greater account for human variation can yield significantly different understandings of disability. Rather than beginning with an assumption about who the ideal and free subject is, they suggest an "inductive modesty," that recognizes that "to accept difference – *that which is unknown to me* – is to accept that some aspects of life (both the lives of others and one's own life) will *remain* unknown" (383).

When informants were either prospective parents, as in the PGS/PGD case, or current guardians, as in the APS case, individual responsibility extended into responsibility toward future generations. For Abby, the decision to screen during her pregnancy was in part motivated by providing her future child the best healthcare upon birth. *"You're not going to stay at your same doctor and get treated the same way if your child has [Genetic Condition]."* Genetic counselor Theresa also acknowledged the difference in feelings of accountability in seeking medical care for yourself versus your future child. Discussing the additional burdens prospective parents sometimes face to pursue genetic testing, she stated, *"They feel obligated, because of course, you have to do what's best 'cause it's your unborn baby."* The guardians interviewed in the APS case also expressed a distinction between the responsibility of caring for oneself and caring for their child. While acknowledging the

"sheer between my experience as a parent caring for a child and the experience of somebody who actually lives with the disease," as Gordon stated, these guardians often also expressed an enormous feeling of responsibility to enable the best possible quality of life for their children, which impacted their decision to pursue DIY. Several informants in this case also suggested that this feeling of parental responsibility is in part what has enabled the DIY community to thrive. Erica (who is herself diabetic) refers to one specific prominent member of the DIY as being particularly impactful in part *because* of her role as a guardian:

> *"I just always remind her of how much, really what she's done for the community by building out these docs and making it so easy to understand what you did and how to do it for yourself and your kids. Like, her desire was to give moms the information to better their kids' lives - because she knew if anyone was going to do it, it was going to be a diabetic mom."*

These cases both highlight different aspects of parental responsibility as inflecting experiences and decisions around medical technology. While members of the DIY case explicitly acknowledge that guardianship does not equal the embodied experience of people with T1D, this difference was not acknowledged in the PGS/PGD case (and notably, no informants of that case identified as disabled). Understanding the tensions between perceived parental responsibility toward (actual or prospective) disabled children and acknowledgment or appreciation of embodied knowledge requires further investigation.

Where responsibility also manifested, perhaps unexpectedly, was in the judgement of others who made different choices regarding the use of biomedical technologies or dis/ability management. While many informants across all three cases expressed an openness and nonjudgmental attitude toward how others live

with disability (or the potential for disability), simultaneously, many expressed disapproval at those whose practices did not align with their own. In all three cases, this often meant the informant perceived others as not being responsible or accountable for themselves or their prospective children, where responsible typically meant self-educated, self-motivated, and self-responsible. This judgement often allowed a person to not identify others with similar conditions as their peers, but as people in need of support and guidance. This can be seen the Blame and Judgement subtheme (under Responsible Parenthood) in the PGS/PGD case, in the Judgement and Altruism subtheme in the DBS case (under Self-Responsibility), and the Who *Can* DIY? subtheme (under The Profile of a DIYer) in the DIY APS case. This particular facet of responsibility may be understood as an internalization of neoliberal discourses that pin responsibility for non-normativity on the individual, but taken in context, however, an alternative explanation emerges. Throughout all three cases, informants explicitly recognized the biased and discriminatory systems in which they are enmeshed, and what I have categorized as judgement in the thematic analysis may actually be read as a form of protective guidance. In other words, informants provide guidance so others will not have the same discriminatory, invalidating experiences they themselves encountered. As mentioned above, nearly all of these expressions of judgment (with the exception of the PGS/PGD case) were paired with expressions of altruism toward others experiencing similar circumstances. Perhaps the clearest argument for this alternative explanation appears in the DIY APS case, when Evelyn states, *"I think a lot of us have a really strong desire to make the person coming after us road a little easier than the road we had, because we all had different struggles, but struggles."*

Personal accountability takes on an additional tenor in the context of DIY diabetes technologies. Many who use DIY technologies expressed acute feeling of personal responsibility. This perceived responsibility, however, was often directly linked to what they viewed as the failure of medical clinicians and device manufacturers to provide the support. Additionally, and in contrast to the other two cases, feelings of responsibility toward the community of DIYers (and people with T1D more generally), also galvanized informants to continue to contribute to DIY technologies and community. In some ways, this example directly resists neoliberal ableistic paradigms in that the lived experience of diabetes becomes celebrated and crucial for the development of DIY tech. Additionally, while many acknowledge the difficulty in recognizing their difference from their non-disabled peers in the past, almost universally, diabetes has been taken up as a social and political identity, resisting the subordination of disabled bodyminds.

Boundaries and Transgressions

The conflicts and tensions with clinicians, manufacturers, regulators, and even family members that arose in all three cases nearly always arose from a transgression across a perceived boundary. Two primary types of boundaries and transgressions were noted throughout all cases: transgressions across boundaries demarcating authority and transgressions that were perceived as violating bodily integrity. How and by whom these boundaries were drawn and surveilled was nearly always determined by a person or organization with greater power than the users of these technologies, who were consequently viewed as transgressors. These transgressions signaled a shifting away from passive and receptive "patient" into agential actor, often challenging the medicalization or pathologization of non-normative bodyminds. By destabilizing the professional-patient relationship, it simultaneously destabilized the "boundaries as to who does the curing (and, ipso

facto, decides and designs the treatment regimen) and who needs curing (or who receives the treatment)" (Shyman, 2016, 368).

As Conrad (1992) has established, the professionalization of medicine occurred in part to fill an authority vacuum that emerged due to the secularization of Western society. Medical categories, diagnoses, and authority has since been used as a means of social control (ibid). Beyond that, as Wendell (1996) asserts, medical authority has gained the power to determine what is ontologically socially, and politically real through the pathologization (and thus subordination) of non-normative and disabled people. Certain types of people, and their knowledge, become disavowed in this process, shifting them into passive, receptive, and ultimately disposable roles (Kafer, 2013; Hong, 2015). Authority transgressions occur when a user (as a disabled person or the prospective parent of a disabled person) gains "too much" knowledge or control over their bodyminds, disrupting or supplanting medical authority.

Perceived transgressions of this sort were reported in all three cases. As noted in the subtheme Knowledge Anxiety (under Knowing and Not Knowing) in the PGS/PGD case, there was a threshold, albeit an ill-defined one, of knowledge about a prospective child's genetic makeup beyond which a prospective parent was being reckless or dangerous – essentially, "knowing too much." The "appropriate" level of knowledge, in these cases, was nearly always synonymous with the recommendation of the healthcare professional. Additionally, in all cases, the knowledge that arises from experience and embodiment was often dismissed or invalidated in the face of competing medical authority. This was acutely felt by many with DBS, who expressed personal value in the practical and embodied expertise that emerged from living with disability but simultaneously experienced dismissal of that knowledge by

medical professionals, as reported in the subtheme Epistemic Invalidation (under Epistemic Authority and (In)Validation). Vickie expressed her frustration at her DBS team by saying, *"They did what they wanted, and they weren't listening to me to be honest with you."* While others similarly expressed their frustration, it was often inflected with a resignation about the power of medical authority (phrases such as "but I'm not a doctor" were common). In both PGS/PGD and DBS, individuals who transgressed these authoritative spaces often experienced anxiety and frustration. The perceived transgressions of the "rogue cowboy hackers" in the DIY APS case, however, were viewed not as discrete moments of clinical interaction, but as a calculated form of resistance against a medical authority that refused to acknowledge the experiential knowledge of the T1D community. Judging from their interactions with medical professionals and manufactures, DIYers interpreted their knowledge and practice as threatening to the authority of specialists and commercial developers. As Evelyn stated of the commercial response to DIY: *"Instead of viewing it as an opportunity, they view it as a threat. They view it as competition and not cooperation."* In response, DIY directly resists the receptive patient role, where person with T1D quietly and gratefully accepts the guidance of the professional. Overall, users of these technologies are caught in an impossible standard in which they are expected to acquire a certain amount of knowledge in order to be perceived as responsible, self-contained neoliberal subjects, but are condemned as reckless, threatening, or dangerous for pursuing too much knowledge or control over their bodyminds.

This form of resistance explicitly rejects medical authority, calling out its detachment from the lived realities of disability, making it not only inappropriate, but detrimental. Members of all cases emphasize this fissures between embodied

experience and medical authority as creating disjunctions that, in many ways, necessitate the above articulated transgressions. In PGS/PGD, the Transferring Knowledge subtheme (under Knowing and Not Knowing) highlights the disconnect between what medical professionals perceive as useful information and what prospective parents need and desire. Melanie discussed a general frustration with the lack of information she was provided throughout her pregnancy, even when she directly requested it. For example, she recalled once asking about fertility treatments and being met with resistance: *"[My clinician] was like, "Oh we won't even talk about that now" … It's like why can't I? Like why can't I talk about it? It'd be better if I talked about it with you than if I googled it. So like why not?"* The Clinical Authority and Communication and Education subthemes in the DBS case (under Epistemic Authority and (In)Validation) emphasize a similar disjunction, with the additional caveat that these disconnects erode clinical trust and contribute to oppositional clinician-patient relationships. The Mismatched Priorities subtheme (under Insufficiency and Invalidation) in the DIY APS case further highlights how the awareness of the medical establishment's authority and distance breed resentment, dissatisfaction, and action. With both DBS and DIY APS, these divisions appear not only in medical practice, but in the design of medical devices, signaling a distance from lived experience in all aspects of medical authority.

As mentioned above, a second set of perceived transgressions occurs in the perceived violation of bodily integrity. Disagreements between users and medical professionals about how and when bodily integrity is violated creates conditions in which users challenge authority by asserting a differential understanding of risk. This phenomenon was most clearly observed in the Invasive Medicine subtheme (under Invasion and Control) in the DBS case and the Determining Risk subtheme (under

Risk and Responsibility) in the DIY APS case. In the former, the surgical implantation of a deep brain stimulator is considered by medical professionals as significantly more invasive than medication regimens due to the transgression of the physical boundaries of the body through surgery. People receiving the procedure, however, asserted the invasiveness of medications, both through their physical side effects, and the surveillance and monitoring by medical professionals necessary for their use. Surgery, despite its "transgressive" nature, was less worrisome both because disabled bodyminds are already subject to invasive medical procedures in the course of regular care and because it signaled the introduction of a system that could be controlled by the user. Bradley provided insight into this when he recounted being offered either narcotics or surgery: *"But when you look at narcotics, it's invasive in a much more perverse way. You know, it's not, your body's not being cut open, but it's so invasive in your life in so many other facets. So I think we're taking a very simplistic look at it when it's obviously much bigger."* Concerning APS, people such as clinicians and family members who were not engaged in diabetes in a sustained way expressed greater fears and concerns about DIY technologies because they failed to grasp the risk, uncertainty, and decision-burden that accompanied everyday engagement with diabetes. According to users, DIY APS was interpreted by others as transgressing the body by engaging in unsafe medical practices, while users observed little difference between DIY and the daily risks of self-management. Carolyn, for example, shared, *"I didn't have any anxiety or any fear. My [non-diabetic] husband did. "How do you know this isn't going to kill you?" And I think my answer might have been, 'Well, the disease is going to kill me if I don't do something.'"* Both cases reveal a differential understanding of risk and embodiment. For those who are not disabled or not actively engaging with disability on a daily basis (see Chapter 6 for a more in-depth discussion of the distinction between

disabled individuals and primary caretaker's experiential knowledge), the wholeness and incorruptibility of the bodymind is valued. Transgressing the boundaries of the body, either through surgical intervention or off-label treatments, is a pollution of the pure and ideal bodymind. For disabled people, whose bodyminds have been subject to scrutiny, violation, and transgression at the hands of the medical establishment, their experience of embodiment is significantly different, and thus so is their conception of risk and invasiveness.

In a social and political environment that grants authority over disability to a medical establishment, embodied knowledge is also viewed as a transgression. What has emerged from this study is the generative possibilities of that transgression. As Goodley (2014) writes, "being disabled is not a tragedy but a possibility, an affirmation, a queer or crip space for rethinking what it means to be human, to live a quality life, and a life with quality" (160).

Relocating Disability and Authority

Disability is not a stable category. The meaning of disability is deeply contextual. Cultural, social, and political frameworks influence how and when biological difference becomes disability. Medical categorization is then not the neutral observation of a natural world, but a deeply political act that is historically, geographically, and socially contingent (Bowker and Star, 1999). As an unstable category, the discourse and use of biomedical technologies deployed to detect, treat, and cure dis/ability meaningfully shifts the ontological, social, and political meaning of disability (Wendell, 1996). Biomedical interventions become possible through the standardization and categorization of disabled bodyminds, which can only occur through credible knowledge production about what disability is and who is responsible for managing it. Therefore, the attempt to relocate credible knowledge

about disability to social, political, and otherwise non-medical contexts is destabilizing to a medical establishment that seeks control and authority to name, locate, and manage dis/ability. The transgressions of authority and knowledge explored in the previous section most often occur when disability is disrupted as a biologically discrete phenomenon and relocated to social, practical, and experiential contexts, drawing it away from medical jurisdiction.

Throughout all three cases, an essential tension exists between an understanding of disability located discretely and biologically in the body – and therefore identifiable and quantifiable through technological intervention – and disability otherwise. The datafication and visualization of disability, through genetic testing, brain scans, or A1C numbers, tacitly supports an understanding of disability as purely biological phenomenon. Additionally, measuring and visualizing disability, in whatever form, is also commonly used as a means to bolster trust and support in clinical authority. The perspectives captured in the Medical or Social subtheme (under Defining Disability) in the PGS/PGD case, for example, emphasize the perceived "realness" of biological and physiological dimensions of congenital disabilities, as opposed to the intangible social impacts of congenital disability, despite recognizing prospective parents' thirst for the lived knowledge of disability. This was especially true of the clinical professionals, such as Anton, who stated that biological outcomes are more "tangible," and Marcie, who shared "And we [genetic counselors] usually start with the medical – mostly because it's easier. And it's a – and it doesn't lead to other discussions." This hard line, and the perceived animosity with disabled communities, contributes to an essentialization of disability to genetic and physiological components, restricting prospective parents' access to disabled communities. In the DBS case, the subtheme Trust (under Clinical Authority in the

Epistemic Authority and (In)Validation theme) acknowledges visualization and datafication techniques, such as MRIs pinpointing specific areas of the brain to be intervened on, that allowed users to develop trust toward their clinicians. Disability becomes visible and tangible through visualization, while simultaneously becoming fully and firmly inside medicine's jurisdiction. Further, as shown in Invasion and Control theme in the DBS case, this framing also articulates the disabled body as distinct and in conflict with the person. As Freddie states of Parkinson's disease, *"You fight your own body. You have to do things when your body is telling you not to."* By locating "disability" as a distinct physiological feature, it reinforces a mind/body duality. This duality serves to both re-entrench disability under medical authority, but also delegitimizes embodiment as a valid form of knowledge by severing the person from the body.

Key to relocating the power to name and manage dis/ability is the establishment of credibility to speak about it authoritatively. As discussed at length in Chapter 2, medicalization has allowed for the creep of medical authority into non-medical jurisdictions primarily through the establishment of authority through credible knowledge claims about disability. This is often done through professionalization (with strictly regulated access to who can obtain membership), which creates seemingly inflexible categories. These perceptions of inflexibility bleed through in interviews even as informants simultaneously recognize and promote the value of embodied and experiential knowledge, suggesting an implicit awareness of the power differentials that characterize medicalization, reminiscent of Wendell (1989). Whether that is Barry, the husband of a DBS recipient flatly stating his wife cannot offer other DBS recipients advice because "*She's not a doctor. You can't say anything*," or Gordon conceding *that "cure is so inaccessible,"* when discussing the

design of DIY diabetes technologies, *"like it's the specialized guild and priesthood of medicine that has all these boundaries around it that you can't cross,"* or genetic counselor Marcie discussing the obligatory nature of testing by casually asking, "*Why would you say no to your doctor?"* In some instances, credibility is established through association with medical authority (such as Mary's personal and professional relationships with neurosurgeons) or through the assumption of technical and medical language and practices (such as the language of experimentation, scientific inquiry, and medical risk in DIY APS). The latter example resonates strongly with Epstein's (1996) account of "activist-experts" during the HIV/AIDS crisis, whose acquisition of scientific knowledge and jargon conferred on them sufficient credibility to participate in the oversight process. As with those activists, this approach in some ways implicitly endorses the hegemonic method of scientific inquiry and authority that characterizes the medical establishment, potentially eroding their contributions as embodied and experiential knowers. Such an explanation may help to explain the strict, if implicit, inclusion criteria for who can participate in DIY APS. On the other hand, as noted in Chapter 6, the DIY diabetes community has in many ways cohered around a political and social identity rather than a medical category, specifically in their identification with and affinity toward broader disability communities, signaling a movement away from clinical authority and medicalization.

Even in the recognition of medical authority, assertions of embodied and practical expertise emerge to trouble the ostensible authority the medical establishment has over (current and future) disabled bodyminds. As Rosalie states of her pregnancy, *"I know more about it…I'm living it now."* Disabled, embodied, and experiential knowledge as an epistemic resource will be explored in greater detail below.

The Technological Fix

In my experience, both disability studies and feminist science and technology studies have traditionally, and necessarily, warned against, condemned, and critiqued biomedical technologies as extensions of hegemonic regimes of power subordinating minority populations. From this study, however, emerges a novel challenge to that critical perspective. Informants struck a decidedly ambivalent relationship with technology. The biomedical technologies in this study are viewed neither as wholly liberatory nor wholly subordinating, troubling a techno-determinist framework that animates much of the discourse around biomedical technologies for disability. Rather, the engagement between bodyminds and technologies is something far more plebian. The human-technological hybridity that emerges through biomedical technologies is not, from the individual perspective, assumed to be transformative nor oppressive (with exceptional cases such as Carl and Vickie, for whom DBS implantation was viewed as destructive). As Abene states of her transition onto higher-tech diabetes management technologies, *"It has changed the way I live my illness, but it has not changed me as a person."* In many ways, regrounding the experience of biomedical technology in everyday experience unravels the alluring rhetoric of technological transformation by reestablishing the humanity embedded in tech. This is reminiscent of Nelson, Shew, and Stevens (2019)'s meditation on their personal narratives of disability and technology, which do not condemn or endorse, but rather recognize the ambivalence (and generative possibility) of disabled bodyminds and technology, writing "there is no one right way to be disabled, nor is there one right way to negotiate one's body in the world with technologies. There isn't even one technology that counts as solution. None of this is super: it is all everyday" (4). The curative promise of biomedical technologies, even in the preventative case of prenatal genetic testing, was not of much significance to

individual users. Rather, the impact on day-to-day life, significantly distanced from the discrete and rigid diagnostic and symptomatic measurements of the clinic, mattered far more. In the PGS/PGD case, this was often expressed in the comfort of knowledge in order to prepare for an upcoming birth. As Gene shared of his experience with genetic screening, it enabled him to *"not live in anticipation or fear or with any sense of dread off an impending doom at all. It's easier to not worry about that."* In DBS, it may take the form of being able to make adjustments at home using a patient remote. For APS, the practical impact of technology often took the form of a full night's sleep or the ability to monitor a young child's blood sugar from hundreds of miles away. Informants spoke to what mattered to their lives, lives that extended far beyond clinical markers of health and illness.

While biomedical technologies were never depicted as wholly liberatory, they did offer a benefit across cases that had little to nothing to do with what they were designed to detect, prevent, or mitigate. In the face of the burden neoliberal individual responsibility, the adoption of technology was perceived both as an act of self-responsibility, and importantly, a method by which to displace the cognitive and emotional burden of navigating a neoliberal ableist world with a non-normative bodymind (or with the potential to create one). For example, by displacing the immediate choices of diabetes management to an algorithm in DIY APS, one also displaces some of the responsibility of body management. By utilizing DBS to reduce visible tremor, one mitigates the affective impacts of navigating the world in a visibly disabled bodymind. By screening and diagnosing genetic conditions in the fetus, one distances and guards oneself from potential future courtesy stigma and judgement (Goffman, 1963). Horrocks (2019) makes a similar argument about the datafication and technification of diabetes management through (regulated) technologies such as

insulin pumps and continuous glucose monitors. He reflects on the desire for cure expressed by many with diabetes, writing "that the desire for a post-Diabetic life – so often actually conceptualized as a *pre*-Diabetic life – is in many ways a desire to escape the labor and torque characteristic of life with a chronic illness. In practice, the desire is discursively linked to a desire for the experience of able-bodiedness in an able-bodied world, a desire to feel normal" (5, emphasis original). Technology then becomes a method of *sharing* the social and political burden of being disabled in an (dis)ableist world.

However, the design of these technologies often falls short. "*They just don't think like a patient thinks*," Mary remarked when discussing a new design for the DBS patient remote that would be unusable for anyone with dexterity issues. She and Barry suggest engineers with Parkinson's should be designing and developing these tools to avoid these gross mismatched, or as Garland-Thomson (2011) might say, misfit, between bodymind and environment. Their contextual, embodied, and practical knowledge of dis/ability grants them pertinent knowledge about the material-discursive world that, through the many examples of 'bad design' raised in this study and beyond, is absent in much of biomedical device design and use. Here, the entire ethos of DIY APS exists a fundamental assertion of the generative value of embodied and experiential expertise. The technologies and practices analyzed in this study are often experienced with frustration, distrust, or dismissal in part because they fail to acknowledge, account for, or incorporate the daily lives of the people who use them. Rather, as they emerge from a hegemonic, objective, and positivist scientific framework (Harding, 1991), they perpetuate and proliferate bias, be that the androcentrism that casts prospective mothers as "moral pioneers," to use Rayna Rapp's (1999) term, or the ableism that bars many people with T1D from accessing

their own data to manage their own care. By acknowledging and privileging the standpoints of the non-scientists who live with and use biomedical technologies, what is revealed is a deep fissure developed by the systemic exclusion of disabled people from the design and deployment of technologies.

Generative alternatives, however, exist in subaltern spaces such as the DIY APS community. In these contexts, "the lived experience of disability…" write Hamraie and Fritsch (2019), "…creates specific expertise and knowledge that informs technoscientific practice" (17). While DIY APS broadly still ascribes and reinforces ideas of personal responsibility and accountability, the development of a coherent DIY community creates an opportunity for alternative cultural imaginings about health, disability, and well-being. Melanie Yergeau's (2014) calls such practices criptastic hacking, an approach that "rails against forced normalization, one that moves from body-tweaking to something collective, activist, and systemic" (para 24). While DIY APS provides the clearest example of these alternative knowledge communities, both the PGS/PGD and the DBS case also illuminated similar spaces. Whether these manifest as online forums where prospective parents can ask questions and read others experiences or in-person DBS support groups where people can share their practical tips for daily living, the prominence of these spaces in people's experiences suggests the insufficiency of medical establishments.

Even here, however, the ambivalence of technology is clear. While on the individual level, there is a displacement of everyday burden, the use of these biomedical technologies reinscribes hegemonic paradigms about medicalization and personal responsibility. Recommendations, then, are not as straightforward as universal access or universal ban. The following sections will articulate some of the

intersectional dimensions of biomedical technology and present a series of recommendations that grapple with this ambivalence.

Asking the Other Question

In 1991, Mari J. Matsuda wrote a call for coalition in feminist scholarship and activism by urging feminists to "ask the other question." "When I see something that looks racist," she writes, "I ask, 'Where is the patriarchy in this?' When I see something that looks sexist, I ask, 'Where is the heterosexism in this?' When I see something that looks homophobic, I ask, 'Where are the class interests in this?' Working in coalition forces us to look for both obvious and non-obvious relationships of domination, helping us to realize that no form of subordination ever stands alone" (1189). In this chapter and throughout this project, the explicit and implicit imposition of ableist discourses, practices, and thought have significantly impacted the experiences of users of biomedical technologies. Taking Matsuda seriously demands an examination of these ableistic phenomena with an attention toward race, class, gender, sexual orientation and other intersecting axes of oppression. As discussed in Chapter 3, this project was originally developed with an additional research question regarding intersectional experiences of these technologies, but after initial recruitment, the diversity of the informants and sample was not such that I could responsibly proffer such an analysis. However, issues of class and gender emerged explicitly during inductive analysis and connections to race, sexuality, and other dimensions were implied. More research is needed in these area to understand the ramifications.

In all cases, informants reflected on their uniquely gendered experiences, although none as explicitly as that examining Prenatal genetic screening and

diagnosis. In the PGS/PGD case, expressions of responsibility among female-identifying pregnant informants, common references to "mothers" as opposed to "parents," and several instances in which embodied and experiential knowledge was linked explicitly to femaleness emphasized the gendered dimension that colored informants' experiences. This is in line with a long lineage of academic literature attending to the specific pressures of accountability that bear on women of child-bearing age (i.e. Rapp, 1999; Stern, 2005; Briggs, 2017). Additionally, nearly all participants, both professionals and prospective parents, were female-identifying, with only two male-identifying informants in the case. The case was also dominated by a heterosexism which assumed a pregnant person was in a male-female relationship (although one prospective parent identified as a queer person in a heterosexual relationship), and a biological essentialism that linked good or responsible motherhood to a biologically innate characteristic. Additionally, class and educational dimensions appeared explicitly throughout the case. Nearly all the prospective parents interviewed worked in higher education, and professionals would often allude to a certain type of prospective parent, suggestive of a wealthy, educated person who, in Marcie's words, lives in urban areas and "*want[s] a perfect baby."* Suggestions of regionality as factoring into health literacy and ultimately into trust of genetic screening and testing also suggests an implicit class element to prenatal testing. Explicitly, Rosalie directly addressed how her reproductive anxieties emerged directly from her class; she currently places herself in the "middle class," juxtaposing it with what she describes as a working class upbringing. Not only in her current class was she part of a generation of women giving birth in her mid-30s (see Briggs, 2017, 101-148 for an in-depth discussion on delayed pregnancy and class), but "*this demographic, you know, there's so much pressure on parents to be perfect and to be great and everything that their kid does reflects on them as a*

person…there definitely is a lot of ownership in parenting in this class that I feel like in the lower class that I came from, it's just a different thing. You don't own it the same way." This differential understanding of the expectations of motherhood bleed into perceptions of pregnancy, including responsibility for congenital disability. Further, there is a substantial amount of previous research about the racialized experiences of pregnant people in how they understand, interpret, and engage with prenatal testing and screening (e.g. Wertz et al, 1991; Browner, Preloran, and Cox, 1999; Bryant et al, 2015) as well as their overall experience of pregnancy (e.g. Bridges, 2011) and reproductive responsibility (e.g. Hartouni, 1997; Briggs, 2017). The absence of the perspectives of people of color in this case signal a substantial limitation, and future work in this area is needed. On a more fundamental level, Kafer (2013) asserts that the figure of the Child – the metaphoric symbol of future humanity – is used to maintain expectations of able-bodiedness/mindedness and heteronormativity in a variety of social and cultural settings. Therefore, certain conditions detected by prenatal testing are understood as threats to the figure of the Child and to the future of humans more broadly. She suggests the proliferation of prenatal testing technologies are tightly coupled with "profound anxieties about reproducing the family as a normative unit" (69). Normative, in this context, refers not only to able-bodiedness, but to heterosexuality, socioeconomic security, and whiteness. There is intense social pressure for prospective parents – primarily prospective mothers – to use these technologies appropriately, and failure to reproduce the idealized Child results in stigmatization. Therefore, it is impossible to discuss the meaning of the ableism embedded in prenatal genetic testing without also attending to the racialized, gendered, and heterosexist dimensions that animate genetic screening and testing in theory and practice.

Drawing from the few statistical analyses available, the majority of which concern DBS for Parkinson's, deep brain stimulation is much more likely to be offered and given to privately insured white men who are financially well-off (Benesh, Gupta and Sung, 2017; Chan et al 2014). While these figures only represent people receiving DBS for Parkinson's disease, these demographics also generally held true in this case study (six of nine DBS users in this study were white men). Gender, in fact, emerged as a significant qualifier of experience for several of the male-identifying informants, resonating with much of the research on masculinity and acquired disability (e.g. Scott, 2014). More so than any other case, disability's challenge to masculinity presented as a crucial element by which to interpret experience. As Meekosha (2004) writes, "the image of disability may be intensified by gender – for women a sense of intensified passivity and helplessness, for men a corrupted masculinity generated by enforced dependence" (765). It is important to note that "masculinity" here does not refer to some innate or biologically essentialist understanding of gender, but to hegemonic masculinity, or the set of practices that legitimize the dominance and control of men (Connell, 2005). In Western culture, this masculinity is typically characterized by a de facto heterosexuality, competition, economic success, and a suppression of vulnerability (Lynch, 2009). Disability confronts hegemonic masculinity on both a collective level by producing alternative masculinities and, when disability is acquired such as is the case with many of the conditions associated with deep brain stimulation, on the individual level as one grapples with their fluid social standing. Common amongst the men in the DBS case, who of course do not all possess all elements that characterize hegemonic masculinity, were attempts to reclaim that masculinity through technological intervention. For example, John noted he received DBS specifically to *"be of service to my family, to my wife."* The links between the desire to maintain his masculinity

(not only through the maintenance of independence but through being of service to his family) directly impacted his decision to pursue biomedical intervention. Carl expressed a desire to reclaim the stoicism of hegemonic masculinity following the psychological side effects of his deep brain stimulator in distinctly masculine terms: *"Stop pointing fingers and just deal with it and be a man. Sorry, I should say, I don't want to sound sexist, be a strong person. A person with strength."* The distinctly gendered experiences of disability have a direct relationship to the decision to pursue and experience of biomedical technologies.

While not explicitly addressed in the majority of the interviews, experiences of DIY APS were inflected with racialized, classed, and gendered experiences. As discussed in Chapter 6, nearly all informants were both white and highly educated. Only one informant disclosed being non-white. Although it should be noted that seven informants were living in Europe at the time of their interviews, and the racial and gender politics of the United States cannot and should not be cleanly mapped onto these contexts. That being said, the masculinized digital spaces that characterize open-source and "hacking" cultures are differentially experienced by women (Brooke, 2019). Generally speaking, there are less women present in "hacking" communities than other computing cultures, and these spaces typically reinscribe patriarchal paradigms, include meritocratic myths and sexist discourses (Jordan, 2017). While beyond the scope of this research, this may not be as pronounced in DIY APS communities, which may exhibit characteristics more closely linked to embodied health activism than traditional hacking communities. In the APS case study, Melody reflected on the significant frustration she encountered in the early days of DIY APS, where she was often ignored, dismissed, or mocked for her emphasis on communication and community-building. *"This happened both*

physically in person as well as some of the comments and activity online…" she remarked, sharing that she eventually wrote a blog post addressing these frustrations and her hopes for the community, *"…I think having a 100% male community and having the kind of community that was starting to replicate in the diabetes space wasn't necessarily a positive one, wasn't a welcoming one, and we certainly wouldn't be able to welcome larger contributors in the future. And I felt like that wasn't what we wanted for our community, so I kind of called it out."*

Informants like Erica, who joined the DIY community after it had been established, remarked on the distinct lack of the hacker archetype, although others like Aditi referenced the divide between "techy" and "non-techy" users. The "techy" ones are implied to be the white, college-educated male-identifying coders in their "*darkened rooms*" with their "*creative and analytical brains,*" as one set of documentation for a DIY APS variant suggested. This understanding is similar to Brooke's (2019) articulation of hacker culture. So, while open-source diabetes technology espouses an infinitely welcoming and infinitely collaborative space, there was a distinct hierarchy articulated between the developers, who were often (though with notable exceptions) coded as male, and users, who are understood as more diverse. Additionally, two prominent women (one of whom was Melody) in the DIY community that were referenced in several interviews as having exceptional communication skills, alluding to a feminine interpersonal ability. Beyond gender, class featured distinctly into conversations of DIY APS, particularly in regard to access to supplies, technologies, and supports to grow health literacy. This resonates with several recent reviews that suggest that access to diabetes technology such as insulin pumps and continuous glucose monitors was contingent on race (in US-based study, Black and Hispanic children where significantly less likely than white children to have access to an insulin pump; Willi et al, 2015) and income level (in a UK-based study, pump use

was significantly lower in areas experiencing socioeconomic deprivation; Clinical Audit and Registries Management Service, 2016). Further, and less well-understood, recent research suggests clinicians have "strong yet often inaccurate views about individual patient capacity to use pumps successfully," perhaps contributing to the myth of the "super user" as educated, white, well-off, and *compliant* (Farrington, 2018). While discussions of access to technology, insulin insecurity, and health literacy featured in this case as barriers to access to DIY APS, there was no explicit recognition of class or race as characteristics that predispose someone to be the kind of "super user" who has access to technology and the self-responsibility to utilize DIY technologies. This raises questions about the potential invisibility of people of color, working class people, people living in rural areas, and other marginalized groups in the DIY community.

An essentialist disability perspective obscures other subordinated identities, thus masking and invalidating a multiplicity of experiences. Noting where intersecting axes of oppression are present (and absent), provides a foundation for understanding how they influence the situated experiences of dis/ability, technology, and health care.

Trustworthiness and Limitations

As discussed in detail in Chapter 3, qualitative research has often been criticized and dismissed as lacking in the rigor that define quantitative work. While "validity" and "reliability" are positivist ideals that cannot and should not be applied to qualitative work, Lincoln and Guba's (1985) framework for "trustworthiness" – articulated through credibility, transferability, dependability, and confirmability – presents a meaningful alternative. Chapter 3 outlines the steps taken toward developing trustworthiness in this study in detail. Rather than rehashing those

components here, I wish only to rearticulate that trustworthiness cannot truly be defined in what a study has *done,* but in *what is done with a study.* By this I mean that while steps toward trustworthiness like transparency and member-checking can be done in process, it is ultimately determined by the users and consumers of this research. I aim over the next several years to work closely with my informants and with other stakeholders while developing this work for publication, ensuring it adheres to those principles of credibility, transferability, dependability, and confirmability, with special attention paid particularly to how it might be leveraged by stakeholder communities who have traditionally been disenfranchised in both research and practice. As of March 2020, a full draft of this dissertation was sent to all informants for feedback.

As discussed in Chapter 3, this study was intentionally small, with each case being exploratory in nature. Time restrictions, limited access to stakeholder communities, and limited funding to travel for in-person interviews all presented methodological limitations. Further, the relative dearth of empirical work on these topics, particularly DBS and APS, also imposed limits on the scope of this project. Considering the limitations of this study, rather than discrediting this project, provides a framework for future research. For example, what might ethnographic encounters in the clinic provide to supplement the interview data collected here? This study relied solely on interviews with informants and publicly available documents. The tensions and confrontations of the clinic emerged from the experiences articulated by informants, but ethnographic work could build and supplement those insights. How might systemic recruitment across geographies and demographics work to tease out the intersectional relationships that frame experiences? The limitations noted above disallowed an extensive examination on intersecting axes of

privilege and oppression as they come to bear on users of these technologies. Expanding this work to include a purposive sampling across geographies and demographics could build on the initial analysis conducted earlier in this chapter. Additionally, insight from other stakeholders, including clinicians, manufacturers, and regulators could confirm or challenge the analyses presented here, producing a richer picture of the human phenomena that animate this space. Finally, the analyses presented here characterizes the biomedical context, but does not intervene on it. What might an intervention bringing together the expertise of designers, clinicians, and disabled people yield for future biomedical device design processes? A future extension of this work must include an intervention that seeks to transform the knowledge practices that create the double bind of accountability and invalidation articulated in this study.

Implications and Recommendations

This work contributes to scholarship and research in a number of ways. Galis (2011), notes that while critical disability studies and science and technology studies have followed parallel trajectories and hold similar orientations toward the political and social constructions of technologies, they have rarely been drawn upon together in scholarship, with the exception of recent scholarship such as the 2019 Crip Technoscience special section of *Catalyst: Feminism, Theory, Technoscience* (Fritsch, Hamraie, Mills, and Serlin, 2019). This study draws together these two fields in order to take seriously the deconstruction of the binary between social and material, the political and social implications of technologies on the categorization and ontology of non-normative bodyminds, and the complex assemblages through which socio-scientific understandings of the self emerge. Additionally, work in critical disability studies in this space has largely been comprised of philosophical and theoretical writing. By producing an empirical study, this work strengthens and supports the

emergence of disability theory on biomedical technologies, confirming tensions between embodied and clinical knowledge, the invalidation of experiences, and the value of disabled knowledge practices. Further, empirical work attending to embodied and experiential expertise has been sparse (Burda et al, 2016), despite the increasing activity of embodied health movements such as DIY APS in challenging the assumptions of scientific and expert knowledge production (Brown et al, 2011). This study has contributed toward the characterizing of the biomedical landscape, creating a foundation upon which to develop research and practices aimed at transforming the knowledge practices that have traditionally disenfranchised and delegitimized disabled people as knowers. More work is needed to characterize, analyze, and critique the broader technological and medical systems in which these cases are embedded. For example, future work should be undertaken to develop an understanding of how disability and accountability are constructed in technology manufacturing, regulatory organizations, policy, and design.

The implications for practice are far-reaching. It is immediately clear that there is a significant disconnect between medical technology manufacturers and technology users in terms of priorities and desires, signaling a distance between the designers of these technologies and the lived realities of users. As I have previously written (see Monteleone, 2018), designers' lack of embeddedness in disabled communities can result in stigmatization, stereotyping, and the reinforcement of oppressive and subordinating practices. One potential pathway forward is sustained and authentic engagement with disabled communities in the design and deployment of biomedical technologies (see Ripat and Woodgate, 2011 for an example). Such practices require not only the token involvement of disabled people downstream in the design process, but seek to develop "richer, more nuanced definitions of

knowledge(s) and [build] research spaces where those knowledges can be expressed and valued. Research and development should challenge traditional paradigms and research processes, interrogate ableist underpinnings, and upend practices that perpetuate the invalidation of…people with disabilities" (Monteleone, 2018, 138).

Mismatch in priorities, expectations, and lived experience also have profound consequences for clinical interactions and the training of medical professionals. This includes a profound disconnect between clinicians and users of these technologies about the type and detail of information prospective users desire to make informed decisions in the clinic. It is imperative to recognize and characterize the nature of this disconnect because, as discussed in Chapter 2, the framework for informed decision-making, despite the rigid and unrealistic "neutral actor" articulated in legal arguments, is individualized and contextual (Raab, 2004), which demands an alternative approach to communication in the clinic. Experiences of invalidation, however, cannot be remedied simply by an increased attentiveness to individual context. Transformation also requires, as above with manufacturers, a rearticulation of knowledge and authority to account for the embodied and experiential expertise of disabled people. In all cases, this might mean the establishment of clear and formal pathways to community resources such that they are not presented as supplemental, but as a key piece of care. Kirschner and Curry (2009) assert that disability-related competencies for physicians are crucial, restructuring care to be patient-centered such that the clinician is responsive to the individual's perception of quality of life, rather than assumptions made in the absence of lived experience. As has been demonstrated with this project, the lack of appreciation of and tolerance for a quality of life that extends beyond the figure of the rigidly independent able-bodied ideal has significant impacts on people's perceptions of themselves and their choices around

biomedical technologies. Iezzoni and Long-Bellil (2012) suggest that even well-intentioned clinicians cannot and should not develop training and practices for disability-related healthcare in the absence of disabled people, in part because clinicians "'just don't get' important aspects of the lives and expectations of persons with disabilities" (139). Some pathways forward include the introduction of disabled people as medical educators during the training of clinicians. For example, it is becoming increasingly common for disabled people to be invited to participate as "standardized patients," or volunteers who are trained to work with medical students in a simulated clinical environment (see Minihan et al, 2004 for an example of how to incorporate disabled people into standardized patient trainings). Further, as suggested by several informants across case studies in this project, formal pathways to community members confronted with the same kinds of decisions around biomedical intervention could provide crucial support.

Additionally, diverse perspectives must also have a presence in the organizational bodies that animate and articulate the visions for biomedical design and practice. These include political roles, given the relationship between technological progress and American social values (i.e. Smith, 1994), as well as leadership and advisory positions professional organizations, hospital systems, and regulatory bodies. The introduction of new technologies into healthcare systems transform choices and consequences for everyone, regardless of if one is a prospective user or not. Introducing the embodied and experiential expertise of disabled people not only as passive recipients of these technologies, but in the design, practice, and regulation of them, could crucially transform not just *how* people experience biomedical technologies, but *what* biomedical technologies enter into the market.

Conclusions

In the preceding chapters, this study has sought to understand the construction and enactment of dis/ability, responsibility, and agency as it is embedded in the experience of choosing and using biomedical technological interventions to identify or treat disabled bodyminds. Increasingly, philosophical scholarship has argued that people with non-normative bodyminds face pressures to intervene in order to more closely approximate the ideal. These pressures can be social,— as when a person feels an obligation to be productive and independent— political,— as when disabled people's citizenship is contingent on proving ability— or material— as when disabled bodyminds must be modified to compensate for non-accommodating infrastructure. A reliance on biomedicine to correct these misfittings, as opposed to structural or social change, is linked to the production of the ideal neoliberal subject as self-governing, independent, and productive. Disabled bodyminds are unruly and unworthy unless and until the individual becomes self-responsible and manages their bodymind through biomedical intervention. While the neoliberal logic that drives this paradigm demands self-management, the medicalization and pathologization of disability invalidates the knowledge and experiences of disabled people in favor of a medical authority. This process produces a context in which self-responsibility of body management essentially means giving oneself over to the recommendations and requirements of medical authority.

This project has functioned to fill a critical gap in the theoretical and empirical work about the experience of disability in medical context. Through this dissertation, I begin to answer questions about how technologies, which are increasingly centered in medical care and practice, transform the meaning and experience of dis/ability. I acknowledge the role technologies play in the social and ontological construction of ability and disability, extending the social theory of disability to include the textures

and contours of socio-technical systems. The increasing reliance of technology in biomedical contexts (Clarke et al, 2010) also enables and encourages specific pathways for knowledge and credibility that shift authority to technical and medical experts, further disempowering disabled people and invalidating embodied and experiential knowledge. Practically, this work uncovers how bodyminds comes to be known and categorized and how technological discourses and design have profound impacts on how disabled people understand themselves and their obligations to themselves, their families, and their communities

As has been iterated throughout this text, the recognition of neoliberal and curative logics that drive biomedical technological interventions does not suggest that individuals cannot or should not pursue medical interventions, nor does it invalidate individual experiences of pain discomfort, or other physiological dimensions of disability. Further, it is not to suggest that individuals are not entering into decisions about biomedical technologies knowingly and willingly. Rather, by centering the narratives of individuals and using a qualitative inductive method of analysis, these individual and embodied experiences have been recognized and given space alongside the social, political, and material frameworks that animate technological intervention for dis/ability.

Technology itself plays an ambivalent role in these contexts. It is at once the physical manifestation of the neoliberal ableism that applies pressure to individuals to look, behave, and interact in rigid alignment with ableist paradigms and a valve to release the pressure of those neoliberal demands. It cannot be denied, however, that medical technologies can and do often provide benefit to their users. As Kristina Gupta (2020) writes, this ambivalence may in fact be a key characteristic of medical technology in Western culture; "Because of systemic inequality," she writes, "many,

if not all, mainstream medical interventions will simultaneously reinforce social inequality and alleviate some individual suffering" (3). Rhetorics of individual agency and independence mobilize discourses around the development and use of these technologies, and yet feelings of guilt, personal responsibility, and limited options are often expressed as driving these decisions. These encounters, however, cannot be considered in isolation. The experience of biomedical technologies exists at the interface of bodymind and environment, but it also exists at the interface between self and community, human and technology, discourse and materiality. Ignoring the complexities that frame the individual experience of biomedical technologies obfuscates the sociality embedded in technological interventions to begin with. Therefore, offering a prescriptive recommendation for the adoption or rejection of a certain biomedical technology is neither appropriate nor sufficient. How then, can this project extend? To follow Gupta's (2020) example once more, perhaps it is by directing our "feminist, queer, antiracist, and crip activists energies…[at] the broader sociopolitical structures that ensure that medical interventions are used largely in the service of normalization and working to ensure that all people, regardless of race, gender, sexuality, class, or ability, have access to the basic resources required to flourish" (4). Technology, this study has shown, has been used as a means to displace the pressures of neoliberal ableism. Therefore, this work has been able to identify those pressure points. What happens when technological innovation is resituated not to ameliorate the bodymind-environment disjunction *via the bodymind,* but to address the causes of neoliberal ableism at their root? Transgressions of authority were characterized as occurring when embodied and experiential expertise came into conflict with medical knowledge. How now to characterize those disruptions in power, to reframe dis/ability, and to cultivate and encourage subaltern disabled knowledge systems? What may happen, as shown

through DIY APS, is medical technologies become less medicalized. When the lives of disabled people are de-pathologized, spaces open for creating alternative imaginaries for inclusive futures.

POSTSCRIPT

In March 2020, a full draft of this document was shared with study informants, along with an invitation to review and share *"not only corrections for factual errors, but any thoughts you might have about the research project, analysis, or write up. This can be elements that resonate with you, things you disagree with or find confusing, or anything else you wish to comment on."* As of this writing (April 8, 2020), this document has been shared with thirty-nine of forty-one informants. The remaining two informants could no longer be reached with the contact information provided. Nine informants have replied thus far. Two of these communications were to share that they would be reviewing the document shortly. One requested a follow-up phone call to discuss their experience following their initial interview. One contained substantive comments that have been recognized in a series of footnotes in Chapter 4. The remaining five were generally positive with no specific requested changes, challenges, or concerns. A sampling of this type of comment is included below. Of these, one person claimed they were *"simply far from being qualified to reply on any point of discussion"* because the content was *"way above my head or level of comprehension."* This comment reveals a potential disconnect between this research and the communities it emerged from, urging reflection on alternative research products for (and with) these informant communities. Invitations to review this document also included an invitation to collaborate on shared research products suitable for their communities.

Selected comments:

"Thank you and your welcome. At least I now feel some good will come out of my story." (DBS informant)

"Wow, Rebecca … quite an amazing body of research!!! Thank you for understanding us and distilling our thoughts!" (APS informant)

Informants comments will be accepted through the revision of this document and will be integrated into this dissertation through the expansion of this postscript. Informant feedback will also be used in subsequent research products, including articles, presentations, and a book manuscript.

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APPENDIX A

IRB RESEARCH PROTOCOLS

A.1 Prenatal genetic screening and diagnosis

A.1.1 Prospective Parents; Researcher[12]

Instructions and Notes:

- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, mark as "NA".
- When you write a protocol, keep an electronic copy. You will need a copy if it is necessary to make changes.

Protocol Title

Include the full protocol title: Prenatal Genetic Testing: Stakeholder Perspectives

Background and Objectives

- Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.
- Describe the purpose of the study.
- Describe any relevant preliminary data or case studies.
- Describe any past studies that are in conjunction to this study.

Prenatal genetic testing (prenatal genetic screening [PGS/PGD] and prenatal genetic diagnosis [PGD]) broadly refers to a suite of screening and diagnostic strategies intended to provide information about fetal genetic disorders. Screening tests included carrier screening prior to and during pregnancy, ultrasound examinations, quad-screening, and cell-free DNA screening. These examinations all provide information regarding statistical likelihood of certain conditions. Diagnostic tests, such as amniocentesis and chorionic villus sampling, provides information about the presence of certain conditions (ACOG, 2016). Disability scholars have long called attention to the role genetic screening and testing play in the construction and stigmatization of congenital disabilities (e.g. Saxton, 2010). Further, despite the ostensible optionality of screening and testing, the routinization of these screening and testing strategies, alongside the perceived power imbalance between expert clinicians and prospective parents may constitute a form of coercion (Thomas, 2017; Tsouroufli, 2011). Further, the settled nature of this case, in which PGS/PGD/PGD is integrated as a routine element of obstetric care, raises further questions about informed autonomous decision-making. Prospective parents are expected to make decisions based on partial, highly medicalized information (Rapp, 2000), with little institutional support (Getz and Kirkengen, 2003) and increasing pressure to pursue technological intervention (Franklin, 1997).

This project seeks to understand the qualitative experience of engaging with prenatal genetic testing from the perspective of multiple stakeholders, including patients,

[12] The PGS/PGD case was conducted under 2 IRBs. The first, approved in 2017, concerned interviews conducted only with genetic counselors. The second, approved in 2018, expanded the stakeholders to include users and other medical professionals. The second also contained additional protocols for returning transcripts for review. Both are produced here.

clinicians, engineers, and corporate representatives, in order to highlight potential tensions between stakeholder expectations, understand the social construction of disability and autonomy in these scenarios, and identify procedural areas for improvement. It is necessary to attend to the experiences and insights of a variety of stakeholders, because a patient receiving PGS/PGD interacts with a network of individuals and organizations such as the hospital, insurance system, medical device industry, family, and paid carers, all of whom influence and are influenced by biotechnological intervention.

The study will include several segments:

- Semi-structured interviews with recipients of PGS/PGD and family members (Interview Consent Form),
- Unstructured interviews with clinicians, manufacturers, engineers, and other experts (Interview Consent Form),
- Document analysis of recipient-directed materials such as guidance documents, FAQs, promotional materials (no human subjects),
- Digital ethnographic observation of online patient communities, including chatrooms, comment threads, blogs, and recipient-made videos (Online Consent Form).

Data Use

Describe how the data will be used. Examples include:

- Dissertation, Thesis, Undergraduate honors project
- Publication/journal article, conferences/presentations
- Results released to agency or organization
- Results released to participants/parents
- Results released to employer or school
- Other (describe)

Data may be used in a variety of academic formats, including conferences, publications including peer refereed articles, and conference presentations. Additionally, white papers or other guidelines for practice in clinical, policy, and corporate settings may be developed using the data. Data will also be used in the dissertation of Rebecca Monteleone. In all cases, identifying information will be deidentified (including names, location more specific than country, distinguishing characteristics), although demographic data such as age, gender, race/ethnicity, and employment status that may be shared during interviews or observation will be maintained.

Raw interview data will be available for review by participants, and results will also be released to them upon request. Approved interview transcripts that have been de-identified may be published for use by other researchers, patient advocates, and more on a data repository such as Figshare.

Inclusion and Exclusion Criteria

- Describe the criteria that define who will be included or excluded in your final study sample. If you are conducting data analysis only describe what is included in the dataset you propose to use.
- Indicate specifically whether you will target or exclude each of the following special populations:
- Minors (individuals who are under the age of 18)
- Adults who are unable to consent
- Pregnant women
- Prisoners
- Native Americans
- Undocumented individuals

Targeted participants will be individuals who are receiving or have received prenatal genetic testing, their families, clinicians, researchers, corporate representatives and engineers. As such, pregnant people receiving obstetric care that includes genetic testing may be recruited and participate. No particular or additional risks to these participants are expected. All participants will be over 18 and have capacity to provide informed consent.

Number of Participants

At least twenty and up to one hundred individuals across all stakeholder categories will participate in interviews, with particular attention paid to enrolling individuals who have received PGS/PGD.

Methods may also include digital ethnography in publicly-accessible forums for patient support and information. Researchers will announce their presence in these spaces, request consent to observe, and allow participants to provide consent to be observed.

Recruitment Methods

- Describe who will be doing the recruitment of participants.
- Describe when, where, and how potential participants will be identified and recruited.
- Describe and attach materials that will be used to recruit participants (attach documents or recruitment script with the application).

All potential participants will be solicited via posted flyers, online posts, or in-person invitations using the recruitment scripts and consent information attached. The only exception to this will be experts, such as clinicians, recruited through personal relationships, who may be contacted via email. Additional avenues to recruitment will be pursued as needed, such as solicitation through professional organizations, but care will be taken to avoid power imbalances that may lead potential participants to feel coerced. Interview recruitment and consent will be accomplished using either flyer, online post, or spoken script (attached).

INTERVIEW RECRUITMENT PROCESS:

- Recruitment will take place through several avenues, beginning in early 2019. Potential recruitment strategies include:
- Posting study information in pregnancy and parenting online forums (online post),

- Using personal networks (recruitment script),
- Recruiting experts during conferences and professional meetings such as the National Society for Genetic Counselors' Annual Meeting (recruitment script),
- Visiting pregnancy support groups (recruitment script),
- Requesting study information be shared through clinics (flyer)

Prior to conducting interviews, all participants will be fully informed of research goals and processes, their right to confidentiality, and the ability to end both contact and the interview without repercussion. Identification and recruitment of participants will take place between Spring 2019 and Winter 2023 (5 years). All interviews will take place either in-person, by phone, or via video-conferencing technologies such as Skype. All participants will provide informed consent prior to beginning the interview, including informed consent to be recorded for research purposes.

In the context of observing online forums, researchers will post recruitment and consent information to these online forums.

Procedures Involved

- Describe all research procedures being performed, who will facilitate the procedures, and when they will be performed. Describe procedures including:
- The duration of time participants will spend in each research activity.
- The period or span of time for the collection of data, and any long term follow up.
- Surveys or questionnaires that will be administered (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants to the online application).
- Interventions and sessions (Attach supplemental materials to the online application).
- Lab procedures and tests and related instructions to participants.
- Video or audio recordings of participants.
- Previously collected data sets that that will be analyzed and identify the data source (Attach data use agreement(s) to the online application).

Primary procedures include semi-structured and unstructured interviews no longer than two hours conducted over a 5 year time span (2018-2023). Participants will be interviewed at least once and will be provided with researcher contact information should they wish to follow up. Participants will be audio-recorded. Participants will also be given the opportunity to review and edit transcripts following interviews after initial interview. Participants will have up to 1 week to review and edit transcripts upon receipt. Participants will also have the option to follow-up with researcher to provide additional information/schedule an additional at any time. Follow interviews instigated by the research team may also be conducted, but this protocol does not yet exist. Should follow up interview protocol be developed, a modification will be submitted to the IRB.

Interviews will be supplemented by a series of digital ethnographic observations. Forums that will be analyzed will be subreddits (topic-specific subcommunities) on Reddit.com such r/pregnant, r/babybump and related subreddits. Reddit threads are publicly viewable but posting and commenting requires an account. I will not obscure or hide my identity and status as researcher when posting. Previous research suggests forums like reddit are

especially well-situated for conversations about sensitive topics because it encourages multiple, throwaway, and unidentifiable accounts (Park and Conway, 2018). I will establish a new thread in these subreddits including study and consent information which users can opt into and analyze conversation in this thread only.

Semi-structured interview questions for recipients and family members and topic sheet for unstructured expert interviews are attached.

Compensation or Credit

- Describe the amount and timing of any compensation or credit to participants.
- Identify the source of the funds to compensate participants
- Justify that the amount given to participants is reasonable.
- If participants are receiving course credit for participating in research, alternative assignments need to be put in place to avoid coercion.

No compensation will be offered. Should this change, the IRB will be made aware.

Risk to Participants

List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. Consider physical, psychological, social, legal, and economic risks.

There are no significant risks associated with this study, other than the risk of loss of confidentiality, but the research protocol will mitigate that risk. All research will be de-identified (although some demographic data will be retained); participants will be assigned unique identifying codes and all raw data (e.g. audio recordings) will be password-protected or physically under lock and key. Additionally, any institutions such as hospitals, clinics, and providers will be de-identified. In the event that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, diagnoses will be de-identified to the level of the organ system. Participants will be fully informed of all efforts to ensure confidentiality, research goals, processes, and their rights as participants prior to consenting to avoid any unforeseen harm. In the event that any participant reports harm of any kind, we will immediately notify the IRB. All correspondence will be recorded.

Potential Benefits to Participants

Realistically describe the potential benefits that individual participants may experience from taking part in the research. Indicate if there is no direct benefit. Do **not** include benefits to society or others.

There are no foreseen material benefits to participants, with the exception of the benefit derived from sharing one's personal experience.

Privacy and Confidentiality

- Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or

to whom they provide personal information. Click here for additional guidance on ASU Data Storage Guidelines.

- Describe the following measures to ensure the confidentiality of data:
- Who will have access to the data?
- Where and how data will be stored (e.g. ASU secure server, ASU cloud storage, filing cabinets, etc.)?
- How long the data will be stored?
- Describe the steps that will be taken to secure the data during storage, use, and transmission. (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data, etc.).
- If applicable, how will audio or video recordings will be managed and secured. Add the duration of time these recordings will be kept.
- If applicable, how will the consent, assent, and/or parental permission forms be secured. These forms should separate from the rest of the study data. Add the duration of time these forms will be kept.
- If applicable, describe how data will be linked or tracked (e.g. master list, contact list, reproducible participant ID, randomized ID, etc.).
- If your study has previously collected data sets, describe who will be responsible for data security and monitoring.

For interviews, data will be collected via voice recorder and transcribed by the project team or a secure transcription service. All participants will be assigned a unique identifier at the time of consent. Voice files and subsequent transcripts will be labeled via assigned number and will be password-protected and saved on a secure server or secure cloud storage. A master list linking interview participants to interview transcripts will be retained so that transcripts can be returned to participants for review. Follow interviews may also be conducted, but this protocol does not yet exist. Should follow up interview protocol be developed, a modification will be submitted to the IRB. This master list will be destroyed within 10 years. Transcripts will be de-identified, with names and institutions removed before being uploaded to a data management system such as Figshare for use by other researchers and patient advocates. Because there is the possibility that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, rare diagnoses will be de-identified to the level of the organ system. A master list linking participants' information to study ID codes will be password-protected and accessible only to the research team.

All data in any written reports will not be linked to participants by name, organizational affiliation, or location more specific than region (e.g. Southwest United States). Transcripts will be reviewed to exclude this information. The raw data – audio – will only be for use by the researchers associated with the approved study and review by participants. Transcripts will be made available more broadly.

Similar confidentiality practices will be employed during digital observation. Usernames and identifying information will be removed. All data in any written reports will not be linked to participants by name, organizational affiliation, or location more specific than region (e.g. Southwest United States). Demographic information such as age, gender, or employment status shared on online forums such as gender, age, or employment status

will be retained if it is not specific enough as to be identifying. This information *will not be solicited* in online forums but may be observed in interaction. This is reflected in the online consent form.

Consent Process

- Describe the process and procedures process you will use to obtain consent. Include a description of:
- Who will be responsible for consenting participants?
- Where will the consent process take place?
- How will consent be obtained?
- If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. Translated consent forms should be submitted after the English is approved.

ONLINE DATA COLLECTION: We request a waiver of formal, signed documentation of informed consent **for online data collection** due to minimal subject risk and the performance of activities outside of a formal research setting. In the interview and digital contexts their agreement to participate will serve as informed consent. All contact information, unless otherwise known through existing professional contact or referral, will be obtained from publicly available sources. Subjects will be provided with written information about the study prior to consent and interview. Study team will review all information on consent forms with participants prior to requesting consent. Participants will be notified that their participation is voluntary and that they may terminate contact and the interview at any point without consequences. All correspondence with potential and actual participants will be documented and digitally saved.

INTERVIEWS: Subjects will be provided with written information about the study prior to consent and interview. Study team will review all information on consent forms with participants prior to requesting consent. **Signed consent will be obtained prior to conducting interviews.** Participants will be notified that their participation is voluntary and that they may terminate contact and the interview at any point without consequences. All correspondence with potential and actual participants will be documented and digitally saved.

Training

Provide the date(s) the members of the research team have completed the CITI training for human participants. This training must be taken within the last 4 years. Additional information can be found at: Training.

Rebecca Monteleone – May 7, 2017

A.1.2 Genetic Counselors

Instructions and Notes:

- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, mark as "NA".
- When you write a protocol, keep an electronic copy. You will need a copy if it is necessary to make changes.

Protocol Title

Include the full protocol title: Genetic Counseling and the Social Construction of Chromosomal Abnormalities

Background and Objectives

- Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.
- Describe the purpose of the study.
- Describe any relevant preliminary data or case studies.
- Describe any past studies that are in conjunction to this study.

Prenatal genetic screening, which broadly refers to a suite of technologies and practices developed to identify chromosomal anomalies in utero, has embedded within it intense social and political implications, including social stigmatization, increased incidence of abortion in fetuses with chromosomal abnormalities, and differential treatment of such fetuses under state and federal law. Disability scholars have recently called to attention the role prenatal genetic screening, interpretation by genetic counselors, and selective or therapeutic abortion play in the "making" and stigmatization of congenital disability (Garland-Thomson, 2012; Hubbard, 2010; Saxton, 2010). Medical classifications such as those produced during prenatal testing shape and perpetuate certain constructions of social, political, and ontological realities, and central to this process are a class of professionals known as genetic counselors. The proposed project seeks to understand how and to what extent genetic counselors, both at the institutional level and in individual practice, shape and perpetuate certain constructions of congenital disability. This goal will be accomplished through the interrogation of professional guidance documents and interviews with practicing genetic counselors. It is the first project in a linked series intended to discern the complex legal, social, political, and technical entanglements that define and redefine the self, biology, and society – a process Charis Thompson (2005) dubs "ontological choreography" – in the space of prenatal genetic screening. The practical findings of this study are intended to contribute to more equitable, just approaches to medical classification of congenital disability. Theoretically, this study will contribute to academic conversations on credibility, problem-framing, and medicalization.

Despite the crucial role genetic counselors play in framing congenital disabilities the apparatus of genetic counseling has been a relatively underexamined site in both critical Disability Studies (DS) (Kafer, 2013) and Science and Technology Studies (STS). Further, a broader, more accurate, and less invasive suite of screening technologies is emerging, and it is vital to interrogate the relationship between disability and technology as it pertains to escalating controversies seeking to redefine disability. These factors – the rising controversies surrounding prenatal genetic screening, the unexamined social and political implications of medical classification emerging from such screenings, and the anticipated introduction of safer, more accurate forms of screening – create a landscape in which the study of framing and construction of disability among genetic counselors becomes critical.

Research will occur in three phases. The first phase will involve textual analysis of guidance documents garnered from the American Board of Genetic Counseling, the National Society of Genetic Counselors, and the American College of Medical Genetics and Genomics. Phase 2 will be comprised of a series of semi-structured interviews with practicing genetic counselors. Questions will broadly address how genetic counselors perceive their role and the role of prenatal genetic testing, their adherence to or deviation from codified rules and ethical regulations, and ascribed constructions of disability. Phase 3 will compare findings from Phases 1 and 2.

Data Use

- Describe how the data will be used. Examples include:
- Dissertation, Thesis, Undergraduate honors project
- Publication/journal article, conferences/presentations
- Results released to agency or organization
- Results released to participants/parents
- Results released to employer or school
- Other (describe)

Data will be used as fulfillment of requirement for the Second Year Project in the Human and Social Dimensions of Science and Technology PhD program in the School for the Future of Innovation in Society for the lead researcher, Rebecca Monteleone, which will take the form of a written report and oral presentation for the student's committee. Additionally, the data will be shared in the form of a research poster at the Society of the Study of New and Emerging Technology Annual Meeting at Arizona State University in October 2017. Additionally, the data may be integrated into additional conference posters and presentations and peer-reviewed articles. Finally, this data may be integrated into the students' eventually dissertation. In all cases, identifying information will be deidentified (including names, locations, distinguishing characteristics) and confidentiality guaranteed.

Inclusion and Exclusion Criteria

Describe the criteria that define who will be included or excluded in your final study sample. If you are conducting data analysis only describe what is included in the dataset you propose to use.

Indicate specifically whether you will target or exclude each of the following special populations:

- Minors (individuals who are under the age of 18)
- Adults who are unable to consent
- Pregnant women
- Prisoners
- Native Americans
- Undocumented individuals

No special populations will be targeted during the course of this study. Targeted participants will be practicing genetic counselors who are engaged with prenatal genetic testing. Questions will *not* inquire into any information regarding specific patients. Participants will likely be located in Phoenix, Arizona, although the geographical location may expand depending on recruitment success. All participants will be over 18 years old.

Number of Participants

Indicate the total number of participants to be recruited and enrolled*:* Three to seven participants will be enrolled**.**

Recruitment Methods

- Describe who will be doing the recruitment of participants.
- Describe when, where, and how potential participants will be identified and recruited.
- Describe and attach materials that will be used to recruit participants (attach documents or recruitment script with the application).

Rebecca Monteleone, the PhD student completing her Second Year Project as illustrated above, will be responsible through identifying and recruiting participants. All potential participants will be solicited via email, phone call, or personal visit using the recruitment script and consent information attached. Additional avenues to recruitment will be pursued as needed, such as solicitation through professional organizations, but care will be taken to avoid power imbalances that may lead potential participants to feel coerced.

Prior to conducting interviews, all participants will be fully informed of research goals and processes, their right to confidentiality, and the ability to end both contact and the interview without repercussion. Identification and recruitment of participants will take place during Summer and Fall of 2017. All interviews will take place either in-person or via video-conferencing technologies such as Skype. All participants will provide informed consent prior to beginning the interview,

including informed consent to be recorded for research purposes. Interviews will last between 30 minutes and 1 hour. Interviews will take place in confidential settings.

At the time of consent, interviewees will be assigned a number that will be used to label all further content, including audio files, transcripts, and data used in analysis and write-ups.

Procedures Involved

Describe all research procedures being performed, who will facilitate the procedures, and when they will be performed. Describe procedures including:

- The duration of time participants will spend in each research activity.
- The period or span of time for the collection of data, and any long term follow up.
- Surveys or questionnaires that will be administered (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants to the online application).
- Interventions and sessions (Attach supplemental materials to the online application).
- Lab procedures and tests and related instructions to participants.
- Video or audio recordings of participants.
- Previously collected data sets that that will be analyzed and identify the data source (Attach data use agreement(s) to the online application).

Participants will be recruited via email, phone calls, or in-person visits and asked to participate in one semi-structured interviewing lasting between 30 minutes and one hour. Interviews will be audio-recorded and transcribed by hand. An interview schedule will be developed from the broad topics articulated in Document A and findings from Phase 1 of the study. IRB will be informed if there are any significant changes made to topics.

It should be noted that while genetic counselors are medical professionals who work directly with patients, the consent form will state that no identifying information about patients will be shared over the course of the interviews and will be verbally reiterated by the interviewer.

Interviews will then be analyzed using an inductive method and guided by a series of research questions and critically compared to findings emerging from textual analysis of guidance documents. Quotes may be published verbatim during dissemination, with any identifying markers removed. Participants may be offered an executive summary of findings at the time of completion.

Participants will also be sent a copy of the draft text (in the form of the lead researcher's dissertation) and will be offered an opportunity to submit anonymous comments via a Google Form. Participants will be contacted via email only.

Compensation or Credit

- Describe the amount and timing of any compensation or credit to participants.
- Identify the source of the funds to compensate participants
- Justify that the amount given to participants is reasonable.
- If participants are receiving course credit for participating in research, alternative assignments need to be put in place to avoid coercion.

No compensation will be offered. Should this change, the IRB will be made aware.

Risk to Participants

List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. Consider physical, psychological, social, legal, and economic risks.

There are no significant risks associated with this study, other than the risk of loss of confidentiality, but the research protocol will mitigate that risk. All research will be de-identified; participants will be assigned unique identifying codes and all data will be password-protected or physically under lock and key. Additionally, any institutions such as hospitals, clinics, and providers will be de-identified. Because there is the possibility that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, all diagnoses will be de-identified to the level of the organ system (i.e. autism would be described as "a neurological condition." Participants will be fully informed of all efforts to ensure confidentiality, research goals, processes, and their rights as participants prior to consenting to avoid any unforeseen harm. In the event that any participant reports harm of any kind, I will immediately notify the IRB and the PI of this project. All correspondence will be recorded.

Potential Benefits to Participants

Realistically describe the potential benefits that individual participants may experience from taking part in the research. Indicate if there is no direct benefit. Do **not** include benefits to society or others.

Privacy and Confidentiality

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information. Click here for additional guidance on ASU Data Storage Guidelines.

Describe the following measures to ensure the confidentiality of data:

- Who will have access to the data?
- Where and how data will be stored (e.g. ASU secure server, ASU cloud storage, filing cabinets, etc.)?
- How long the data will be stored?

• Describe the steps that will be taken to secure the data during storage, use, and transmission. (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data, etc.). • If applicable, how will audio or video recordings will be managed and secured. Add the duration of time these recordings will be kept. • If applicable, how will the consent, assent, and/or parental permission forms be secured. These forms should separate from the rest of the study data. Add the duration of time these forms will be kept. • If applicable, describe how data will be linked or tracked (e.g. master list, contact list, reproducible participant ID, randomized ID, etc.). • If your study has previously collected data sets, describe who will be responsible for data security and monitoring.
Data will be collected via voice recorder and transcribed by hand by Rebecca Monteleone, lead researcher on this project. All participants will be assigned a unique identifier at the time of consent. Voice files and subsequent transcripts will be labeled via assigned number and will be password-protected and saved on a flash drive rather than cloud storage. Transcripts will be de-identified, with names and institutions removed. Because there is the possibility that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, all diagnoses will be de-identified to the level of the organ system (i.e. autism would be described as "a neurological condition."). There will be no master list linking participants' identifying information to study ID codes as interviews will occur only once and no follow up is necessary. Participant contact information is kept in one password protected document, however, there is no documentation linking specific participants to specific data. In other words, contact information for all participants was retained, but there is no master list linking participants' identifying information to study ID codes All data in any written reports will not be linked to participants by name, organizational affiliation, or location. Raw data will be coded to exclude this information. The final report will be shared with the lead researcher's committee and may be submitted for publication in a peer-reviewed journal or for presentation at an academic conference. The raw data – audio and interview transcripts – will only be for use by the researchers associated with the approved study.
Consent Process • Describe the process and procedures process you will use to obtain consent. Include a description of: • Who will be responsible for consenting participants? • Where will the consent process take place? • How will consent be obtained? • If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in that language. Indicate the language that will be used

by those obtaining consent. Translated consent forms should be submitted after the English is approved.

I request a waiver of formal, signed documentation of informed consent due to minimal subject risk and the performance of activities outside of a formal research setting. Informed consent will take place through transmission of recruitment text and consent documentation (see attached). Their agreement to participate in the study will serve as informed consent. All contact information, unless otherwise known through existing professional contact or referral, will be obtained from publicly available sources.

Subjects will be provided with written information about the study prior to consent and interview. Participants will be notified that their participation is voluntary and that they may terminate contact and the interview at any point without consequences. All correspondence with potential and actual participants will be documented and digitally saved. Subjects will have access to the lead researcher, Rebecca Monteleone, with any questions, and the primary investigator, Dr. Mary Margaret Fonow, will be given as an additional point of contact, if necessary.

Training

Provide the date(s) the members of the research team have completed the CITI training for human participants. This training must be taken within the last 4 years. Additional information can be found at: Training.

Rebecca Monteleone – May 7, 2017

A.2 Deep Brain Stimulation

Instructions and Notes:

- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, mark as "NA".
- When you write a protocol, keep an electronic copy. You will need a copy if it is necessary to make changes.

Protocol Title

Include the full protocol title: Deep Brain Stimulation: Stakeholder Perspectives

Background and Objectives

- Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.
- Describe the purpose of the study.
- Describe any relevant preliminary data or case studies.
- Describe any past studies that are in conjunction to this study.

Deep brain stimulation is an increasingly common procedure, with more than 100,000 patients worldwide having already received implants for conditions including Parkinson's disease, essential tremor, dystonia, major depressive disorders, and obsessive-compulsive disorders. Despite this relative frequency, very little research has attempted to capture the qualitative experience of DBS, including phenomenological effects (Gilbert, et al), patient access to information and support (Wagner, et al), and engagement with decision-making (Gagliardi, et al). Recent research suggests that as healthcare increasingly relies on biotechnology as a means of intervention, "health information places inappropriate demands on patients, often assuming they understand their own health conditions and have adequate literacy skills to take appropriate actions" (Wagner, et al, 2016). Lack of accessible information disproportionately impacts people from low socio-economic classes and other marginalized communities (ibid). This fact, compounded with a clinical inattentiveness to the financial and social costs of medical devices, results in unintended pressures and consequences for recipients of implants and other invasive and high-tech devices (Okike, et al, 2014). Further, a recent study conducted with physicians in Canada suggests that patient engagement in decision-making around medical devices is not prioritized (Gagliardi, et al, 2017). Physicians may question patients' ability to make competent decisions, ignoring their embodied experience and personal autonomy. Medical professionals may assume patients wish decisions to be made on their behalf, enforcing a paternalistic paradigm. Further, physicians can assume patient engagement is unnecessary in situations where non-intervention may result in death, asserting their right to impose their expert authority regardless of the patient's wishes (ibid).

Further, the quantification of health, which obscures the qualitative experience of receiving and living with biotechnologies, means that "well-being [is] now narrowly defined in terms of the quantified data gathered by the PHT [personal health technologies]" (Lupton, 2014, 5). Challenges to patient autonomy and responsible decision-making multiply in contexts of emerging technologies. The Nuffield Council (2013) report on novel neurotechnologies notes "the lack of clear evidence of risks and benefits of some interventional techniques also presents challenges to responsible clinical decision-making" (p. xx). Tallacchini (2011) further suggests that emerging and experimental technologies expose their recipients not only to the burden of health risks, but to a lifetime of medical surveillance.

This project seeks to understand the qualitative experience of engaging with deep brain stimulation from the perspective of multiple stakeholders, including patients,

clinicians, engineers, and corporate representatives, in order to highlight potential tensions between stakeholder expectations, identify procedural areas for improvement, such as reforming post-operative support systems. It is necessary to attend to the experiences and insights of a variety of stakeholders, because a DBS patient interacts with a network of individuals and organizations such as the hospital, insurance system, medical device industry, family, and paid carers, all of whom influence and are influenced by biotechnological intervention.

The study will include several segments:

- Semi-structured interviews with recipients of DBS, carers, and family members (Interview Consent Form),
- Unstructured interviews with clinicians, manufacturers, engineers, and other experts (Interview Consent Form),
- Document analysis of recipient-directed materials such as guidance documents, FAQs, promotional materials (no human subjects),
- Digital ethnographic observation of online patient communities, including chatrooms, comment threads, blogs, and recipient-made videos (Online Consent Form).
- Pre-existing recipient-made blogs, videos, statements, and photos will also be collected and reproduced in an archive with permission from recipient (Media Release Form).

Data Use

Describe how the data will be used. Examples include:

- Dissertation, Thesis, Undergraduate honors project
- Publication/journal article, conferences/presentations
- Results released to agency or organization
- Results released to participants/parents
- Results released to employer or school
- Other (describe)

Data may be used in a variety of academic formats, including conferences, publications including peer refereed articles, and conference presentations. Additionally, white papers or other guidelines for practice in clinical, policy, and corporate settings may be developed using the data. Data will also be used in the dissertation of Rebecca Monteleone. In all cases, identifying information will be deidentified (including names, location more specific than country, distinguishing characteristics), although demographic data such as age, gender, race/ethnicity, and employment status that may be shared during interviews or observation will be maintained.

Raw interview data will be available for review by participants, and results will also be released to them upon request. Approved interview transcripts that have been de-identified will be published for use by other researchers, patient advocates, and more on a data repository such as Figshare.

Additionally, we intend to work with patients to develop a repository (i.e. blog, online archive, etc.) for individuals to share their patient experiences. Pre-existing testimonials (blogs, videos, statements, and photos) will be collected and shared, contingent on participant permission. In these cases, participants will have the choice to identify themselves. Participants will also be able to share testimonials anonymously.

Inclusion and Exclusion Criteria

Describe the criteria that define who will be included or excluded in your final study sample. If you are conducting data analysis only describe what is included in the dataset you propose to use.

Indicate specifically whether you will target or exclude each of the following special populations:

- Minors (individuals who are under the age of 18)
- Adults who are unable to consent
- Pregnant women
- Prisoners
- Native Americans
- Undocumented individuals

Targeted participants will be individuals who are receiving or have received deep brain stimulation, their families and carers, clinicians, researchers, corporate representatives and engineers. All participants will be over 18 and have capacity to provide informed consent.

Number of Participants

Up to one hundred individuals across all stakeholder categories will participate in interviews, with particular attention paid to enrolling individuals who have received DBS.

Methods may also include digital ethnography in publicly-accessible forums for patient support and information. Researchers will announce their presence in these spaces, request consent to observe, and allow participants to opt out of observation.

Recruitment Methods

- Describe who will be doing the recruitment of participants.
- Describe when, where, and how potential participants will be identified and recruited.
- Describe and attach materials that will be used to recruit participants (attach documents or recruitment script with the application).

All potential participants will be solicited via email, phone call, online post, or personal visit using the recruitment script and consent information attached.

Additional avenues to recruitment will be pursued as needed, such as solicitation through professional organizations, but care will be taken to avoid power imbalances that may lead potential participants to feel coerced. Recruitment and consent will be accomplished using the same document (attached).

INTERVIEW RECRUITMENT PROCESS:

Recruitment will take place through several avenues, beginning in early 2019. Potential recruitment strategies include:

- Posting study information in DBS and Parkinson's online forums,
- Using personal networks,
- Recruiting experts during conferences and professional meetings such as the 2019 IEEE EMBS Conference on Neural Engineering,
- Visiting DBS support groups

Prior to conducting interviews, all participants will be fully informed of research goals and processes, their right to confidentiality, and the ability to end both contact and the interview without repercussion. Identification and recruitment of participants will take place between Fall 2018 and Winter 2023 (5 years). All interviews will take place either in-person, by phone, or via video-conferencing technologies such as Skype. All participants will provide informed consent prior to beginning the interview, including informed consent to be recorded for research purposes.

In the context of collection of pre-existing testimonials and reviewing online forums and support groups, researchers will post recruitment and consent information to online forums.

Procedures Involved

Describe all research procedures being performed, who will facilitate the procedures, and when they will be performed. Describe procedures including:

- The duration of time participants will spend in each research activity.
- The period or span of time for the collection of data, and any long term follow up.
- Surveys or questionnaires that will be administered (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants to the online application).
- Interventions and sessions (Attach supplemental materials to the online application).
- Lab procedures and tests and related instructions to participants.
- Video or audio recordings of participants.
- Previously collected data sets that that will be analyzed and identify the data source (Attach data use agreement(s) to the online application).

Primary procedures include semi-structured and unstructured interviews no longer than two hours conducted over a 5 year time span (2018-2023). Participants will be interviewed at least once and will be provided with researcher contact

information should they wish to follow up. Participants will be audio-recorded. Participants will also be given the opportunity to review and edit transcripts following interviews after initial interview. Participants will have up to 1 month to review and edit transcripts upon receipt. Participants will also have the option to follow-up with researcher to provide additional information/schedule an additional at any time. Follow interviews instigated by the research team may also be conducted, but this protocol does not yet exist. Should follow up interview protocol be developed, a modification will be submitted to the IRB.

Interviews will be supplemented by a series of digital ethnographic observations, including observing dialogues in chatrooms, online support groups, and analyzing patient experience blogs, vlogs, and other testimonials. For dynamic sites (such as chatrooms), study information and consent information will be posted, and participants will have the opportunity to opt-in to data collection. For static pages (such as blogs), participants will be contacted with study information and consent information and asked permission to a) analyze, and b) reproduce their accounts.

All participants will also be asked if they would like to contribute to the patient experience repository (with or without their name attached).

Semi-structured interview questions for stakeholders are attached.

Compensation or Credit

- Describe the amount and timing of any compensation or credit to participants.
- Identify the source of the funds to compensate participants
- Justify that the amount given to participants is reasonable.
- If participants are receiving course credit for participating in research, alternative assignments need to be put in place to avoid coercion.

No compensation will be offered. Should this change, the IRB will be made aware.

Risk to Participants

List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. Consider physical, psychological, social, legal, and economic risks.

There are no significant risks associated with this study, other than the risk of loss of confidentiality, but the research protocol will mitigate that risk. All research will be de-identified (although some demographic data will be retained); participants will be assigned unique identifying codes and all raw data (e.g. audio recordings) will be password-protected or physically under lock and key Dr. Michael's office in CIDSE. Additionally, any institutions such as hospitals, clinics, and providers will be de-identified. In the event that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, diagnoses will be de-identified to the level of the organ system. Participants will be fully informed of all efforts to ensure confidentiality, research goals, processes, and their rights as participants prior to

consenting to avoid any unforeseen harm. In the event that any participant reports harm of any kind, we will immediately notify the IRB. All correspondence will be recorded.

Potential Benefits to Participants

Realistically describe the potential benefits that individual participants may experience from taking part in the research. Indicate if there is no direct benefit. Do **not** include benefits to society or others.

There are no foreseen material benefits to participants, with the exception of the benefit derived from sharing one's personal experience.

Privacy and Confidentiality

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information. Click here for additional guidance on ASU Data Storage Guidelines.

Describe the following measures to ensure the confidentiality of data:

- Who will have access to the data?
- Where and how data will be stored (e.g. ASU secure server, ASU cloud storage, filing cabinets, etc.)?
- How long the data will be stored?
- Describe the steps that will be taken to secure the data during storage, use, and transmission. (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data, etc.).
- If applicable, how will audio or video recordings will be managed and secured. Add the duration of time these recordings will be kept.
- If applicable, how will the consent, assent, and/or parental permission forms be secured. These forms should separate from the rest of the study data. Add the duration of time these forms will be kept.
- If applicable, describe how data will be linked or tracked (e.g. master list, contact list, reproducible participant ID, randomized ID, etc.).
- If your study has previously collected data sets, describe who will be responsible for data security and monitoring.

Data will be collected via voice recorder and transcribed by the project team or a secure transcription service. All participants will be assigned a unique identifier at the time of consent. Voice files and subsequent transcripts will be labeled via assigned number and will be password-protected and saved on a secure server or secure cloud storage. A master list linking interview participants to interview transcripts will be retained so that transcripts can be returned to participants for review. Follow interviews may also be conducted, but this protocol does not yet exist. Should follow up interview protocol be developed, a modification will be submitted to the IRB. This master list will be destroyed within 10 years. Transcripts will be de-identified, with names and institutions removed before being

uploaded to a data management system such as Figshare for use by other researchers and patient advocates. Because there is the possibility that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, rare diagnoses will be de-identified to the level of the organ system. A master list linking participants' information to study ID codes will be password-protected and accessible only to the research team.

All data in any written reports will not be linked to participants by name, organizational affiliation, or location more specific than region (e.g. Southwest United States). transcripts will be reviewed to exclude this information. The raw data – audio – will only be for use by the researchers associated with the approved study and review by participants. Transcripts will be made available more broadly.

Consent Process

- Describe the process and procedures process you will use to obtain consent. Include a description of:
- Who will be responsible for consenting participants?
- Where will the consent process take place?
- How will consent be obtained?
- If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. Translated consent forms should be submitted after the English is approved.

We request a waiver of formal, signed documentation of informed consent due to minimal subject risk and the performance of activities outside of a formal research setting. Informed consent will take place through transmission of recruitment text and consent documentation (see attached). In the interview and digital contexts their agreement to participate will serve as informed consent. All contact information, unless otherwise known through existing professional contact or referral, will be obtained from publicly available sources. Participants submitting pre-existing testimonials to the repository will grant written consent via the Media Records Release Form.

Subjects will be provided with written information about the study prior to consent and interview. Study team will review all information on consent forms with participants prior to requesting consent. Participants will be notified that their participation is voluntary and that they may terminate contact and the interview at any point without consequences. All correspondence with potential and actual participants will be documented and digitally saved.

Training

Provide the date(s) the members of the research team have completed the CITI training for human participants. This training must be taken within the last 4 years. Additional information can be found at: Training.

Rebecca Monteleone – May 7, 2017

Katina Michael - November 19, 2018

[redacted]

A.3 Artificial Pancreas System

Instructions and Notes:

- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, mark as "NA".
- When you write a protocol, keep an electronic copy. You will need a copy if it is necessary to make changes.

Protocol Title

Include the full protocol title: OpenAPS: Stakeholder Perspectives

Background and Objectives

- Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.
- Describe the purpose of the study.
- Describe any relevant preliminary data or case studies.
- Describe any past studies that are in conjunction to this study.

OpenAPS refers both to a technology and a patient advocacy movement (also articulated as #WeAreNotWaiting). The technology is a simplified Artificial Pancreas System designed by individuals with Type 1 Diabetes and is characterized by a small computer (such as a Raspberry Pi) that collects data from one's insulin pump and continuous glucose monitor in order to monitor and automatically adjust insulin delivery overnight and between meals (OpenAPS, 2018). Most importantly, the OpenAPS implementation system is open source, and constructed by users themselves. OpenAPS developer/users communicate almost exclusively via online chatrooms and social media and operate their devices outside of FDA-approval processes. Therefore, this site provides an opportunity to interrogate how accountability and agency are articulated in such spaces – the OpenAPS movement is adamant about self-determination, noting on its website that "you'll have to build your implementation yourself (no one can/will do it for you!)" (OpenAPS, 2018, para 3). Further, it also provides a space to understand the relationship between dis/ability (broadly defined) and the DIY Bio movement.

This project seeks to understand the qualitative experience of engaging with open source artificial pancreas system technologies (modifications to insulin pumps/continuous glucose monitors/diabetes maintenance) from the perspective

of multiple stakeholders, including patient-activists, clinicians, engineers, and corporate representatives, in order to highlight potential tensions between stakeholder expectations, understand the social construction of disability and autonomy in these scenarios, and identify procedural areas for improvement. It is necessary to attend to the experiences and insights of a variety of stakeholders, because a person using OpenAPS interacts with a network of individuals and organizations such as the hospital, insurance system, medical device industry, family, and online community, all of whom influence and are influenced by biotechnological intervention.

The study will include several segments:

- Semi-structured interviews with recipients of OpenAPS and family members (Interview Consent Form),
- Unstructured interviews with clinicians, manufacturers, engineers, and other experts (Interview Consent Form),
- Document analysis of recipient-directed materials such as guidance documents, FAQs, promotional materials (no human subjects),
- Digital ethnographic observation of online patient communities, including chatrooms, comment threads, blogs, and recipient-made videos (Online Consent Form).

Data Use

Describe how the data will be used. Examples include:

- Dissertation, Thesis, Undergraduate honors project
- Publication/journal article, conferences/presentations
- Results released to agency or organization
- Results released to participants/parents
- Results released to employer or school
- Other (describe)

Data may be used in a variety of academic formats, including conferences, publications including peer refereed articles, and conference presentations. Additionally, white papers or other guidelines for practice in clinical, policy, and corporate settings may be developed using the data. Data will also be used in the dissertation of Rebecca Monteleone. In all cases, identifying information will be deidentified (including names, location more specific than country, distinguishing characteristics), although demographic data such as age, gender, race/ethnicity, and employment status that may be shared during interviews or observation will be maintained.

Raw interview data will be available for review by participants, and results will also be released to them upon request. Approved interview transcripts that have been de-identified may be published for use by other researchers, patient advocates, and more on a data repository such as Figshare.

Inclusion and Exclusion Criteria • Describe the criteria that define who will be included or excluded in your final study sample. If you are conducting data analysis only describe what is included in the dataset you propose to use. • Indicate specifically whether you will target or exclude each of the following special populations: • Minors (individuals who are under the age of 18) • Adults who are unable to consent • Pregnant women • Prisoners • Native Americans • Undocumented individuals
Targeted participants will be individuals who use OpenAPS, their families, clinicians, researchers, corporate representatives and engineers. All participants will be over 18 and have capacity to provide informed consent.
Number of Participants At least twenty and up to one hundred individuals across all stakeholder categories will participate in interviews, with particular attention paid to enrolling individuals who use OpenAPS. Methods may also include digital ethnography in publicly-accessible forums for patient support and information. Researchers will announce their presence in these spaces, request consent to observe, and allow participants to provide consent to be observed.
Recruitment Methods • Describe who will be doing the recruitment of participants. • Describe when, where, and how potential participants will be identified and recruited. • Describe and attach materials that will be used to recruit participants (attach documents or recruitment script with the application).
All potential participants will be solicited via posted flyers, online posts, or in-person invitations using the recruitment scripts and consent information attached. The only exception to this will be experts, such as clinicians, recruited through personal relationships, who may be contacted via email. Additional avenues to recruitment will be pursued as needed, such as solicitation through professional organizations, but care will be taken to avoid power imbalances that may lead potential participants to feel coerced. Interview recruitment and consent will be accomplished using either flyer, online post, or spoken script (attached).

INTERVIEW RECRUITMENT PROCESS:

- Recruitment will take place through several avenues, beginning in early 2019. Potential recruitment strategies include:
- Posting study information in online forums (online post)
- Using personal networks (recruitment script),
- Recruiting experts during conferences and professional meetings such as the American Diabetes Association Scientific Sessions (recruitment script),
- Requesting study information be shared through clinics (flyer)

Prior to conducting interviews, all participants will be fully informed of research goals and processes, their right to confidentiality, and the ability to end both contact and the interview without repercussion. Identification and recruitment of participants will take place between Spring 2019 and Winter 2023 (5 years). All interviews will take place either in-person, by phone, or via video-conferencing technologies such as Skype. All participants will provide informed consent prior to beginning the interview, including informed consent to be recorded for research purposes.

In the context of observing online forums and support groups, researchers will post recruitment and consent information to online forums.

Procedures Involved

Describe all research procedures being performed, who will facilitate the procedures, and when they will be performed. Describe procedures including:

- The duration of time participants will spend in each research activity.
- The period or span of time for the collection of data, and any long term follow up.
- Surveys or questionnaires that will be administered (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants to the online application).
- Interventions and sessions (Attach supplemental materials to the online application).
- Lab procedures and tests and related instructions to participants.
- Video or audio recordings of participants.
- Previously collected data sets that that will be analyzed and identify the data source (Attach data use agreement(s) to the online application).

Primary procedures include semi-structured and unstructured interviews no longer than two hours conducted over a 5 year time span (2018-2023). Participants will be interviewed at least once and will be provided with researcher contact information should they wish to follow up. Participants will be audio-recorded. Participants will also be given the opportunity to review and edit transcripts following interviews after initial interview. Participants will have up to 1 week to review and edit transcripts upon receipt. Participants will also have the option to follow-up with researcher to provide additional information/schedule an additional at any time. Follow interviews instigated by the research team may also be

conducted, but this protocol does not yet exist. Should follow up interview protocol be developed, a modification will be submitted to the IRB.

Interviews with users will follow the semi-structured interview schedule attached. Due to the variable nature of experts being recruited, interviews with experts will be unstructured and organized around their area of expertise and the list of topics attached. Other than the nature of questions, these interviews will follow the same protocol as user interviews (no more than 2 hours, participants have opportunity to review transcripts, etc.)

Interviews will be supplemented by a series of digital ethnographic observations, including observing dialogues in chatrooms, online support groups, and analyzing patient experience blogs, vlogs, and other testimonials. Forums observed (including OpenAPS Gitter thread and topically-relevant reddit subreddits such as r/diabetes) will be publicly viewable. If posting and commenting requires the creation of an account, I will not obscure or hide my identity or status as a researcher. For dynamic sites (such as chatrooms), study information and consent information will be posted, and participants will have the opportunity to opt-in to data collection. I will establish a new thread in these subreddits including study and consent information which users can opt into and analyze conversation in this thread only.

For static pages (such as blogs), participants will be contacted with study information and consent information and asked permission to analyze their accounts.

Semi-structured interview questions for users and topics for unstructured interviews are attached.

Compensation or Credit

- Describe the amount and timing of any compensation or credit to participants.
- Identify the source of the funds to compensate participants
- Justify that the amount given to participants is reasonable.
- If participants are receiving course credit for participating in research, alternative assignments need to be put in place to avoid coercion.

No compensation will be offered. Should this change, the IRB will be made aware.

Risk to Participants

List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. Consider physical, psychological, social, legal, and economic risks.

There are no significant risks associated with this study, other than the risk of loss of confidentiality, but the research protocol will mitigate that risk. All research will be de-identified (although some demographic data will be retained); participants will be assigned unique identifying codes and all raw data (e.g. audio recordings)

will be password-protected or physically under lock and key. Additionally, any institutions such as hospitals, clinics, and providers will be de-identified. In the event that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, diagnoses will be de-identified to the level of the organ system. Participants will be fully informed of all efforts to ensure confidentiality, research goals, processes, and their rights as participants prior to consenting to avoid any unforeseen harm. In the event that any participant reports harm of any kind, we will immediately notify the IRB. All correspondence will be recorded.

Potential Benefits to Participants

Realistically describe the potential benefits that individual participants may experience from taking part in the research. Indicate if there is no direct benefit. Do **not** include benefits to society or others.

There are no foreseen material benefits to participants, with the exception of the benefit derived from sharing one's personal experience.

Privacy and Confidentiality

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information. Click here for additional guidance on ASU Data Storage Guidelines.

- Describe the following measures to ensure the confidentiality of data:
- Who will have access to the data?
- Where and how data will be stored (e.g. ASU secure server, ASU cloud storage, filing cabinets, etc.)?
- How long the data will be stored?
- Describe the steps that will be taken to secure the data during storage, use, and transmission. (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data, etc.).
- If applicable, how will audio or video recordings will be managed and secured. Add the duration of time these recordings will be kept.
- If applicable, how will the consent, assent, and/or parental permission forms be secured. These forms should separate from the rest of the study data. Add the duration of time these forms will be kept.
- If applicable, describe how data will be linked or tracked (e.g. master list, contact list, reproducible participant ID, randomized ID, etc.).
- If your study has previously collected data sets, describe who will be responsible for data security and monitoring.

Data will be collected via voice recorder and transcribed by the project team or a secure transcription service. All participants will be assigned a unique identifier at the time of consent. Voice files and subsequent transcripts will be labeled via assigned number and will be password-protected and saved on a secure server or secure cloud storage. A master list linking interview participants to interview

transcripts will be retained so that transcripts can be returned to participants for review. Follow interviews may also be conducted, but this protocol does not yet exist. Should follow up interview protocol be developed, a modification will be submitted to the IRB. This master list will be destroyed within 10 years. Transcripts will be de-identified, with names and institutions removed before being uploaded to a data management system such as Figshare for use by other researchers and patient advocates. Because there is the possibility that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, rare diagnoses will be de-identified to the level of the organ system. A master list linking participants' information to study ID codes will be password-protected and accessible only to the research team.

All data in any written reports will not be linked to participants by name, organizational affiliation, or location more specific than region (e.g. Southwest United States). transcripts will be reviewed to exclude this information. The raw data – audio – will only be for use by the researchers associated with the approved study and review by participants. Transcripts will be made available more broadly.

Similar confidentiality practices will be employed during digital observation. Usernames and identifying information will be removed. All data in any written reports will not be linked to participants by name, organizational affiliation, or location more specific than region (e.g. Southwest United States). Demographic information such as age, gender, or employment status shared on online forums such as gender, age, or employment status will be retained if it is not specific enough as to be identifying. This information *will not be solicited* in online forums but may be observed in interaction. This is reflected in the online consent form.

Consent Process

- Describe the process and procedures process you will use to obtain consent. Include a description of:
- Who will be responsible for consenting participants?
- Where will the consent process take place?
- How will consent be obtained?
- If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. Translated consent forms should be submitted after the English is approved.

ONLINE DATA COLLECTION: We request a waiver of formal, signed documentation of informed consent **for online data collection** due to minimal subject risk and the performance of activities outside of a formal research setting. In the interview and digital contexts their agreement to participate will serve as informed consent. All contact information, unless otherwise known through existing professional contact or referral, will be obtained from publicly available sources. Subjects will be provided with written information about the study prior to consent and interview. Study team will review all information on consent forms with participants prior to requesting consent. Participants will be notified that their

participation is voluntary and that they may terminate contact and the interview at any point without consequences. All correspondence with potential and actual participants will be documented and digitally saved.

INTERVIEWS: Subjects will be provided with written information about the study prior to consent and interview. Study team will review all information on consent forms with participants prior to requesting consent. **Signed consent will be obtained prior to conducting interviews.** Participants will be notified that their participation is voluntary and that they may terminate contact and the interview at any point without consequences. All correspondence with potential and actual participants will be documented and digitally saved.

Training

Provide the date(s) the members of the research team have completed the CITI training for human participants. This training must be taken within the last 4 years. Additional information can be found at: Training.

Rebecca Monteleone – May 7, 2017

APPENDIX B

CONSENT FORMS

B.1 Prenatal genetic screening and diagnosis

B.1.1 Prospective Parents; Researcher

Prenatal Genetic Testing: Stakeholder Perspectives
Consent Form

My name is Rebecca Monteleone, and I am a PhD student in the School for the Future of Innovation in Society at Arizona State University. I, working under Dr. Mary Margaret Fonow, am conducting a research study to understand the qualitative experience of engaging with prenatal genetic testing from the perspective of multiple stakeholders, including patients, clinicians, scientists, and corporate representatives, in order to highlight potential tensions between stakeholder expectations and identify procedural areas for improvement.

I am inviting your participation, which will involve a single interview lasting no longer than 2 hours (optional follow-up interview possible at a future date). Interviews will be audio-recorded. The interview will not be recorded without your permission. Please let me know if you do not want the interview to be recorded; you also can change your mind after the interview starts, just let me know.

During the interview, you have the right not to answer any question, and to stop participation at any time. Within 6 months of the initial interview, you will be sent the interview transcript for review. You will have up to one week to review and edit the transcript and return to the research team. At any time, you may withdraw your consent. Transcripts will all be de-identified, and once approved, will be shared on a data management platform for use by other researchers, patient advocates, and others. Following the interview, if you wish to contact the researchers to share additional information or have a follow-up interview, you may contact me at **PGS/PGDPerspectives@gmail.com.**

You will also receive a draft of the written research product. You will have an opportunity to review and comment on this document. Your comments may be incorporated into the text. If your comments are used verbatim in subsequent drafts of the research product, they will be de-identified and not linked to you in any way.

Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, there will be no penalty. If you are currently receiving treatment, participation (or non-participation) in this study will in no way impact your care. You must be 18 years or older and have capacity to consent to participate in this study.

Although there is no direct benefit to you for participating, your participation will contribute to the development of more holistic, comprehensive, and supportive care systems for individuals receiving prenatal genetic testing. There are no foreseeable risks or discomforts to your participation.

Your confidentiality is important to us. All interview data will be collected via a voice recorder and transcribed by the research team or a secure transcription service. Your name will not be associated with your interview transcript, and you will be assigned a

unique identifier at the time of consent. Voice files and the master list linking participant information to interview transcripts will be password protected and saved on a secure server or secure cloud storage. **This list will be retained so that you can be contacted to review your transcript and for potential follow-up interviews**. This list will be destroyed within 10 years.

Identifying information such as names, locations more specific than region (e.g. Southwest United States), and organizational affiliation will be removed from transcripts prior to being uploaded into a data management system for use by other researchers. Because there is the possibility that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, rare diagnoses will be de-identified to the level of the organ system. Some demographic information, such as gender, age, and employment status will be retained. Your responses will be confidential. The results of this study may be used in reports, presentations, or publications but your name will not be used.

If you have any questions concerning the research study, please contact me, Rebecca Monteleone and my advisor Mary Margaret Fonow at **PGS/PGDPerspectives@gmail.com**. If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

Please sign below if you wish to be part of the study.

Name (printed):

_____

Signature:

_____

Date:

_____

Consenting Researcher:

_____

Document Revision Date: December 10, 2018

B.1.2 Genetic Counselors

Consent Information

STUDY TITLE: Genetic Counseling and the Social Construction of Chromosomal Abnormalities

I, Rebecca Monteleone, am a graduate student under the direction of Professor Mary Margaret Fonow in the School for the Future of Innovation in Society at Arizona State University. I am currently conducting a research study to understand how genetic counselors think about prenatal genetic screening and chromosomal abnormalities.

I am inviting your participation, which will involve a single verbal interview of 30-60 minutes. This interview may take place in person, over the phone, or via a video-conferencing program as is convenient. You have the right not to answer any question, and to stop participation at any time. Your participation in this study is voluntary. You have the right to not participate or to withdraw from the study at any time without consequence.

While no direct compensation is provided, the research paper developed with this data will be made available to you at the conclusion of the study. We cannot promise any benefits to you or others from your taking part in this research. There are no foreseeable risks or discomfort to you caused by participation.

This interview will be audio recorded and your participation is contingent upon agreeing to be recorded. Recording is an important part of the research process, as it provides rich, accurate data.

Privacy and confidentiality considerations will be maintained. Efforts will be made to keep your responses confidential and your name, likeness, organization, location, and other identifying information will *not* be published or shared in any way. Quotes used in the final report will not be able to be traced to you. Interview transcripts and the final report will use pseudonyms so that there is no direct connection between you and the report. The data may be used in future reports, presentations, or publications, but none of your identifying information will be shared at any point.

If you have any questions concerning the research study, please contact the research team, Dr. Mary Margaret Fonow at MaryMargaret.Fonow@asu.edu or Rebecca Monteleone at rgmontel@asu.edu. If you have any questions about your rights as a participant in research, or if you feel you have been placed at risk in any way, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

Thank you for your consideration.

B.2 Deep Brain Stimulation

Deep Brain Stimulation: Stakeholder Perspectives
Consent Form

My name is Dr. Katina Michael, and I am a professor in the School for the Future of Innovation in Society and the Fulton Schools of Engineering at Arizona State University. I, along with my graduate research assistant Rebecca Monteleone, am conducting a research study to understand the qualitative experience of engaging with deep brain stimulation from the perspective of multiple stakeholders, including patients, clinicians, engineers, and corporate representatives, in order to highlight potential tensions between stakeholder expectations, identify procedural areas for improvement, such as reforming post-operative support systems.

I am inviting your participation, which will involve a single interview lasting no longer than 2 hours. Interviews will be audio-recorded. The interview will not be recorded without your permission. Please let me know if you do not want the interview to be recorded; you also can change your mind after the interview starts, just let me know.

During the interview, you have the right not to answer any question, and to stop participation at any time. Within 6 months of the initial interview, you will be sent the interview transcript for review. You will have up to one month to review and edit the transcript and return to the research team. At any time, you may withdraw your consent. Transcripts will all be de-identified, and once approved, will be shared on a data management platform for use by other researchers, patient advocates, and others. Following the interview, if you wish to contact the researchers to share additional information or have a follow-up interview, you may contact us at **Katina.michael@asu.edu**.

You will also receive a draft of the written research product. You will have an opportunity to review and comment on this document. Your comments may be incorporated into the text. If your comments are used verbatim in subsequent drafts of the research product, they will be de-identified and not linked to you in any way.

Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, there will be no penalty. If you are currently receiving treatment, participation (or non-participation) in this study will in no way impact your care. You must be 18 years or older and have capacity to consent to participate in this study.

Although there is no direct benefit to you for participating, your participation will contribute to the development of more holistic, comprehensive, and supportive care systems for individuals receiving DBS. There are no foreseeable risks or discomforts to your participation.

Your confidentiality is important to us. All interview data will be collected via a voice recorder and transcribed by the research team or a secure transcription service. Your name will not be associated with your interview transcript, and you will be assigned a

unique identifier at the time of consent. Voice files and the master list linking participant information to interview transcripts will be password protected and saved on a secure server or secure cloud storage. This list will be retained so that you can be contacted to review your transcript and for potential follow-up interviews. This list will be destroyed within 10 years.

Identifying information such as names, locations more specific than region (e.g. Southwest United States), and organizational affiliation will be removed from transcripts prior to being uploaded into a data management system for use by other researchers. Because there is the possibility that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, rare diagnoses will be de-identified to the level of the organ system. Some demographic information, such as gender, age, and employment status will be retained. Your responses will be confidential. The results of this study may be used in reports, presentations, or publications but your name will not be used.

As part of this project we will also be collecting pre-existing audio, video, and written testimonials from participants who have received DBS in order to create a publicly available online archive of patient experiences. If you would like to submit something to this archive, please contact me to share your testimonial and fill out a **Media Records Release Form.**

If you have any questions concerning the research study, please contact the research team at: **Katina.Michael@asu.edu**. If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

Please sign below if you wish to be part of the study.

Name (printed):

_____

Signature:

_____

Date:

_____

Consenting Researcher:

_____

Document Revision Date: December 10, 2018

B.3 Artificial Pancreas Systems

Open Source APS: Stakeholder Perspectives
Consent Form

My name is Rebecca Monteleone, and I am a PhD student in the School for the Future of Innovation in Society at Arizona State University. I, working under Dr. Mary Margaret Fonow, am conducting a research study to understand the qualitative experience of engaging with open source APS technologies from the perspective of multiple stakeholders, including users, clinicians, scientists, and corporate representatives, in order to highlight potential tensions between stakeholder expectations and identify procedural areas for improvement.

I am inviting your participation, which will involve a single interview lasting no longer than 2 hours (optional follow-up interview possible at a future date). Interviews will be audio-recorded. The interview will not be recorded without your permission. Please let me know if you do not want the interview to be recorded; you also can change your mind after the interview starts, just let me know.

During the interview, you have the right not to answer any question, and to stop participation at any time. Within 6 months of the initial interview, you will be sent the interview transcript for review. You will have up to one week to review and edit the transcript and return to the research team. At any time, you may withdraw your consent. Transcripts will all be de-identified, and once approved, will be shared on a data management platform for use by other researchers, patient advocates, and others. Following the interview, if you wish to contact the researchers to share additional information or have a follow-up interview, you may contact me (Rebecca Monteleone) at **APSPerspectives@gmail.com.**

You will also receive a draft of the written research product. You will have an opportunity to review and comment on this document. Your comments may be incorporated into the text. If your comments are used verbatim in subsequent drafts of the research product, they will be de-identified and not linked to you in any way.

Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, there will be no penalty. If you are currently receiving treatment, participation (or non-participation) in this study will in no way impact your care. You must be 18 years or older and have capacity to consent to participate in this study.

Although there is no direct benefit to you for participating, your participation will contribute to the development of more holistic, comprehensive, and supportive care systems for individuals using open source APS. There are no foreseeable risks or discomforts to your participation.

Your confidentiality is important to us. All interview data will be collected via a voice recorder and transcribed by the research team or a secure transcription service. Your name will not be associated with your interview transcript, and you will be assigned a unique identifier at the time of consent. Voice files and the master list linking

participant information to interview transcripts will be password protected and saved on a secure server or secure cloud storage. **This list will be retained so that you can be contacted to review your transcript and for potential follow-up interviews.** This list will be destroyed within 10 years.

Identifying information such as names, locations more specific than region (e.g. Southwest United States), and organizational affiliation will be removed from transcripts prior to being uploaded into a data management system for use by other researchers. Because there is the possibility that interviewees may describe patient conditions that are sufficiently rare as to be identifiable, rare diagnoses will be de-identified to the level of the organ system. Some demographic information, such as gender, age, and employment status will be retained. Your responses will be confidential. The results of this study may be used in reports, presentations, or publications but your name will not be used.

If you have any questions concerning the research study, please contact me, Rebecca Monteleone, and my advisor Mary Margaret Fonow at **APSPerspectives@gmail.com**. If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

Please sign below if you wish to be part of the study.

Name (printed):
_____

Signature:
_____

Date:
_____

Consenting Researcher:
_____

Document Revision Date: December 10, 2018

APPENDIX C

RECRUITMENT DOCUMENTS

C.1 Prenatal genetic screening and diagnosis

C.1.1 Prospective Parent Flyer

WHAT IS YOUR EXPERIENCE WITH PRENATAL GENETIC TESTING?

VOLUNTEERS WANTED
FOR RESEARCH STUDY

PGS/PGD: Stakeholder Perspective

Have you or your partner received prenatal genetic testing during a pregnancy? We are conducting a research study about the experience of prenatal genetic testing for multiple stakeholders, including recipients, families and clinicians. We are hoping to develop a more holistic, comprehensive, and supportive care systems for individuals receiving prenatal genetic testing and are looking for your input.

We are looking for participants to conduct a 1-2 hour interview about your experience. We welcome interviews with participants who are **over the age of 18**, have the **capacity to consent**, and **have received (or are the partner of someone who has received) prenatal genetic testing** which includes Non-invasive prenatal testing (NIPT), amniocentesis, chorionic villus sampling (CVS), quad screen/multiple marker, and more

This research is conducted by Rebecca Monteleone (Arizona State University School for the Future of Innovation in Society) under the direction of Dr. Mary Margaret Fonow, Arizona State University School of Social Transformation

CONTACT INFORMATION	CONTACT INFORMATION	CONTACT INFORMATION	CONTACT INFORMATION	CONTACT INFORMATION	CONTACT INFORMATION	CONTACT INFORMATION	CONTACT INFORMATION	CONTACT INFORMATION

C.1.2 Prospective Parent Online Recruitment Example (for forums)

Have you or your partner received genetic testing such as amniocentesis, non-invasive prenatal testing (NIPT), quad screen/multiple marker testing during pregnancy? I am conducting a study about the experience of prenatal screening and would like to interview you! If you are interested and would like more information, please comment below, send me a direct message, or email me at rgmontel@asu.edu.

C.1.3 Genetic Counselor Recruitment Email

Dear (Insert Name),

My name is Rebecca Monteleone and I am a second-year PhD student in the School for the Future of Innovation in Society at Arizona State University. [*Add reference to mutual professional contact if subject was referred*]. I am conducting a research study to understand how genetic counselors think about prenatal genetic screening and the social construction of chromosomal abnormalities. Genetic counselors play an important but relatively unexamined role in the prenatal care process. With the advent of less invasive genetic screening technologies, the role that genetic counselors play in interpreting and communicating genetic data will become increasingly important.

I am reaching out to you because you are either a genetic counselor yourself or work closely with genetic counselors who may be interested in participating. Please find additional information about the study below.

Interviews are a key component of my investigation and I would be incredibly appreciative if I could have 30-60 minutes of your time to ask a few questions about how you think about genetic counseling, prenatal genetic screening, and chromosomal abnormalities. The interview is designed to help me understand the role of genetic counselors and prenatal genetic screening as the technologies that enable screening become less invasive and more ubiquitous.

It is incredibly important to me, as a researcher, to mitigate any discomfort or risk to you, should you decide to take part. Interviews will be digitally recorded, but only I will have access to these files, and I will be solely responsible for transcribing them. Your responses will be confidential, and you can decline to answer questions at any point during the interview. Your name, organizational affiliation, and any other identifying information will be removed from the data. Interviews and quotes will be attributed to a pseudonym and there will be no direct connection between you and the data. While no direct compensation is provided, my study outcome – a research paper – can be made available to you at the conclusion of the study.

If you are willing to participate, can recommend any colleagues interested in participating, or have any additional questions, please feel free to contact me at rgmontel@asu.edu or call (330) 705-5021. We can then determine the most convenient time and method (phone, Skype, in-person) to conduct an interview.

The interview is voluntary, so refusal to participate or deciding to discontinue participation at any time will not incur any consequences. If you have any questions

about the research study, please feel free to contact myself or my faculty advisor, Dr. Mary Margaret Fonow, at MaryMargaret.Fonow@asu.edu.

Please let me know if you are able and willing to participate. I look forward to hearing from you.

Kindest regards,

Rebecca Monteleone

PhD Student, Human and Social Dimensions of Science and Technology
Alliance for Person-Centered and Accessible Technologies
Arizona State University
(330) 705 5021
NSF IGERT Fellow, 2016-2018
Fulbright Postgraduate, 2014-15

C.2 Deep Brain Stimulation

WHAT IS YOUR EXPERIENCE WITH DEEP BRAIN STIMULATION?
VOLUNTEERS WANTED
FOR RESEARCH STUDY

DBS: Stakeholder Perspective

Have you or a loved one received deep brain stimulation? We are conducting a research study about the experience of deep brain stimulation for multiple stakeholders, including recipients, carers and clinicians. We are hoping to develop more holistic, comprehensive, and supportive care systems for individuals receiving deep brain stimulation and are looking for your input.

We are looking for participants to conduct a 1-2 hour interview about your experience. We welcome interviews with participants who are **over the age of 18**, have the **capacity to consent**, and **have received (or are the carer for someone who has received) deep brain stimulation** for any condition, including but not limited to Parkinson's Disease, essential tremor, major depressive disorder, and obsessive-compulsive disorder.

This research is conducted by Rebecca Monteleone (**rgmontel@asu.edu**) under the direction of Dr. Katina Michael (**kmichae6@asu.edu)**, Arizona State University School for the Future of Innovation in Society

For more information or to volunteer, you can:

a) **Email rgmontel@asu.edu,**
b) **Call 330-705-5021, or**
c) **Follow the QR code**

DBS Perspectives rgmontel@asu.edu 330-705-5021	DBS Perspectives rgmontel@asu.edu 330-705-5021	DBS Perspectives rgmontel@asu.edu 330-705-5021	DBS Perspectives rgmontel@asu.edu 330-705-5021	DBS Perspectives rgmontel@asu.edu 330-705-5021	DBS Perspectives rgmontel@asu.edu 330-705-5021	DBS Perspectives rgmontel@asu.edu 330-705-5021	DBS Perspectives rgmontel@asu.edu 330-705-5021	DBS Perspectives rgmontel@asu.edu 330-705-5021

C.3 Artificial Pancreas Systems

C3.1 APS Flyer

HAVE YOU BUILT OR USED A DIY ARTIFICIAL PANCREAS SYSTEM (APS)?

VOLUNTEERS WANTED
FOR RESEARCH STUDY

APS: Stakeholder Perspective

Do you or your child use an open source closed loop system like OpenAPS, AndroidAPS, or Loop? I am conducting a study about the experience of using these systems and modifying T1D devices and would like to interview you!

I am looking for participants to conduct a 1-2 hour interview about your experience. We welcome interviews with participants who are **over the age of 18 (if child is using system, interview with guardian only)**, have the **capacity to consent**, and **have modified your insulin pump/CGM using open source code or instructions**.

This research is conducted by Rebecca Monteleone (Arizona State University School for the Future of Innovation in Society) under the direction of Dr. Mary Margaret Fonow, Arizona State University School of Social Transformation

For more information or to volunteer, you can:

1) Email APSPerspectives@gmail.com
2) Call (330) 705-5021,
3) Follow the QR Code

C.3.2 APS Online Recruitment Example (for online forums)

Have you modified your child's insulin pump and/or continuous glucose monitor using open source code or guidance? Are you part of the OpenAPS movement? I am conducting a study about the experience of OpenAPS and "hacking" T1D devices and would like to interview you! If you are interested and would like more information, please comment below, send me a direct message, or email me at APSperspectives@gmail.com

[Note: I received admin approval to post this message]

C.4 Email Communication to Review Dissertation

Hello,

I am writing because you were involved in a research study [Biomedical Technology]. First, thank you for your participation. Your interview was included in my recently drafted dissertation and will be used in future publications and presentations. I am inviting your feedback on this draft. This is entirely voluntary, so you may choose to not provide any feedback.

Below, you will see a link to a Google Drive folder. In that folder, you will find seven drafted chapters. You are welcome to review all chapters at your leisure, to select certain chapters, or to not review the document at all. If you choose to review the document, please submit any comments to this Google Form. I am seeking not only corrections for factual errors, but any thoughts you might have about the research project, analysis, or write up. This can be elements that resonate with you, things you disagree with or find confusing, or anything else you wish to comment on. Your feedback will be anonymous unless you choose to disclose information about yourself in your comments. Your comments may be incorporated into the text. If your comments are used in subsequent drafts of the research product, they will be de-identified and not linked to you in any way.

I am also attaching an updated consent form, which includes a new clause about this review process. This form is for your information only. **You do not need to sign and return it.** The new clause is also copied below:[13]

You will also receive a draft of the written research product. You will have an opportunity to review and comment on this document. Your comments may be incorporated into the text. If your comments are used in subsequent drafts of the research product, they will be de-identified and not linked to you in any way.

If you choose to give feedback, please do not comment directly on the document, as this may jeopardize your confidentiality. Instead, please submit your comments into this Google Form. Please email me directly at rgmontel@asu.edu with any questions.

Direct link to Google Form: https://forms.gle/tT7XN4YoPf9GLjrA6

This document is very much a work in progress. Your comments and feedback *will* impact the final text. I appreciate any time or insight you provide. Your involvement in this project is what makes it possible, and so I hope that this text in its final version accurately reflects your experiences.

[13] An IRB modification was submitted for the Genetic Counseling protocol. Under that modification, the consent form did not need to be reshared, so this section was removed from that correspondence.

Please reach out with any questions, comments, or concerns. Please also feel free to contact me (rgmontel@asu.edu) if you have any interest in sharing this research with your communities.

Warmly,

Rebecca Monteleone

APPENDIX D

INTERVIEW SCHEDULES

D.1 User and Family Interview Schedule (for all three case studies)

NOTE: Interviews with recipients and family members will be semi-structured, so the below questions represent a broad outline for the topics that will be discussed during interviews. **Interviews conducted with experts will be unstructured and variable depending on the expert.**

1. Describe yourself in whatever terms you prefer.
2. Describe your daily life prior to {intervention}.
    a. What was managing your {condition} like?
    b. What kinds of tools, resources, and support was available to you? Was it sufficient?
3. How did you learn about {intervention}?
    a. Where did you learn about it?
        i. Did you seek out information or was it provided to you?
    b. Who spoke to you? When? Where? For how long?
    c. Was it recommended to you by someone? Who?
    d. Had you thought about this intervention prior to it being recommended to you?
4. What were you thinking about when you decided to pursue {intervention}?
    a. Did you feel like treating your {condition} was a personal responsibility?
    b. Did you consider not pursuing {intervention}? Why or why not?
    c. What other {interventions} did you consider?
5. What did you understand about {intervention} prior to receiving it?
    a. Where did you learn this information?
6. What were you expecting from {intervention}?
7. Were those expectations met? Why or why not?
8. Was the {intervention} covered by insurance? If not, how did you pay for it?
9. Do you feel your [race/class/gender/ability/sexuality – as appropriate] impacted your experience with {intervention}
    a. NOTE: this question will be reframed as rapport is built during the interview.
10. How did you think about {condition} prior to intervention? Now?
    a. Do you consider {condition} a disability, illness, condition, etc.?
    b. What does it mean to be disabled/ill?
        i. Does {intervention} change that meaning?
    c. What does it mean to be healthy/well {with or without condition}?
11. What were the positive outcomes of your {intervention}? If any?
12. What were the negative outcomes of your {intervention}? If any?
13. Have you had any contact with the manufacturer or surgeon post-surgery?
14. If you could tell the manufacturer of your device, or surgeon anything related to your {intervention}, what would that be?
15. Has the {intervention} changed you as a person? If so, in what ways?
16. What are you hopes for these {interventions}?
17. What are your fears with respect to the {intervention}?

18. Is there anything you need/needed when undergoing the procedure that you didn't have?
19. Is there anything else you want to say that I haven't asked you?

D.2 Professional Interview Schedule[14]

D.2.1 PGS/PGD

EXPERTS

Note: these interviews will be unstructured and variable based on expertise. Below are broad topic areas that will be discussed.

- Nature of work with PGS/PGD
- Professional opinion on use of PGS/PGD
- Personal opinion on use of PGS/PGD
- Thoughts on conditions related to PGS/PGD
- Thoughts on compliance or non-compliance of pregnant persons recommended to undergo PGS/PGD
- Technological aspects of PGS/PGD
- Commercialization aspects of PGS/PGD
- Clinical aspects of PGS/PGD
- Future of PGS/PGD
- Parental responsibility and PGS/PGD
- Patient expectations
- Hopes and concerns about PGS/PGD

D.2.2 APS

EXPERTS

Note: these interviews will be unstructured and variable based on expertise. Below are broad topic areas that will be discussed.

- Awareness of closed loop systems [historically and currently]
- Nature of work/interaction with closed loop systems
- Professional opinion on use of closed loop systems
- Personal opinion on use of closed loop systems
- Thoughts on conditions and quality of life related to closed loop systems
- [for clinicians] Thoughts on patient use of closed loop systems
- Technological aspects of closed loop systems
- Accessibility of closed loop systems
- (Anti-)Commercialization aspects of closed loop systems
- Clinical and regulatory aspects of closed loop systems
- Future of closed loop systems
- User responsibility and closed loop systems
- User expectations
- Hopes and concerns about closed loop systems

[14] No expert topics were requested from the IRB for the DBS case study.

D.3 PGS/PGD Genetic Counselor Interview Schedule

Interview Schedule: Genetic Counseling and the Social Construction of Chromosomal Abnormalities

Hello and thank you for agreeing to speak with me today. I am interested in learning more about how you, as a genetic counselor, think about prenatal genetic screening and chromosomal abnormalities. As a reminder, this interview will be recorded, and you have the right to withdraw at any time.

1. In your opinion, what is the role of a genetic counselor during prenatal care?
    a. What is the ideal role of a genetic counselor in your opinion?
    b. Can you describe what you typically do during the course of a pregnancy?
2. What is the role of prenatal genetic screening during prenatal care?
    a. In your opinion, should PGS/PGD and genetic counseling play a more important or less important role during pregnancy? Why?
3. When communicating with patients about chromosomal abnormalities – especially chromosomal abnormalities that are not incompatible with life – how do you communicate the social impacts on the future child and family?
4. When communicating with patients about chromosomal abnormalities – especially chromosomal abnormalities that are not incompatible with life (result in disability rather than death) - how do you communicate the medical impacts on the future child and family?
5. When assisting a patient with decision-making, particularly about continuing a pregnancy, how do you determine what options to present? How to present them? What order?
6. As a genetic counselor, how do you think about congenital disability?
    a. How do you talk about the lived experiences of having a disability to patients?
    b. Where did that understanding of disability arise from?
7. How is your profession perceived by people who are not medical professionals? Especially those engaged in disability rights activism.
8. Does your professional training and guidance provide insight into talking about disability and assisting patients' decision-making about genetic disability?
    a. If yes, do you generally agree with that guidance? How do you feel it could be improved?
    b. If no, how did you learn to communicate about disability?
9. What are some of the key guidance documents that GCs consult when practicing in prenatal diagnosis?
10. Can you recommend any colleagues who may also be interested in participating? (Snowballing recruitment)

APPENDIX E

DOCUMENT COLLECTION TABLES

E.1 Prenatal Genetic Screening and Diagnosis Documents

Table 12

PGS/PGD/PGD Analyzed Documents

	Document Source	*Document Title*	*Document Type*	*Number of Pages*
1	NSGC	About Genetic Testing	Procedure Description	2
2	NSGC	Genetic Counseling v Genetic Testing	Informational Documentation	4
3	NSGC	What Can Genetic Testing Tell You and How Can It Help?	Informational Documentation	3
4	NSGC	Before and During Pregnancy	Patient Guidance	2
5	NSGC	Questions Expectant Mothers Should Ask Before Prenatal Screening	Informational Blog	2
6	NSGC	Am I a Candidate for Genetic Testing?	Patient Guidance	2
7	NSGC	How Does the Testing Process Work?	Informational Documentation	1
8	NSGC	How Do I Understand My Results?	Patient Guidance	1
9	NSGC	I Have My Results, What Happens Next?	Patient Guidance	2
10	ACOG	Prenatal Genetic Screening Tests	Procedure Description	6
11	ACOG	FAQs Prenatal Genetic Diagnostic Tests	FAQs	5
12	Natera	Panorama Test	Procedure Description	12
13	Natera	Why Panorama	Research	3
14	Natera	Expecting Twins?	Informational Documentation	4
15	Natera	Vistara	Procedure Description	5
16	Harmony	Get Harmony	Procedure Description	2
17	Harmony	Non-Invasive Prenatal Test	Procedure Description	2
18	Harmony	Range of Conditions	Informational Documentation	7
19	Harmony	Expecting Parents Discussion Guide	Patient Guidance	1
20	Harmony	Personal Stories of Three Moms and Their Journeys	Patient Stories	4
21	Integrated Genetics	Pregnancy	Procedure Description	4

22	Integrated Genetics	Maternit21 Plus	Procedure Description	4
23	Integrated Genetics	MaternitGenome	Procedure Description	2
24	Integrated Genetics	Serum Screening	Procedure Description	2
25	Integrated Genetics	Amniocentesis	Procedure Description	1
26	Integrated Genetics	Chorionic Villus Sampling	Procedure Description	1
27	Integrated Genetics	Pregnancy Calendar	Patient Guidance	3
28	Integrated Genetics	Genetic Diseases and Disorders	Informational Documentation	38
29	Integrated Genetics	Results	Patient Guidance	3
30	Integrated Genetics	Reproductive Genetic Counseling	Patient Guidance	2
31	Progenity	Prenatal Care	Procedure Description	8
32	Progenity	PreParent (Practice)	Clinician Information	13
33	Progenity	Innatal	Procedure Description	9
34	Progenity	Resura	Procedure Description	9
35	Progenity	Genetic Counselors	Fact Sheet	2
36	Centogene	Non-Invasive Prenatal Testing - No Risk to Mother and Baby	Procedure Description	6
37	Myriad	Myriad Prequel Prenatal Screen	Procedure Description	7
38	Myriad	Myriad Foresight Carrier Screen	Procedure Description	6
39	Mayo Clinic	Genetic Testing	Procedure Description	6
40	NIH	15 for 15: Noninvasive Prenatal Genetic Testing	Informational Blog	4
41	U of M Health	What Moms-to-Be Should Know About Prenatal Genetic Testing	Informational Blog	4

E.2 Deep Brain Stimulation Documents

Table 13

DBS Analyzed Documents

	Document Source	*Document Title*	*Document Type*	*Number of Pages*
1	Barrow Neurological	Am I a Candidate for DBS?	Patient Guidance	2
2	Barrow Neurological	Asleep Deep Brain Stimulation (DBS)	Procedure Description	1
3	Barrow Neurological	Deep Brain Stimulation (DBS)	Procedure Description	1
4	Barrow Neurological	Make the Most of Your Appointment	Patient Guidance	2
5	Boston Children's Hospital	Deep Brain Stimulation	Procedure Description	2
6	Boston Children's Hospital	How Tim Froio Became a Bionic Man	News Story	6
7	Boston Children's Hospital	Deep Brain Stimulation (DBS) In-Depth	Procedure Description	2
8	Boston Children's Hospital	Frequently Asked Questions about Deep Brain Stimulation	FAQ	2
9	Boston Children's Hospital	Deep Brain Stimulation (DBS) Recent Publications	Research	1
10	Children's Hospital Colorado	About Deep Brain Stimulation (DBS) in the Neuroscience Institute	Procedure/Clinic Description	3
11	Children's Hospital Colorado	Research on Deep Brain Stimulation	Research	1
12	Children's Hospital Colorado	Colorado Teen Djimon Hill Shows Progress from Deep Brain Stimulation	Patient Story	1
13	Children's Hospital Colorado	Djimon: Deep Brain Stimulation Lets Him (Finally) Relax	Patient Story	2
14	Dignity Health	Deep Brain Stimulation	Procedure Description	1
15	Johns Hopkins	Deep Brain Stimulation	Procedure Description/Patient Guidance	8
16	Johns Hopkins	Myths and Facts: 7 Parkinson's Disease Misconceptions	Information Sheet	2

17	Johns Hopkins	Treatment for Parkinson's Disease	Information Sheet	1
18	Johns Hopkins	Deep Brain Stimulation (DBS)	Procedure Description	1
19	Johns Hopkins	Brain Stimulation Research	Research	3
20	Johns Hopkins	Self-Harming Behavior in Children with Autism: Can Electroconvulsive Therapy Help?	Informational Blog Post	2
21	Johns Hopkins	Parkinson's Disease: 5 Reasons to Hope	Informational Blog Post	2
22	Johns Hopkins	Deep Brain Stimulation	Informational Blog Post	1
23	Mayo Clinic	Deep Brain Stimulation	Procedure Description	4
24	Mayo Clinic	Mayo Clinic's Approach	Clinic Description	2
25	Mayo Clinic	Surgical Procedures: Deep Brain Stimulation	Procedure Description	1
26	Mayo Clinic	[excerpt] Obsessive Compulsive Disorder	Procedure Description	1
27	Mayo Clinic	[except] Cluster Headache	Procedure Description	1
28	Mayo Clinic	[excerpt] Phantom Pain	Procedure Description	1
29	Mayo Clinic	[excerpt] Tourette's	Procedure Description	1
30	Northwestern	Helping You Move Forward with Confidence	Patient Booklet	10
31	Northwestern	Deep Brain Stimulation: Is It Right for You?	Patient Booklet	6
32	Northwestern	Five Frequently Asked Questions About Hospitalization for Patients with Parkinson's Disease	FAQ	6
33	Northwestern	Northwestern Memorial First Hospital in Region to Perform New Frameless Technique for Brain Surgery	Procedure Description	2
34	Northwestern	Parkinson Patient Information Checklist for Hospital Stays:	Patient Guidance	2
35	Northwestern	Patient and Family Symposium: Annual Keystone Symposium on Parkinson's Disease	Event	2
36	Northwestern	Patient's Guide to Deep Brain Stimulation (DBS) for Parkinson's Disease	Patient Guidance	11

37	Northwestern Medicine	Northwestern Medicine Deep Brain Stimulation	Procedure/Clinic Description	1
38	Northwestern Medicine	Deep Brain Stimulation	FAQ	2
39	Northwestern Medicine	Deep Brain Stimulation for Movement Disorders	Media	1
40	Northwestern Medicine	The ABC's of DBS	Information Sheet	2
41	Northwestern Medicine	Judy's Second Shot with DBS	Patient Story	2
42	Northwestern Medicine	Essential Tremor Treatments	Information Sheet	1
43	NYU Winthrop Hospital	Deep Brain Stimulation at NYU Winthrop Hospital	Procedure/Clinic Description	1
44	Providence Health and Services	Deep Brain Stimulation	Procedure Description	5
45	Providence Health and Services	Parkinson's Disease: When is Deep Brain Stimulation an Option?	Informational Blog Post	2
46	Rush University	Deep Brain Stimulation	Procedure Description	3
47	Rush University	Newly Approved Brain Stimulator Offers Hope for Individuals with Uncontrolled Epilepsy	News Story	2
48	Rush University	Clinical Trail Tests Genetic Screening for Deep Brain Stimulation Surgery	News Story	2
49	Rush University	Parkinson's Treatment Puts an End to Mixed Signals	News Story	3
50	Rush University	Grateful Patient Creates Legacy to Support Movement Disorder Research	Patient Story	1
51	Rush University	5 Facts About Parkinson's Disease	Information Sheet	5
52	Saint Luke's Health System	Deep Brain Stimulation	Procedure Description	6
53	Saint Luke's Health System	Advantages of Asleep CereTom Assisted Deep Brain Stimulation (DBS) Surgery	News Story	2
54	Saint Luke's Health System	KCTV: Morning Joe: Groundbreaking Surgery at Metro Hospital Quells Man's Tremors	Patient Story	1

55	Saint Luke's Health System	Parkinson's Disease Couldn't Stop Barry	Patient Story	1
56	Saint Luke's Health System	KCTV: Special Procedure Leaves Man with Parkinson's Living a More Comfortable Life	Patient Story	1
57	Saint Luke's Health System	Tim's New "Superpower" put an End to his Essential Tremor	Patient Story	2
58	Saint Luke's Health System	Parkinson's Disease: Plenty of Road	Patient Story	1
59	Saint Luke's Health System	Sant Luke's Marion Bloch Neuroscience Institute	Clinic Description	3
60	UCSF Health	Deep Brain Stimulation	Procedure Description	2
61	University of Iowa Hospitals and Clinics	Deep Brain Stimulation (DBS)	Procedure Description	2
62	University of Iowa Hospitals and Clinics	While You're Waiting for Surgery Day to Arrive	Patient Guidance	1
63	University of Iowa Hospitals and Clinics	Deep Brain Stimulation Surgery Helps Parkinson's Patient get her Life Back to Normal	Patient Story	5
64	University of Minnesota	About Deep Brain Stimulation	Procedure Description	10
65	UW Health	Deep Brain Stimulation (DBS)	Procedure Description	2
66	UW Health	What Happens During Deep Brain Stimulation (DBS) Surgery?	Information Sheet	2
67	UW Health	After Deep Brain Stimulation (DBS) Surgery	Patient Guidance	2
68	UW Health	Types of Deep Brain Stimulation (DBS)	Information Sheet	2
69	UW Health	Deep Brain Stimulation (DBS) Frequently Asked Questions	FAQ	2
70	UW Health	Advantages and Risks of Deep Brain Stimulation (DBS) Surgery	Information Sheet	1
71	UW Health	Deep Brain Stimulation Video Series	Media	1
72	UW Health	Deep Brain Stimulation: Interpretive Magnetic Resonance Imaging (iMRI)	Patient Booklet	8

E.3 DIY Artificial Pancreas Systems

Table 14

APS Analyzed Documents

	Document Source	*Document Title*	*Document Type*	*Number of Pages*
1	OpenAPS	Homepage/Device Description	FAQ	6
2	OpenAPS	In the News	Media	1
3	OpenAPS	Outcome	Research	4
4	OpenAPS	Reference Design	Device Description	8
5	OpenAPS	OpenAPS's Documentation	User Guidance	140
6	OpenAPS	Ways to Contribute to OpenAPS	Informational Post	1
7	Android APS	AndroidAPS Documentation	User Guidance	51
8	Loop	Welcome to Loop	User Guidance	33
9	Beyond Type 1	Guide to DIY Looping	Informational Post	4
10	Diabettech	How to Get Started with DIY 'Artificial Pancreas' Systems	Informational Post	10
11	FDA	FDA Warns People with Diabetes and Health Care Providers Against the Use of Devices for Diabetes Management Not Authorized for Sale in the United States: FDA Safety Communication	Official Communication	3
12	OpenAPS, AndroidAPS, Loop Communities	Statement on FDA Warning	Press Release	1

APPENDIX F

IRB PERMISSION LETTERS

F.1 Prenatal Genetic Screening and Diagnosis

F.1.1 Prospective Parents; Researcher

ASU Knowledge Enterprise Development

EXEMPTION GRANTED

Mary Fonow
Social Transformation, School of (SST)
480/965-2351
MaryMargaret.Fonow@asu.edu

Dear Mary Fonow:

On 1/8/2019 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Prenatal Genetic Testing: Stakeholder Perspectives
Investigator:	Mary Fonow
IRB ID:	STUDY00009361
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• V2_Form-Social-Behavioral-Protocol_PGS Study.docx, Category: IRB Protocol; • V2_Recipient Interview Questions_PGS.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • V2_Recruitment Flyer_Online Post_Spoken Script.pdf, Category: Recruitment Materials; • V2_Online Consent Information.pdf, Category: Consent Form; • Expert Interview Topics_PGS.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Email recruitment.pdf, Category: Recruitment Materials; • V2_Interview Consent Information.pdf, Category: Consent Form;

The IRB determined that the protocol is considered exempt pursuant to Federal Regulations 45CFR46 (2) Tests, surveys, interviews, or observation on 1/8/2019.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Rebecca Monteleone
Rebecca Monteleone

F.1.2 Genetic Counselors

ASU Knowledge Enterprise Development

EXEMPTION GRANTED

Mary Fonow
Social Transformation, School of (SST)
480/965-2351
MaryMargaret.Fonow@asu.edu

Dear Mary Fonow:

On 6/2/2017 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Genetic Counseling and the Social Construction of Chromosomal Abnormalities
Investigator:	Mary Fonow
IRB ID:	STUDY00006340
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• Interview Schedule, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Consent Information, Category: Consent Form; • HRP-503a, Category: IRB Protocol; • Recruitment Document, Category: Recruitment Materials;

The IRB determined that the protocol is considered exempt pursuant to Federal Regulations 45CFR46 (2) Tests, surveys, interviews, or observation on 6/2/2017.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Rebecca Monteleone
Rebecca Monteleone

F.2 Deep Brain Stimulation

ASU Knowledge Enterprise Development

EXEMPTION GRANTED

Katina Michael
Future of Innovation in Society, School for the
480/965-6316
katina.michael@asu.edu

Dear Katina Michael:

On 12/12/2018 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Deep Brain Stimulation: Stakeholder Perspectives
Investigator:	Katina Michael
IRB ID:	STUDY00009280
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• V2_Media Records Release.pdf, Category: Consent Form; • V3_Form-Social-Behavioral-Protocol_DBS Study.docx, Category: IRB Protocol; • V3_Interview Consent Information.pdf, Category: Consent Form; • Interview Questions_Implantees and Carers.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • V2_Online Consent Information.pdf, Category: Consent Form;

The IRB determined that the protocol is considered exempt pursuant to Federal Regulations 45CFR46 (2) Tests, surveys, interviews, or observation on 12/12/2018.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc:
Rebecca Monteleone

F.3 DIY Artificial Pancreas Systems

ASU Knowledge Enterprise Development

EXEMPTION GRANTED

Mary Fonow
Social Transformation, School of (SST)
480/965-2351
MaryMargaret.Fonow@asu.edu

Dear Mary Fonow:

On 1/2/2019 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Open Artificial Pancreas System: Stakeholder Perspectives
Investigator:	Mary Fonow
IRB ID:	STUDY00009362
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• Expert Interview Topics_OpenAPS.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • V2_User Interview Questions_APS.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • V2_Recruitment Flyer_example online post_spoken script.pdf, Category: Recruitment Materials; • V2_Interview Consent Information.pdf, Category: Consent Form; • V2_Online Consent Information.pdf, Category: Consent Form; • V2_Form-Social-Behavioral-Protocol_OpenAPS Study.docx, Category: IRB Protocol;

The IRB determined that the protocol is considered exempt pursuant to Federal Regulations 45CFR46 (2) Tests, surveys, interviews, or observation on 1/2/2019.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Rebecca Monteleone
Rebecca Monteleone