

The Turn to Practice in Medicine: Towards Situated Drug Safety

by

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B.Eng., University of Alberta, 2011

Thesis Submitted in Partial Fulfillment of the
Requirements for the Degree of
Master of Arts

in the

School of Communication

Faculty of Communication, Art and Technology

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SIMON FRASER UNIVERSITY

Spring 2016

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Abstract

Research in medicine is often undertaken with the aim to produce abstract knowledge. This thesis is concerned with how this aim relates to the on-the-ground practice of medicine and the influence that conceptualizations of care have on the ways that we do research, identify problems, and design and implement solutions. Following the work of scholars in science and technology studies, I outline and argue for the *turn to practice*, an approach to research that takes an interest in “situated action” and knowledge as practiced (Suchman, 1987/2007). Drawing on an action research intervention in clinical care related to medications, I demonstrate how practice-oriented research can be done in medicine. I contrast mechanistic conceptualizations of care with ethnographic accounts, showing how drug safety proceeds through the situated and local activities of providers, and that improvement initiatives might be reappraised to enable rather than constrain or interrupt this work.

Keywords: sociomaterial; practice; situated; ethnography; medicine; drug safety

Acknowledgements

Thank you to Ellen Balka, for giving a chance to a social scientist trapped in an engineer's education. Ellen's approach to the practice of research and enthusiasm for working with others was inspiring and left me with the academic direction and ethic that I spend much of this thesis exploring. Having her in my corner helped me to survive and thrive through graduate school, a new discipline, and a start in a new city.

Thanks to Corinne Hohl for her ongoing support and stimulating conversations about medical practice. I am lucky to have had the opportunity to work with someone interested in developing such a diverse research team and program and so driven to improve care. Thanks also to the rest of the Pill Talk team: Serena Small, Chantelle Bailey, Bryn Lander, Katherin Badke, Maeve Wickham, Christine Ackerley and Adam Chruscicki. I've never worked with a team where collaboration was so easy.

I am grateful to my committee members for their time and support. Thanks to Andrew Feenberg for challenging me on major theoretical points and preventing me from falling into lockstep with the actor-networkers. Also, thanks to Ina Wagner for her careful review of the final draft and insightful questions and comments. Andrew and Ina's feedback made for a rewarding thesis defence and provided me with a number of ideas to explore beyond this work.

Thank you to the School of Communication administration and faculty for providing an environment so conducive to interdisciplinary work and for supporting my studies through teaching and research assistantships and a graduate fellowship. I am also lucky to have had the opportunity to work out of the Centre for Clinical Epidemiology and Evaluation, where I found a welcoming community of researchers.

Thank you to my friends for tolerating my being a sporadic hermit and for distracting me in the best possible ways. To Jessica Knowler, the feminist who has influenced my thinking more than Haraway ever could, and who has fueled me through this thesis with her amazing food, laughter, and love. Finally, special thanks to my parents, Kevin and Leigh-Ann Peddie, and my brothers, Matthew and Luke Peddie, the team that I can always count on for love and support in whatever odd endeavour I choose.

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List of Acronyms

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
ANT	Actor-Network Theory
B.C.	British Columbia
C2E2	Centre for Clinical Epidemiology and Evaluation
CSCW	Computer Supported Cooperative Work
EBM	Evidence-Based Medicine
EMR	Electronic Medical Record
FDA	Food and Drugs Administration
GP	General Practitioner
ICT	Information and Communication Technology
IT	Information Technology
RCT	Randomized Controlled Trial
SCOT	Social Construction of Technology
SSK	Sociology of Scientific Knowledge
STS	Science and Technology Studies

Chapter 1.

Introduction

1.1. Introduction

It is only after having written this thesis that I realize that it documents my academic trajectory from engineering to communication studies to an action research intervention in healthcare. It is a way of giving order to how my thinking about the world has changed in the last 5 years or so. In engineering, I was fascinated with science, how with calculus the activity of the world could be modeled with such incredible precision, and how with this modeling (of mechanics, heat transfer, stress, flow, vibration, etc.), one could design with the highest assurance that objectives would be met. Looking back, I find it interesting that I was then involved in clinical interventions (in the design of instruments to improve spine surgeries) but I managed to never step foot in a hospital besides to briefly meet a collaborating surgeon on his break. I also took my first science and technology studies (STS) course while in engineering, and was enthralled with the critiques of science and elaborations of its social dimension. This was what led me to communication studies at Simon Fraser University, where I sharpened my critical and theoretical skills, especially in the critical theory of the Frankfurt school. My interest in STS never waned, however, and after my coursework I dove into a self-guided exploration of STS theory, taking particular interest in the anthropological and ethnographic strains emerging after Latour and Woolgar's (1979/1986) *Laboratory Life*.

At the same time, I was working on an action research project in healthcare with an interdisciplinary team out of the Centre for Clinical Epidemiology and Evaluation (C2E2). I was working with social scientists but also physicians, pharmacists, pharmacologists, and epidemiologists. I was spending time doing observations in emergency departments, conducting focus groups with clinicians, attending research

rounds, and presenting our research. Increasingly, I struggled with how to link the worlds of clinical practice, health research, and the theory I was learning in class and in my own reading. I felt like a strange multi-identity boundary crosser going from seminars on Lukács and Marcuse to observations in the emergency department to my office in C2E2.

This feeling of dissonance is what led me to an affinity with the work of Annemarie Mol, whose 2002 book, *The Body Multiple: Ontology In Medical Practice*, introduced me to the *turn to practice* in STS, a reaction to previous approaches to knowledge that were concerned with the epistemological question of how objective knowledge could be created. Underpinning these more traditional approaches to knowledge production was a presumed divide between abstract knowledge and practical action, and between knowledge and the material world. Knowledge was taken as the representation of a referent world. Mol troubles this presumption by demonstrating that knowledge is something that is *done*, something that is revealed in *practice*. Further, she argues that the material world (humans and non-humans alike) is itself something that is revealed only in the unfolding relations of practice – it is related to, performed, *enacted* in particular ways. Beginning with this understanding of knowledge and reality, research is about doing the ethnographic work of following what unfolds in action.

I came to see how there are a number of boundary crossers like Mol in STS who worked to make sense out of philosophical and sociological theory which seemed in many accounts of medicine to be so distant from worlds of practice. Interestingly, many of these researchers had one foot in medicine – to name a few: my supervisor Ellen Balka, Susan Leigh Star, Marc Berg, Stefan Timmermans, Casper Bruun Jensen, Sonja Jerak-Zuiderent, and Teun Zuiderent-Jerak. The work of these STS theorists shares a common concern with combining empirical and theoretical resources to both produce concrete interventions in clinical practice and add to theoretical knowledge. Like Mol, they are part of the turn to practice in that they reject universalizing knowledge or overarching normative commitments in favour of attention to local circumstances and activities, practitioner knowledges, and the various ways that improvement might take root.

Why is this turn necessary and what does it turn away from? There are two very general “styles” of doing research in medicine (Mol, 2002, p. 154). The first and

undoubtedly the dominant style is *positivist*. Familiar from my engineering days, positivism is the style of working where one makes models of the world, generalizes, and intervenes accordingly. It is about analyzing empirical data in an effort to create impartial, universal forms of knowledge that can direct action. One of its formulations in medical research is the clinical trial, which involves the collection of data under experimental controls to prove that a certain technology or practice is effective. Alternatively, many clinical epidemiological studies will utilize clinical and administrative data generated in the activity of care to examine effectiveness and design improvements.

Positivist research is a very valuable way to answer some questions in medicine, like whether a new drug is effective compared to a placebo. However, in the last 30 years its purview has expanded to all domains of care, including the practice of care itself (Timmermans & Berg, 2003). Given positivism's narrow methodological approach (for example, a concern with only a limited set of quantifiable outcomes, lack of attention to context) and its orientation to reducing variability and complexity and guaranteeing certainty in medical practice, its expansion into the activity of care raises new concerns related to the conduct and claims of medical research. It is possible that positivist accounts of medical events and clinical work may lead to the design of tools and interventions (e.g., clinical guidelines, protocols, information and communication technologies) that shape clinical and research practice in undesirable ways. As well, positivist efforts to enforce adherence to specific conceptions of medicine, especially ones that attempt to guarantee certainty and coherence, may exclude or conceal other ways of doing medicine that may be better.

The shortcomings of the positivist style have long been recognized and serve as the starting point for a second style of medical research: critical or *social constructivist* research. Social constructivist research in medicine is promising in that it attends to issues of context, epistemology, and values that may escape more positivist qualitative work. Graham et al. (2011) raise concerns about the disappearance of this kind of critical work in healthcare in Canada. However, critical studies have their own shortcomings. For example, they tend to focus on hot political and ethical issues in medicine (e.g., genetics, birth control, end-of-life care), and especially charged moments in medical care (e.g., patient/physician decision-making) while remaining detached from the on-the-ground

practices that shape and create these moments and trajectories (e.g., Taussig, 1980; Mishler, 1984; Moller, 2000). As Timmermans & Berg (2003) argue, the worst of these studies fail to do the legwork required for empirically-grounded analysis of the varied, complex, and changing worlds of medical practice, and lean on reductive stories of a “medical-industrial complex with dark motives and dependent victims” (p. 97). These accounts, produced “at arm’s length” from practice (Gingras, 1995, p. 123), also struggle to find purchase in medical communities, who are unlikely to read academic journals in medical philosophy, sociology, or anthropology, and even less likely to identify with simplistic accounts of their practice or those couched in the language of social theory. An opportunity is missed to infuse practical intervention and collaboration in medicine with sociological insight.

In both the positivist and social constructivist style, there is a tendency to separate the social or qualitative dimension from its technical practice. Qualitative research might, for example, describe the role of patients’ or physicians’ feelings, values, and attitudes about a certain medical decision, when that decision is integrally shaped by things like diagnostic procedures, treatments, technologies, care pathways, and experiments. This artificial separation between the social and the technical skews how research understands medical practice. Mol (2006) makes this clear in her account of atherosclerosis care, which she shows is shaped by competing versions of diagnostic methods and the indicators of improvement that accompany them. The success of a patient’s treatment might be understood as either “pain-free walking distance” or “blood pressure in the ankle of the affected leg” depending on the conception of the disease (p. 407). Mol’s central point is that practice in medicine is neither purely technical, nor technical in a way that is socially infused, rather it is always made up of a different type of social element – human activity.

The turn to practice in STS has provided the foundations for a style of medical research that escapes some of the shortcomings of positivism and social constructivism. It is a reimagining of research in such a way that local practice is paramount. The researcher is not able to stand outside looking in on reality, rather they are caught up in it and changing it. They are not concerned with determining what things are, as much as they are concerned with how things come to be and what their effects are. They are close

to the action, attempting to do justice to heterogeneity and complexity, but in a way that is constructive, that seeks not to only critique but to intervene and add to. And finally, they are alert, attentive to circumstances as they unfold, to emerging possibilities and directions for action.

This thesis is about articulating and demonstrating this practice-oriented style of research. It is about changing the conceptual models that inform interventions in medicine so that we can better appreciate the local context and practical activity of care. Following Mol (2002), I argue that the current positivist and social constructivist ways of doing research in medicine get caught up with conceptualizations of how medicine is done or should be done, and that these conceptualizations are too reductive or focus on only very specific parts of medical practice and patient health. They thus forfeit critical reflection around the conditions that integrally shape these situations, and miss opportunities for progressive intervention. These conceptualizations and their shortfalls are important to articulate and understand because they fundamentally inform how we intervene in clinical care: how we do research, identify problems, design and implement solutions, and pursue improvement.

I suggest that we might do research that doesn't attempt to conceptualize practice, to model, quantify, or critique it, but to explore how it is done and the ways that people relate to the circumstances that constrain, enable, and guide their actions. We might find ways to bring forward the on-the-ground, situated action of medicine – activities like note-taking, discussing, looking up, counselling, counting, ordering, comparing, inputting, or following up. We might get our hands dirty doing ethnographic, interdisciplinary, and cooperative work. And in developing rich accounts of these varied practices and the material resources that come into play, we might arrive at more precise understandings of how action in care unfolds in context, what interventions are needed, and how they will affect care. We might also move away from what Mol (2002) calls a “politics of who” – for-and-against arguments around who gets to decide in medicine– to a “politics of what” (p. 166), accounts of what worlds are created by different configurations of practices, and which ones we might provisionally bring into being. This involves teasing out how even the little things are political, how seemingly mundane routines, technologies, or processes open up multiple and divergent ways of living.

This thesis is an exploration of research styles in medicine, an argument for research that is practice-oriented, and a beginner's attempt to demonstrate how this kind of research might be done. I take up insights from the turn to practice in STS and apply them to a case study of a clinical intervention in which I am involved, the Pill Talk project. Pill Talk is an action research project that has involved extensive participant observation and focus group work as part of the participatory design of a novel adverse drug event reporting platform. This project is novel in that it attempts to reconcile the worlds of research and care and rejects the positivist urge to produce data or implement solutions from outside. Instead, our methods tried to bring richer accounts of the care setting into the research world and offer practitioners in the clinical world a concrete role in the tool's design. While this thesis is not about this project specifically (I say little about our design process), it is about this orientation, and the ways that we can link our conceptualizations of medicine (created in worlds as diverse as epidemiology research centres and philosophy departments) with its practice (carried out in worlds like the emergency department).

My ethnographic accounts from the Pill Talk project offer a view of how drug safety is done that can be contrasted with some of the mechanistic models that instruct drug safety science and patient safety research. In drawing out the practical action of care, my accounts point to multiple ways in which drug safety and patient care were done. I describe the uncertainty and complexity inherent in this activity, the intertwinement of diagnostic, treatment, and documentation processes that are often taken as distinct, the problems of translating activity into data, and the many areas where there are possibilities for improvement. I also was able to analyze how an intervention in clinical practice, in this case our Pill Talk platform, will open up new positive opportunities for improved care, but will also bring new complexity, problems, and harms.

1.2. Overview of Thesis

This research was undertaken with the goal of making a theoretically and empirically informed case for practice-oriented research in medicine. My first aim is to familiarize the reader with the theoretical trajectory in which the turn to practice in STS is situated. In Chapter 2, I begin by outlining three loosely defined styles: positivism, social

constructivism, and sociomaterial practice. As I will explain later, these paradigms are not definitive, rather they are my way (following others in STS) of assembling the varied theoretical literatures under shared themes and assumptions. Accordingly, for each paradigm I provide a general overview of what literatures I've considered together, and how they relate. I try to write with attention to the premise that theory is something that is done, a style, a unique way of drawing together ideas, normativities, literatures, and empirical examples. I note also that theory does work to orient action (though it does not determine it): it shapes how problems are identified and defined; suggests what should be taken as true, just, or good; and instructs how to intervene. Thus, when I write about positivism, for example, I try to talk about the ways that it shows people how to relate to their world and might affect their action.

For each style, I draw out some of the ways in which it appears in the action of medicine, whether it be in policy and regulation, academic literature, or clinical practice. I also try to put these styles in conversation with one another, to show how they contrast and conflict. My aim is for the reader to arrive at the end of the chapter with a clear understanding of the different modes of doing research in medicine and the turn to practice as an extension of and as a response to preceding ways of doing research. I also try to make evident the types of changes that the turn to practice brings to research and offer a convincing argument that practice-oriented research is a style that is theoretically robust and should be embraced in concert with others.

Chapters 3 and 4 focus on my empirical work, in which my goal is to demonstrate what research after the turn to practice might look like and its value to intervening in medicine. It also serves to reinforce my theoretical argument from Chapter 2, showing how attention to action may provide a convincing understanding of how the world works. In Chapter 3, I begin by familiarizing the reader with the case study, providing a history of adverse drug events and pharmacovigilance (drug safety science), outlining some of the policy discourses that inform approaches to drug safety in Canada and around the world, and introducing the Pill Talk project in which I participated. I describe the action research approach that defined this project, relating it to the turn to practice, and then outline the methods we employed and our rationale for using them. Since I present this case and our methods as demonstrative of practice-oriented research, I reflect on what is entailed in

method beyond its formal account. I speak to its actual practice, giving a short account of the activities and complexities of doing my participant observation work. I also am attentive to the fact that the work of ethnography comes after observation, in the conversion of notes and memory into an account. For this reason, I end by offering a reflection on my writing, a significant methodological practice that often goes unrecognized.

In Chapter 4, I present and discuss my findings for the case study. The chapter as a whole aims to contrast positivist, mechanistic conceptualizations of drug safety with ethnographic accounts of drug safety as situated action. I start by drawing on a clinical research article to introduce the problems associated with defining adverse drug events as objective, measurable, classifiable things. This introduction gives the reader a sense of what ADEs are and the troubles involved in their identification, without advancing a hard definition. It sets the stage for the next section, in which I draw on observational work to look at ADEs as entities that are practiced. From the accounts that I offer, I show how common assumptions about or simplified understandings of drug safety in care (for example, the clean separation between diagnosis, treatment, and documentation practices) may shape the chosen routes of improvement in ways that may be ineffective or undesirable. I point to the dynamism and uncertainty of care, and to how there is no formula for enacting good care, it is rather a process of responding to the particular circumstances that shape, constrain, and enable a provider's action at any given time. I also suggest that these aspects of care and drug safety are often lost in translations of activity into reified forms like reports or data. I close the chapter by arguing that this matters for how we intervene in medicine, which, if we take it as a straightforward, rational, or calculable implementation process, may influence care in negative ways that are poorly understood. To illustrate how practice-oriented research can inform interventions in care, I reflect on the Pill Talk intervention and how our ethnographic work added a contextual awareness and an appreciation of the new uncertainties, complexities, and possible harms that our intervention would inevitably carry.

Finally, in the concluding chapter I summarize findings and return to the central argument that research in medicine could be reimagined in a way that observes the

insights of the turn to practice. I close by outlining new directions for this kind of research, highlighting ongoing work and resources that might be mobilized.

Chapter 2.

The Scientific, the Social, and the Situated

First, the production of universal, totalizing theory is a major mistake that misses most of reality, probably always, but certainly now; and second, taking responsibility for the social relations of science and technology means refusing an anti-science metaphysics, a demonology of technology, and so means embracing the skillful task of reconstructing the boundaries of daily life, in partial connection with others, in communication with all of our parts. (Haraway, 1991, p. 181)

2.1. Introduction

In this chapter I introduce the turn to practice in STS as the theoretical basis for my understanding of the social study of medicine might be done. It was a resource that I constantly drew upon in my fieldwork, analysis, and writing. In Chapter 1, I introduced the argument that existing conceptualizations of medicine (or reality in general for that matter) are reductive and influence what we think is going on and how we think we should intervene in ways that aren't fully appreciated. But what does it mean to "conceptualize"? What are the objects of medicine, really? The way that these questions are answered affects the way that research is done, and I answer them differently than others. Indeed, it is the way that medicine and social science *treat* their problems – their methodological "styles" (Mol, 2002, p. 154) – that I wish to first explore.

My approach in this chapter is to lay out two commonly adopted styles of inquiry that I (following others) present an alternative to. The first style is *positivism*. Among other effects, positivism hierarchizes, prioritizes, or disqualifies various ways of producing knowledge about a material world based on a specific understanding of bias and offers the justification for the standardization and systematization of work based on a specific understanding of efficiency. The second style takes various names, but I will refer to it as *social constructivism*. Social constructivism is a backlash to positivism that instead explores how all of the knowledge that is created with positivist intent is mediated by social influence. The third style is a different rendering of constructivism that has taken root largely in in the field of STS and that takes knowledge and reality as intertwined, as

performed in *sociomaterial practice*. I will introduce this turn to practice, examine some critiques, and explore how it might shape social science and medicine. My goal is to put the three of these styles into relief, exploring some of the ways they are taken up in medicine, and to make an argument for moving away from some of the assumptions that are central to positivism and social constructivism.¹ In Chapters 3 and 4, I will take up the task of doing research into medical practice in a way that observes this move.

2.2. Positivism

It is perhaps not useful to speak of positivism as if it were a single theory, or indeed even as if it were merely a theory. It is an attitude or a style that has been written about and acted upon in a litany of different and competing ways. Indeed, there have been positivists who have spent their academic careers refuting the positivisms before them (e.g., Karl Popper), and there are positivist ways of understanding and acting in the world that precede Enlightenment theorizations. What positivists do have in common – or at least as I group them here – is that they take ways of creating knowledge and set them against a criterion upon which their *validity* can be ordered, often referred to as a “demarcation criterion” (Lakatos, 1973/1999).² For some positivisms, a demarcation criterion distinguishes between meaningful statements and nonsense (e.g., the positivism of Auguste Comte). Others claim less, arguing that we might only demarcate scientific and non-scientific knowledge (e.g., Karl Popper). The specifics of the criterion and the rigidity with which it is applied are contested terrain among positivisms, but in general, for knowledge to qualify as scientific or objective, it must minimize *bias*, the prejudice introduced by the human knowledge maker (Denzin & Lincoln, 1999); or put in another way, it must be based on strictly observationally-derived terms (Keat, 1981).

Bias’s place at the heart of positivist criteria stems from the ontological distinction between a knowing subject and an objective world that is known (Polkinghorne, 1989). Positivists maintain that nature exists external to the individual human, and enduring truths

¹ There are many divergent positivisms and social constructivisms, however in this thesis I will use the singular “positivism” and “social constructivism” to stand for the plural.

² Validity can be internal (how well do claims mirror the object under investigation) and external (how generalizable are the claims to other settings) (Denzin & Lincoln, 1994, p.100).

about nature may be revealed through the logical manipulation of observations of that world (Polkinghorne, 1989; Sismondo, 2004). The positivist endeavour, then, is to develop a logic – a set of formal links between these observations (raw data) and general statements about it (theory) (Sismondo, 2004). These links must be formal so that the practice of knowledge-making is consistent, that is, the final product is a real reflection of the objective world, uncontaminated by the individual inquirer. As for the raw data to which theory might be linked, again bias must be absent. In general, then, data is best when it comes in a form that is empty of any prior theoretical notions and can be interpreted in the same way by any reasonable, qualified observer (Keats, 1981). These conditions are most readily met by quantitative data, which open up the opportunity for a statistical analysis that leaves little room for the analyst to impose themselves on the findings (Keats, 1981). Thus, quantitative data-driven methods are the positivist research method of choice (Guba & Lincoln, 2005).

René Descartes advanced the idea that, given the scientific method's ability to categorize and quantify a reality external to us, we might understand it as a mechanical system. That is, we might break down natural and social realities into constituent components and processes. In 1866, John Stuart Mill articulated this as a foundation of positivism: "Whoever regards all events as part of a constant order, each one being the invariable consequent of some antecedent condition, or combination of conditions, accepts fully the Positive mode of thought" (Mill, 1875, p.16). As frameworks that are able to establish this "constant order" and identify certain knowledges as more valid than others, positivisms are taken up for use in making decisions. Indeed, for positivists, the value of knowledge hinges on its effectiveness, its ability to enable control over the object of research (Denzin & Lincoln, 1994). It's quite an intuitive and promising idea: if we have the best possible understanding of our reality (an empirical one), then we can manipulate it to better meet our needs. Positivisms offer not only a method, but also a justification for the compartmentalization, quantification, and optimization of life, work, and nature. They are the backbone to narratives of progress, the idea that, through the scientific method, we can constantly move towards a truer understanding of the world and achieve a greater level of control over it and a thus greater quality of life.

Positivisms are not only narratives, conceptual frameworks, intuitions, or sets of ideas; they are actively *done* in the world. They play a role in how we identify problems and which solutions we choose. They give credence and authority to some sets of practices over others – like categorizing, counting, or ordering over story-telling, historicizing, or describing. They bear on how we design buildings and machines, care for bodies, grow and cook food, make money, educate children, and organize people. Taylorism (or scientific management) is perhaps the most familiar example of the positivistic strategy at work. Frederick Taylor developed an approach to management based on the separation of the conception of work and its execution (Pruijt, 1997). In practice this meant creating a domain of management that developed a science of worker behaviour. The data of this science were things like units of time required to carry out the movements that constituted production tasks, and their analysis could yield general laws about how the work could be done in the most efficient way (Timmermans & Berg, 2003). The workers, then, had only to follow the plan devised by management. Management then observed how their plans worked and tinkered with the program so that it would be most productive.

As someone from an engineering background, this mechanistic conception of processes is familiar. In engineering sciences, processes are modeled as *feedback control systems*. Pumps, engines, ovens, guidance systems – all have variable outputs that must be controlled –respectively, flow rate, RPMs/torque, temperature, trajectory. The basic premise is that for a system to work the designer must decide what outputs are desired, design a way to measure how close the system is performing to the desired outputs at any given time, and incorporate the ability for the system to correct itself if it deviates from these outputs (see Figure 2.1). The classic example is an airplane's autopilot guidance system. The desired outputs as an airplane approaches a runway might be related to an optimal spatial trajectory, an optimal velocity, an optimal acceleration, and an optimal pitch and yaw. Sensors built into the aircraft (responsive to ground control signals) are able to measure these outputs precisely and determine how much they deviate from an optimal reference. Then this information is fed back into a controller that will adjust the plane's steering mechanisms (its spoilers, ailerons, elevators, rudder, etc.) and correct its course.

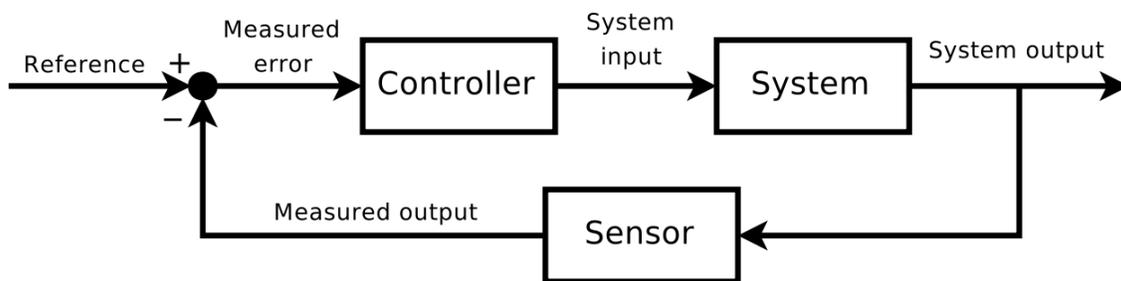


Figure 2.1. Control feedback system diagram.

Note. Reprinted from *Wikimedia Commons*, by Orzetto, 2008, Retrieved February 13, 2016, from https://commons.wikimedia.org/wiki/File:Feedback_loop_with_descriptions.svg. Copyright 2008 by Orzetto. Reprinted with permission.

Such systems can be incredibly useful. They can be designed to operate in extremely efficient ways and may remove the need for a human operator (along with the costs, flaws, and idiosyncrasies that come with them). We might imagine, for example, that one day these systems are perfected to such a degree that planes won't need pilots – just as elevator systems have been perfected to the point that they don't need operators (Mayerwitz, 2015). And we might imagine that work and life processes might be optimized as well. Theoretically, if we quantified intelligence, we could measure the success of various educational systems, analyze feedback and adapt the system's design, and thus tailor our system to produce an optimally intelligent society. Likewise, we could engineer systems for other aspects of society like the economy, public health, crime prevention, resource management, or urban planning.

To some degree, this feedback-based approach is something that people have always done. We observe how things are working, identify problems or areas for improvement, formulate solutions, and make changes. The difference today, however, is that these feedback and analysis processes are becoming automated. We can collect unprecedented amounts of information and analyze them in ways that allow us to draw far more accurate and precise conclusions, and we can do it fast. Decision-making in business and in policy-making can be made to be data-driven and “rational”, informed by empirical analysis as opposed to intuition or ideology. Advocates of data science suggest that these capabilities will define our future (e.g., Pentland, 2012). Today, it's our Netflix suggestions that are tailored to our interests. Tomorrow, it will be the planning of our nations, markets, governments (Pentland, 2012).

It's important to note, however, that positivisms have not in fact created the uniform, ordered worlds that their advocates fetishize and their detractors deride. The practice of science, and the adaptation of its results into practical change, is a far more messy and complex process than a strict adherence to methodological principles. I will elaborate on this point further in Section 2.4. For now, let us consider positivisms as resources to orient action in the world, resources that, in their inclination to control and optimize, are justification for the reduction and management of heterogeneity.

2.2.1. Positivism in Medicine

Medicine has long been shaped by a positivistic science that has offered new knowledge, methods, and technologies to the medical practitioner. However, the late 1980s brought a decisive shift in the relation between positivist medical research and medical practice: efforts to scientize were for the first time aimed at the *content* of medical work – the clinician's practice (Timmermans & Berg, 2003; Sackett, 2002). Timmermans and Berg (2003) note several reasons for this shift. First, people had started to notice and problematize the radical variability of medical practice, specifically the use of surgical operations. It became clear that the more informed and uniform approach to certain interventions offered significant benefits to both patients and healthcare organizations trying to optimally allocate resources. The increasing scrutiny of practice, increasing healthcare costs, and increasing skepticism of the expert/professional pressed the medical profession to take up standardization as a defensive measure to “maintain its position as the exclusive safekeeper and wielder of medical knowledge” (Timmermans & Berg, 2003, p.100). New information technologies also offered enormous potential both for medical communication and the large-scale generation of data. And finally, arguments for the standardization of practice fell in line with the desires of business, government and insurance companies to make medical practices calculable, and thus more amenable to cost control.

This turn to standardization intertwined with the emergence of the evidence-based medicine (EBM) movement, which aimed to ensure that patient care was informed to the greatest degree possible by scientifically validated knowledge, from prescribing practices to regulatory decisions to program implementation (Mykhalovskiy & Weir, 2004). The

focus of EBM in practice was the creation of clinical practice guidelines, which are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (Timmermans & Berg, 2003, p. 3). Importantly, the development of the guidelines was to be, above all, empirical. Traditional consensus conferences – where diverse groups of experts in the field would gather to develop such guidelines – were attacked as unscientific because they let social dynamics and personal biases colour their final results, and because they represented an outdated reliance on scientific authority (Evidence-based Medicine Working Group, 1992). More systematic methodologies emerged as the “gold standard” – specifically meta-analyses of randomized clinical trials (Timmermans & Berg, 2003, p.4). Archie Cochrane, one of the first champions of EBM, also pointed to it as a way to encourage public investment in care by satisfying the desire for effectiveness to be weighed against efficiency in large scale health care programs (Cochrane, 1972). For this reason, EBM researchers also incorporated cost-benefit analyses into their evaluative methods so that clinical and policy decisions could be informed by economic evidence, such that the pay-off of a treatment for a patient would be worth the cost to them and to the system (Timmermans & Berg, 2003).

The move towards EBM has taken root in multiple ways in medicine – through the emergence of new EBM-oriented institutions and journals, a strong and growing presence in medical education and academic literature, an upswing in randomized clinical trials, the rise of strategic health management research, and the development and implementation of thousands of different clinical guidelines around the world (Timmermans & Berg, 2003; Mykhalovskiy & Weir, 2004). The growth in EBM has radically reorganized and prioritized certain activities. As clinical epidemiologist David Sackett (2002) describes, the emergence of EBM was part of a series of “evolutions and revolutions” in “evidence generation, its rapid critical appraisal, its efficient storage and retrieval, and evidence synthesis” (Sackett, 2002, p. 1161). Clinical epidemiology, an outgrowth of a traditional epidemiology that dealt with patterns of health and disease in defined populations, emerged as the discipline that could tie these advancements together with the aim of bringing quality evidence to bear on point-of-care decision making (Sackett, 2002).

From its beginning, EBM advocates have refrained from taking a hard line stand for empiricism, and have admitted a certain degree of “traditional skill” and clinical expertise (Evidence-based Medicine Working Group, 1992, p. 2421). However, the notion that practice should be evidence-based to be valid has clear positivist commitments and is still practiced in ways that lack flexibility (Mykhalovskiy & Weir, 2004). Variation and uncertainty are seen as occurring only because there are still gaps in knowledge, gaps that can be systematically identified and filled (e.g., Richardson et al., 1995). The aspiration is a rational medicine, a medicine that is closer to an exact science – a system reliant on the production of evidence around medications and their effects, the synthesis and dissemination of this evidence in the form of clinical practice guidelines, and the uptake of these guidelines in practice (Timmermans & Berg, 2003).

Evidence in EBM takes on a specific, generally positivist meaning where again the enemy of knowledge is bias. Accordingly, the methodologies used in the production of evidence are viewed in a hierarchical manner, on the basis of their perceived objectivity or susceptibility to bias – from the “gold standard” of systematic reviews of randomized controlled trials (RCTs) down to “soft” evidence like spontaneous reports or case studies. RCTs generally entail the comparison of one treatment against a control (either another approved treatment or a placebo) (Dumit, 2012). Patients are randomly allocated to receive either the treatment or the control, and their health is then carefully followed through regular follow-up visits and tests (Dumit, 2012). In the ideal trial, all groups involved – evaluators, providers, and patients are blinded as to which treatment a patient is receiving (Dumit, 2012). Specific outcomes are followed, quantified, and compared using statistical methods (Dumit, 2012). The advantage of this approach is that efficacy can be very concretely compared and very small differences between treatments can be detected (Dumit, 2012). The EBM movement’s prioritization of this kind of clinical trial evidence – along with the rise of epidemiological and genomic sciences that quantified an individual’s risk of developing disease – has led to a form of medicine that is based increasingly on interpreting and applying statistics and less on a physician’s experiential expertise (Dumit, 2012).

This is not to say that qualitative research has no place in EBM. Often, however, when present in EBM qualitative research assumes a positivist, evaluative, and generally

more quantitative character. Orlikowski and Baroudi (1991) describe this type of positivist qualitative research in their categorization of information science research as containing “formal propositions, quantifiable measures of variables, hypothesis testing, and the drawing of inferences from the sample to a stated population” (p. 5). It again posits an objectively given reality (albeit a social one) that might be discovered through rigorous methods and instruments that have been tested for their reliability (like standardized questionnaires). However, this form of qualitative research which is informed by positivism differs not only in its outlook and methods from other forms of qualitative research, but also in its purpose, which is to support the EBM mission of integrating evidence into care. As Green and Britten (1998) suggest, the role of qualitative research is to “bridge the gap between scientific evidence and clinical practice” (p. 1230). That is, such positivist informed qualitative research offers a more scientific approach to the questions that the supposedly more objective methods are ill-adapted to, like the question of how to get people to use evidence. The field of knowledge translation has emerged out of this aim, which (at least in its initial formulation) tries to systematically find ways to facilitate the “synthesis, dissemination, exchange, and ethically-sound application of knowledge” (Canadian Institutes of Health Research, 2012). It is thus interested in examining questions such as: Is best evidence being applied and why or why not? What are the barriers or limitations to using evidence in clinical care? How can we make providers and their patients use evidence better, or comply better with guidelines? How do we make patients do what they’re told by their physician, or follow their treatment properly? What are the beliefs, attitudes, or preferences that are guiding provider or patient behaviour? As well, positivist qualitative research may aim to give order or quantity to some of the messier, social outcomes of the care system (e.g., quality of life, patient satisfaction) so that these outcomes can be weighed in cost-benefit calculations.

The EBM vision can easily be compared to the feedback control system described in the previous section (See Figure 2.2). Referring to components in the graphic below, the system is day-to-day clinical care. The sensors are clinical audits, clinical data collection, or incident reports (like adverse drug event reports). The references are evidence derived primarily from clinical trials. And the controllers are health management – made up of the researchers, regulators, and policy-makers that design and implement new technologies, protocols, guidelines, or best practices. The idea is that we can create

a cycle of improvement based on a highly-managed medicine, with a systematic and robust defence against error, variation, and uncertainty. Innovation comes primarily from 3 junctures – better sensors (like bigger and better data collection), better references (more evidence), and better controllers (knowledge mobilization/translation instruments). Note that the system itself, here, is thought of more as a place where plans are executed – where evidence, technology, guidelines, protocols are applied – rather than as a place where plans are devised.

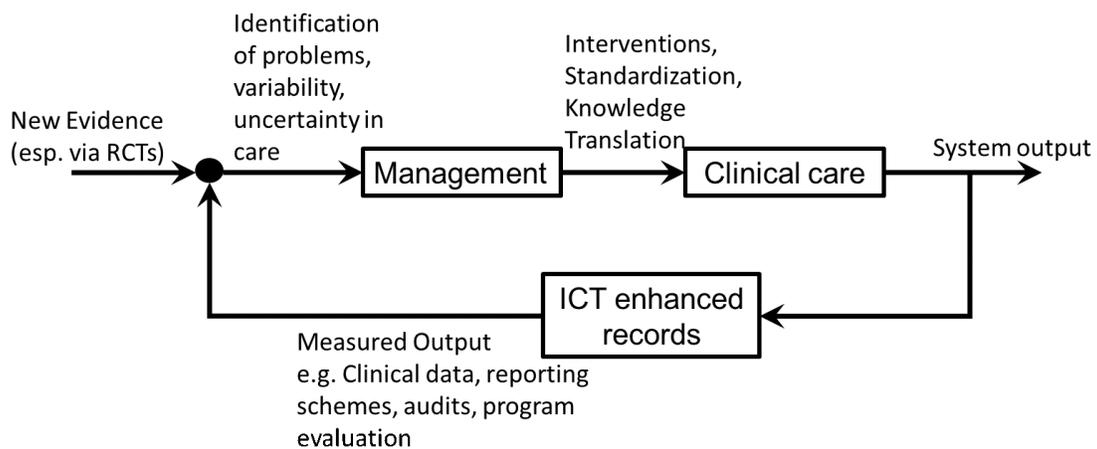


Figure 2.2. Feedback control system diagram for EBM

Like Taylorism, EBM separates the conception of medicine from its execution. The result is, first, that the autonomy of the on-the-ground health provider is reframed as subordinate to their responsibility to adhere to guidelines; and second, the practice of medicine (the myriad ways that providers deal with the complexities of every day care) is subordinate to the science of medicine (the application of evidence generated under specific experimental conditions). Consider the U.S. Institute of Medicine report, *To Err is Human* (described in detail in section 3.2.2). The report drew attention to the error and risk involved in medical care and called for ways to “design in” safeguards (p. 4). The authors argued for treating clinical care as a system – one that people at a management level could tinker with, add to, and adjust to increase safety and decrease risk:

More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. For example, stocking patient-care units in hospitals with certain full-strength drugs, even though they are toxic unless diluted, has resulted in deadly mistakes. Thus, mistakes can best be prevented by designing the health

system at all levels to make it safer--to make it harder for people to do something wrong and easier for them to do it right. (Kohn, Corrigan, & Donaldson, 2000, p. 4)

Thinking in terms of a control feedback system, then, the solution to patient safety concerns is improving each element in the loop: the sensors (error reporting, monitoring, oversight); the references (the clinical safety knowledge base); and the controllers (the implementation of things that make it harder for people to do something wrong and easier for them to do it right, such as regulatory mechanisms and standards, training, protocols, technology, and knowledge translation more generally). Note that these improvements appear to come from outside of the system. They are a health care system science that is the domain of management, researchers, regulators, and clinical epidemiologists. In the *To Err is Human* report, the individual health provider (and their practice) are of little concern. The problem is presented as structural, and while the report suggests that health providers must be “vigilant” and “responsible for their actions” (p. 5), the vast emphasis remains on managerial solutions.

I should emphasize, here, a point impressed upon me by one clinician. That is, there are two types of managerial solutions that clinicians have to grapple with. The first are those that are driven by managerial zeal. These are things like new technologies or processes that management decides are necessary based on their own inclinations. For example, they might be drawn to hype for new technologies, solutions that have high visibility or political value, or solutions that resonate intuitively.³ The second type of managerial solutions are those that are true to the positivist ideal. These solutions are based on some amount of evidence, and there is scientific assurance that they work. For this clinician, the Taylorist conception/execution divide of health care work is not a problem in itself. She still has the freedom to use good clinical judgement and problem-solving. The problem for her is that the science of health management isn't scientific enough and gets in the way with clunky solutions.

³ A common example is the introduction of automation. Automated technology like electronic medical records are often taken at face value as definite improvements over the status quo, without any evaluation of their impacts in practice.

Positivist medicine, then, doesn't necessarily leave health workers as cogs in management's machine, as it left the assembly line workers in Frederick Taylor's factories. It can be taken as a way to make management types implement solutions and produce tools that are useful to providers and not hindrances. For some, it is a way to make medical practitioners accountable for the choices that they make. For some, it is a worthy ideal but one that we can't expect to see in practice. Perhaps the greater point here is that positivist medicine neither manifests in a singular way, nor is singularly bad or good. Rather, it alters in a very specific way how those involved in health care identify problems and design solutions. It privileges certain problems, knowledges, practices, forms of information, solutions, and organizational structures over others.

2.3. Social Constructivism

Positivism has long been criticized for failing in its efforts to be bias-free – or rather for failing to recognize that being bias-free is impossible, that knowledge creation via any method is a social activity and that there is no direct, logical route from the material world to our knowledge of it (Sismondo, 2004). In the literature, this genre is often characterized as critical and centres on the argument that knowledges are always, unavoidably, socially constructed.⁴ The critical argument extends from the Kantian notion that there is a chasm between the objective world (the things-in-themselves) and our knowledge of it (the things-as-we-perceive-them). Kant argued that humans unavoidably impose structures onto the world, that our conceptions of things are always constructed via a priori modes of understanding sensory input (Lukács, 1971). These a priori modes are intuitive, cognitive frames that structure our perception and ingrained historical, socialized forms to which we relate new information (Lukács, 1971). This provides the basis of the social constructivist argument: that the journey from observation to theory is always *mediated* and the mediating forms involved can never be the transcendent links positivists might wish them to be.

⁴ My use of "critical" here is very broad, referring to literatures that reject the positivist argument or are non-deterministic.

Like positivism, there is no definitive social constructivism. Ian Hacking (1999) points to how social constructivist work interprets and presents the above argument in varying ways and to varying degrees, making room for many offshoots (including social constructionism, constructivism, constructionism, or deconstructionism).⁵ I will, however, make one general (and somewhat contestable) umbrella claim for social constructivist approaches: they concern themselves more with epistemology (how we make knowledge about the world) than with ontology (the nature of the material world itself).⁶ Ian Hacking (1999) suggests three ways in which this epistemological concern is expressed in social constructivist work. First, facts are shown to be contingent, as the constructivist slogan goes: “it could be otherwise” (Hacking, 1999). If knowledge is mediated by impermanent and imperfect human constructs then it is clear that, given different mediating constructs, different knowledge of the world would be produced. Second, kinds are taken as nominal (Hacking, 1999). The names/types/categories/classifications that we see in the world are imposed by humans and are more cognitive or linguistic phenomena than they are essences actually out there in the world (Sismondo, 2004). Third, the stability of knowledge is shown to be achieved not through its accordance with evidence, but for external, social reasons (e.g., cultural, institutional, economic reasons) (Hacking 1999).

What does the social constructivist argument *do* in the world? Most significantly, it undermines positivist certainty and authority. It reveals how positivist claims to being bias-free have instead served to entrench and legitimate structural biases to the exclusion of others. Thomas Kuhn’s 1970 *The Structure of Scientific Revolutions* was perhaps one of the most effective strikes at the positivist paradigm. Kuhn presented a picture of the

⁵ For example, Burr (2015) argues that the difference between constructivist and constructionist literatures is that constructivists (especially in psychology) tend to suggest that constructs are more individually created versus constructionist literatures which stress the formative influence of social structures and interactions. In short, constructivism refers more to individual knowledge while constructionism refers more to a collective ‘making’ of artifacts in social interaction and language. Hacking (1999) identifies as a constructivist, dropping the social for its redundancy and taking a conservative position on contingency. In this thesis, I treat the variants under one umbrella of epistemological constructivism.

⁶ There are constructivisms that do explore ontological questions. For example, in Latour’s (2003) essay “The promises of constructivism”, he argues for an ontological constructivism that emphasizes the processual and material nature of knowledge creation versus an epistemological constructivism that too often fixates on knowledge as constituted by “social stuff”. This kind of ontological constructivism has generally been a departure from the critical genre in specific disciplines like science and technology studies and anthropology. I will describe this type of constructivism at length in section 2.4.

history of science that defied the basic assumption of philosophers and scientists alike that the advancement of science was cumulative and brought humans closer to some kind of truth. Kuhn (1962) instead argued that scientific progress is episodic. Facts, theories, research questions, and methods are products of their unique paradigm, of the conceptual framework that dominates their historical and intellectual context. Within paradigms, facts and theories accumulate and advance until they are beset by unexplainable anomalies (data incongruent with theory) (Kuhn, 1962). Eccentricities are born out of the struggle to recover from this crisis and alternate paradigms emerge (Kuhn, 1962). Opinion then polarizes between the old and new (Kuhn, 1962). Kuhn notes that it is at this point that an interesting phenomenon occurs – those within each paradigm are left only with circular arguments drawing on the theory and facts of their respective paradigms (Kuhn, 1962). Their arguments are *incommensurable* – communication is blocked as each party's arguments are couched in their own epistemological languages (Kuhn, 1962). Kuhn argued that the advancement beyond this phase isn't a matter of logic or reason, but one of persuasiveness (Kuhn, 1962).

The structural biases of positivism did not only privilege certain conceptual frameworks, they also privileged certain people and their worldviews. Feminist critiques challenge the supremacy of positivist disciplines that, like the dominant cultures they exist in, too often exclude the voices and viewpoints of women, minorities, non-Westerners, and the economically disadvantaged. Feminist critiques show how positivistic endeavours, despite their claims to objectivity, have incorporated and reinforced cultural assumptions or social conventions around race and gender. Emily Martin (1991), for example, shows how the language and metaphors used in biology to describe the activities of sperm and egg correspond to stereotypical cultural definitions of male and female: the sperm as active and aggressive, the female as passive. She points to how this representation is both a distortion of evidence (the egg is as active or more active than the sperm in fertilization) and an exertion of power: “that these stereotypes are now being written in at the level of the cell constitutes a powerful move to make them seem so natural as to be beyond alteration” (p. 500).

Another central strand of critique is that of critical theory, which argues that positivism in the modern world extends beyond the domains of science and technology

into culture, where positivism reduces thought to the contemplation of means and erases the ability to reflect critically on the ultimate goals of society (Feenberg, 2015). That is, positivist rationality contains within it an ideology that is instrumental, where thought is oriented only to the short term achievement of technical goals (e.g., economic growth, job creation, control over the environment, extending the length of life). Further, the positivist mode of thought erases the historical context of its objects, obscuring their contingent and social nature (Lukács, 1971). It conditions people to accept the notion that there is a single, natural order of things (Lukács, 1971). The result is that a narrow definition of efficiency presides as the ultimate orientation of society and there is no opportunity for reflection or societal consensus. Instead, non-linguistic media like money and power are needed to coordinate action (McCarthy, 1984, p. xxxii). Such an irrational mode of organizing the efforts of society results in destructive contradictions. Despite modern society's capabilities, there is extraordinary waste, poverty, insecurity, and environmental destruction.

These are just a few examples of the critiques offered by social constructivists. But they are indicative of the more general functions of constructivism: to bring to the fore the social and cultural contexts that knowledge of all kinds is inescapably bound to, or mediated by – to elucidate the complex, invisible or taken-for-granted ways in which “society extends into the structures of human experience in the form of ideas, concepts, and systems of thought” (McCarthy, 1996, p. 1). Interpretivist research like hermeneutics or phenomenology, for example, explores the world not as one that can be objectively understood, but as one that is individually or collectively interpreted (Orlikowski & Baroudi, 1991).⁷ Thus, it is not a material world that is of interest, but the contexts, cultures, and situations in which the people's perspectives of the world are forged (Orlikowski & Baroudi, 1991). Indeed, shedding light on social context – to the exclusion of ontological questions – is the focus of much social constructivist work, especially within the sociology of

⁷ Hermeneutics is the art of understanding and interpreting the world (e.g., how do people come to have such varying interpretations of similar events and things?). Phenomenologists are concerned with the similarities in our understandings of things and our commonsense notions of how they are, they're interested in the question of whether things have essences.

knowledge. In the words of Durkheim: “the world exists only so far as it is represented to us” (Cited in McCarthy, 1996, p.2).

David Bloor’s understanding of the sociology of knowledge (articulated in his and Barry Barnes’s strong programme), for example, emphasizes that the social study of science must treat true and false beliefs symmetrically (Bloor, 1976/1991).⁸ It is out of the social scientist’s domain to comment on the material justifications for a scientist’s belief (Bloor, 1976/1991). Rather, they examine the social origins of “shared beliefs about nature” (Bloor, 1999, p. 87). Such a distinction suggests that there is a division between a technical and social domain, dedicated to ontological and epistemological questions respectively, and populated by positivist scientists and social constructivists respectively.⁹ As Latour (2005) points out, the sense that there is a social side, aspect, or dimension to the technical world, social factors that affect it, or a social context which it is embedded in, has become commonplace. The basic lexicon of the social has even broken out of social constructivist literature and into common parlance: “Offering comments about the inevitable social dimension of what we and others are doing ‘in society’ has become as familiar to us as using a mobile phone, ordering a beer, or invoking the Oedipus complex, at least in the developed world” (Latour, 2005, p. 4).

The social constructivist division between the social and technical also extends to technology. The contingency and socially negotiated nature of knowledge applies equally to the artifacts that we create. Unlike the positivist view of technology, which, in general, would take it as a value-neutral tool to achieve specific outcomes (e.g., production rate, accident rate, speed, power), social constructivists are interested in revealing ways in which technologies are underdetermined, the ways in which their design and their place in society are dependent on social context (Sismondo, 2004). The use of case histories in the field of STS has been a particularly effective means of drawing attention to this context-driven development (Feenberg, 2015). A textbook example in the field is Bijker,

⁸ The Strong Programme took shape out of two primary texts: Barnes’ (1974) *Scientific Knowledge and Sociological Theory* and Bloor’s (1976) *Knowledge and Social Imagery*.

⁹ Of course, Bloor wouldn’t suggest that the positivist scientist actually has access to the ontological domain – he would reject that outright. But as far as roles go, the sociologist is designated to only consider the social, and the study of ontology is of little consequence –for we can only study reality to the extent that we know about it, and knowledge is social. The only ones then making positive assertions as to what might exist are scientists.

Hughes, & Pinch's (1987) analysis of the historical trajectory of the design of the contemporary bicycle, which showed that the design that we've come to accept as normal was underdetermined. There was no objective measure like safety, speed, or efficiency to guide its historical trajectory. Instead, it was the result of the competing interests of the various social groups of bicycle riders. For young male riders, the bicycle was chiefly for speed and style, whereas for others it was about safe and stable fun. The capacity for there to be competing claims about what a bicycle *is* reveals what Pinch and Bijker call the interpretive flexibility of technologies.

Interpretive flexibility could also apply to scientific facts. Indeed, the social constructivist position suggests that everything in the world is subject to interpretation, that an absolute knowledge of anything is impossible. Social constructivism is, at its core, relativist. Relativism is a controversial position. The notion that any truth claim is as correct as another is, quite justifiably, offensive to many. However, social constructivism claims relativism in a specific way. David Bloor, a regular defender of the relativist position, offers a few core characteristics of his formulation of relativism: (a) relativism is opposed to absolutism (the idea that there can be knowledge that is universally true), their opposition is binary (there is no in-between position), and, while imperfect, relativism is the far more preferable and plausible of the two; (b) relativism (at least in Bloor's case) is materialist – i.e. it does not suggest that material existence is merely a phenomena of the mind (idealism), but rather that people's understandings of an external, material world are contingent; and (c) relativism does not suggest that "anything goes," truth is rather a contingent notion that is relative to shared convention or paradigm – i.e., within a certain epistemic community, one can certainly make judgements as to the validity of a statement (Bloor, 2008).¹⁰ Relativism raises questions about the validity of social constructivist work as well. Most social constructivist work, especially feminist qualitative research, attempts to grapple with this question by drawing explicit attention to their own methods, assumptions, and social situation – especially the ways in which their findings suppress alternative understandings and complexity (Olesen, 2005). They attempt to acknowledge

¹⁰ For Bloor, relativism boils down to a critical scepticism of knowledge claims: "relativism is the idea that both true and false beliefs are, with regard to the causes of their credibility, equally problematic" (Bloor, 2008, p. 15).

that knowledge creation is non-innocent and their findings are not generalizable beyond the local context in which they were created (Haraway, 1988).

The changes that social constructivisms have brought into the world are diverse. On the one hand, they have helped to justify the politicization of scientific facts and technologies. The notion that technical knowledge and artefacts have a social component has achieved mainstream currency. On the other hand, however, social constructivists have come up against (and, to some degree, incited) a fury of opposition, most significantly from the positivist scientific community. The social constructivist critique was taken as an attack on a well-established culture and community and, to some, the notion of truth itself, so it is hardly surprising it met with both defence and counterattack. The positivist scientific community protested that their critics used misinterpretations and oversimplifications to discredit their disciplines and used rhetoric-laden, non-rigorous scholarship to advance ideological agendas (e.g., see Gross & Levitt, 1994). Certainly, some of this reaction was itself ill-informed and ideologically driven. However, it also included salient points that drew attention to weaknesses in social constructivist work and provided impetus for reflection on the field's goals and strategies for achieving them. Many in the field now urge a more earnest engagement with practitioners and their disciplines, a more relevant, honest, rigorous, and less pretentious research practice, and an approach that tries to build and not only cut down (e.g., see Latour, 2004).

2.3.1. Social Constructivism in Medicine

What has social constructivism done in the worlds of medicine? Its chief task has likely been the questioning of claims to certainty and authority that are associated with what is taken as a patriarchal and positivist biomedical paradigm. Table 1 outlines what Miller & Crabtree (2005) identify as the 10 premises of the biomedical paradigm, (see Table 1), and the ways that they manifest in the everyday worlds of clinical care. These premises and characteristics have become well-established jumping-off points for critiques of biomedicine.

Table 2.1. Ten premises of biomedicine as described by Miller & Crabtree (2005, pp. 610-611)

Ten premises of biomedicine	Characteristics that follow
<ul style="list-style-type: none"> • Scientific rationality. • An emphasis on individual autonomy rather than family or community. • The body as machine with an emphasis on physicochemical data and on objective numerical measurement. • Mind-body separation and dualism. • Diseases as entities. • The patient as object and the resultant alienation of physician from patient. • An emphasis on the visual. • Diagnosis and treatment from the outside. • Reductionism and the seeking of universals. • Separation from nature. 	<ul style="list-style-type: none"> • Male centeredness. • Physician centeredness. • Specialist orientation. • An emphasis on credentials. • High value placed on memory. • A process orientation accentuating ritual with supervaluation on "science" and technology. • Therapeutic activism with an emphasis on short-term results. • Death seen as defeat. • Division of the clinical space into "front" (admin) and "back" (clinicians). • The definition, importance, and sanctity of "medical time." • An emphasis on patient satisfaction. • Profit-driven system. • Reverence for privacy of the doctor-patient relationship. • Disregard of ecological and international impacts. • Intolerance of other modalities.

The first slant of these critiques was hardly social constructivist in that it had only a very thin notion of epistemological critique. Mol (2002) and Timmermans & Haas (2008) find the most clear articulation of the origins of the critical perspective in medicine in the pioneering medical sociology of Talcott Parsons, who advanced the notion that we might see health as made up of two sides: a biological or technical side that is the domain of the physician's expertise, and a social side that is the domain of the patient or sociologist's expertise:

Summing up, we may say that illness is a state of disturbance in the 'normal' functioning of the total human individual, including both the state of the organism as a biological system and of his personal and social adjustments. It is thus partly biologically and partly socially defined. Participation in the social system is always potentially relevant to the state of illness, to its etiology and to the conditions of successful therapy, as well as to other things. (Parsons, 1951, p. 451).

As Mol (2002) argues, this distinction allowed Parsons to carve out a space for a social understanding of health and medicine. This understanding has persisted until today and is evident in the more functionalist medical sociology, sociology of health and illness, or social epidemiology which attempt to point to the social contexts, factors, and forces involved in health and treatment. While Parsons' formulation of medicine was only critical in that it moved away from the crudest biological reductionism, it did open up a new way of thinking about and studying health alongside biomedicine (Mol, 2002). It has made room for a version of medicine that was perhaps more just, in that it positioned the patient not as an object of a scientific discipline, but as a socially embedded participant. The experience of the patient, their interaction with health care, or their place as the sick in society could be explored and prioritized. Their health and their treatment could be studied in relation to social categories like socioeconomic inequality or gender or race.¹¹ And in general, the social side to care provision could be opened up to examination: one could study the role of the physician or the culture, social structure, and norms of health care workplaces.

From this division between the biological and the social that we might trace to Parsons, there is an addition to the biomedical schema of medicine. There is an emphasis of what exists alongside medicine's technical practice, or maybe as a backdrop to it. A more properly social constructivist study of medicine that instead undermines, critiques, and takes away from biomedicine emerged in the 1960s and 70s in the literature on medicalization: the "process by which more and more of everyday life has come under medical dominion, influence, and supervision" (Zola, 1983, p. 295; Conrad, 1992). This body of literature aimed to break down the categories, language, and conceptual frameworks of technical medicine to reveal them as contingent, constructed, and power laden (Conrad, 1992). There was an urgency, here, because of the apparent expansion of medical understanding and subsequent intervention into areas of life that were previously outside of its domain (Conrad & Barker, 2010). Medicalization was seen as a method of social control, because it labeled and treated any human state or behaviour

¹¹ The "social determinants of health" remain the subject of contemporary social epidemiology (Berkman & Kawachi, 2000) and as Mol (2002) points out, many introductions to medical sociology still refer to Parsons' concepts like the "sick role" as legitimate.

that deviated from an established norm as pathological and thus was a way to stigmatize, manage, and eliminate difference (Conrad & Barker, 2010).¹²

Marxist critiques pick up on this thread as well. Taussig (1980), for example, describes how the signs and symptoms of disease are constituted in multiple, contingent human relations – which are foreclosed by a technical practice that asserts their singularity as objective things. Following, Marx and Lukács, he ties this reification to an overarching capitalist culture. Waitzkin (1979) draws attention to how capitalist production demands the constant creation of new markets for new products, driving knowledge creation, decision making, and technology uptake in health care. Using a coronary care unit as a case study, Waitzkin (1979) argues that as health care systems grapple with questions of cost-effectiveness, the demands of corporate capitalism contradictorily push them to expand their purview, medicalizing previously non-medical conditions, embracing unproven scientific / technological solutions, and investing in expensive intensive care technologies while rudimentary services remain inaccessible to most. This expensive expansion is coupled with a deskilling of the medical labour force as it becomes more important (and cheaper) to hire technicians than skilled, well-rounded practitioners (Waitzkin, 1979).

Critiques of medicalization were increasingly bolstered by a number of case studies (e.g., on mental illness, child abuse, hyperactivity, alcoholism) and historical analyses of the evolution of certain concepts, definitions, or treatments to their modern medical form (e.g., Foucault's *Madness and Civilization*) (Conrad, 1992). This was where the medicalization literature took on an especially social constructivist bent. The threat was not so much a hegemonic order of medical professionals as it was the hegemonic language and categories, concretized as social facts and tied to power relations, that they used (Conrad, 1992). The role of a sociology of medicine, then, was to open up for inquiry the process of social interaction in which these social facts were constructed (Spector & Kitsuse, 1977).

¹² See Zola (1972) or Freidson (1970) for some of the foundational texts of this body of literature.

As the contingent nature of the medical profession's categories was emphasized in sociological literature, sociologists became increasingly reluctant to use those categories and developed alternate broad or flexible language for illness (Timmermans & Haas, 2008). Timmermans and Haas (2008) refer to this as an "ontological gestalt switch where sociologists turn data about specific diseases into medical sociology concepts" (p.663). They note that this switch is most explicit in the literature on chronic illness where sociologists will take multiple different diagnoses or complexes of symptoms and clump them together under "chronic illness" so that they might be analyzed in a way that is removed from the influence of medical categories (p. 663). As in Bloor's strong programme, sociologists that take this approach commit themselves to a study of disease that refrains from commenting on the truth or falsity of a medical category and rather tries to track its construction or direct attention towards the social or phenomenological experience of illness (Timmermans & Haas, 2008). In work like Goffman's (1961) on stigma, for example, the stigmatized individual comes to their understanding of self and stigma as they learn and internalize societal norms and as they realize the implications of their aberrant state in their participation in a social world. The experience of illness might thus be conceived similarly: as constructed in social interactions and sustained by its internalization and outward performance (Goffman, 1961; Goffman, 1959).

Some social constructivist work has more closely examined the professional creation of medical knowledge, especially given the rise of the positivistic evidence-based medicine movement. Miller and Crabtree (2005), for example, argue that while the randomized controlled trial (RCT) has high internal validity (its claims are consistent with the phenomenon observed, confounders are accounted for, bias is minimized), it has dubious external validity (generalizability, applicability to other settings) and offers little information that would allow an outside researcher to situate the experiment in its local context or understand its results within a greater one:

Read any RCT report, and the only voice you hear is the cold sound of the intervention and faint echoes of the investigator's biases. The cacophonous music of patients, clinicians, insurance companies, lawyers, government regulatory bodies, consumer interest groups, animals and habitats, community agencies, office staff, corporate interests, and family turmoil is mute. Local politics and contradictory demands become the sound of a thin hush. (Miller & Crabtree, 2005, p. 613)

As Glasgow, Lichtenstein, and Marcus (2003) point out, contextual information is crucial: the narrow and highly controlled local conditions of experiment (e.g., the use of homogenous, highly-motivated patient groups; the exclusion of complications, comorbid problems; the increased resources available including expert staff; the narrow set of outcomes measured) differ wildly from the comparably chaotic real-world settings in which interventions might be integrated.

As well, social constructivist work problematizes the meaning and use of clinical facts produced by RCTs. That is, how should probabilistic evidence be used – and how is it used – for making decisions with a particular patient? As Dumit (2012) points out, decision-making is starting to privilege statistics over the direct clinical encounter:

Health and illness have become epistemic, a question of third-party knowledge and measurement in reference to established facts. One might say that both patients and doctors are alienated from illness in that they cannot tell when they need treatment or whether the treatment is working. (p. 114)

A key point, here, is that the probabilistic knowledge offered by RCTs indicates only *relationships* – for example, a relation between a certain intervention and an experimental cohort’s mortality rate. It does not however, offer any kind of model for why that relationship exists; physicians are left without practical models for understanding and treating individual patient cases, models like “pathophysiology and mechanisms-of-action and a deterministic rationale” (Tanenbaum, 2012). RCT facts have the added effect of transforming our conception of health from one based on diseases of physiology to one based on diseases of risk (Dumit, 2012). For example, we might now expect to treat high cholesterol as a disease itself because it is identified as a risk factor for coronary heart disease (Dumit, 2012).

Other ways of developing and using an evidence base that incorporate social constructivist insights have been suggested. Miller et al. (2003) argue instead for a “double helix trial design” that would include two strands of inquiry, qualitative and quantitative, brought together by common research question, which in balance create reflexive but concrete and actionable knowledge around clinical care. Glasgow, Lichtenstein, & Marcus (2003) call for more explicit attention to the conditions and needs

of clinical practice when designing trials and suggest participatory research methods, and advocate for a shift in focus from internal to external validity –incorporating reporting of external validity measures into research literatures. Greenhalgh, Howick, & Maskrey (2014) push for an EBM “Renaissance” in which evidence would be generated by independent research sources where usability and sensitivity to context would define the gold standard: “the research agenda must become broader and more interdisciplinary, embracing the experience of illness, the psychology of evidence interpretation, the negotiation and sharing of evidence by clinicians and patients, and how to prevent harm from over-diagnosis” (Greenhalgh, Howick, & Maskrey, 2014, p. 4). While these literatures on EBM tend to focus on RCTs, many observations might equally be applied to other research practices like the use of electronic clinical data which – in the age of health information and communication technology (ICT) and clinical epidemiology – is perhaps as significant a source of evidence as RCTs.

As a final point, social constructivism have been used to examine technology in health care, whose effects are often otherwise assumed to be given. Timmermans & Berg (2003) review 25 years of scholarship in the journal *Sociology of Health and Illness* and identify two major ways that this literature takes up the question of technology in medicine. First, there is the argument that medical technologies are inscribed with ideological biases that structure social life. For example, in extensions of the medicalization critique, medical technology is presented as a tool for correcting deviance (e.g., pharmaceutical therapies for anxiety, depression, anger, alcoholism) (Conrad, 1979). A second prominent position, which Timmermans & Berg (2003) argue is consistent with a weak form of social constructivism, imagines technologies as passive entities that come to be meaningful through their interpretation in social environments. For example, Wiener et al. (1979) describe how the fetal heart monitor is defined in various social processes: mothers find reassurance in the device, providers enrol it as a tool for convincing others they’ve acted correctly.

In sum, social constructivist literatures have served to draw out and emphasize a social side to medicine. They’ve served to cast suspicion upon and critique the reductionism of positivist medicine. They’ve problematized medical categories and redirected attention to the lived experience of health or the meaning attributed to it in social

interaction, as opposed to its biological representation. They've raised epistemological issues related to context and generalizability with the evidence production and application in medicine and they've advanced alternative approaches. And it's clear that the social constructivist notion extends beyond explicit sociological literature. It has always existed in practitioner work that struggles to reconcile positivistic practices with complex human worlds. Social constructivism can be found in physician editorials in medical journals, discussions around the design of research or the course of action for a patient, calls for a return to the art of medicine, or in medical textbooks that now include sections on shared decision-making. To put it generally, social constructivism is found where there are people doing medicine in ways that show a recognition that the body, health, and medicine are not closed systems and cannot be objectively calculated and controlled.

2.4. Sociomaterial Practice

2.4.1. STS and the Turn to Practice

In sections 2.2 and 2.3, I have tried to outline a theoretical shift: from positivism's erection of objective truths, systems, and progress, to their erosion by a social constructivism that calls attention to the social mediation between the world and our conceptions of it. Both of these theoretical frameworks have been concretized in various ways in the worlds of medicine. I now want to introduce a second shift, one that has largely occurred within the field of science and technology studies (STS), and one that I think is only just starting to make inroads into medicine and medical research.

To start, I'll briefly introduce some of the history and commitments of STS. STS was born out of social constructivist critiques of the sort mentioned in section 2.3. Prior to the 1970s, philosophy of science was mostly preoccupied with defining ideal science and distinguishing between scientific and non-scientific knowledge (Sismondo, 2004). The goal of philosophers of science was to formalize the practice of science, to create a sort of code for scientists to follow to guarantee legitimacy and progress. Critique, however, continued to trouble these efforts. Historiographical accounts of scientific practice and progress revealed that the notion of formal science that had been advanced had never really existed, and far from guaranteeing progress, might serve only to entrench the status

quo (e.g., Lakatos, 1970; Feyerabend, 1975). Thomas Kuhn's (1962) book, *The Structure of Scientific Revolutions* was likely the most influential of these critiques. As mentioned in section 2.3, Kuhn replaced the formal view of science with one that claimed that scientific development was more like puzzle-solving, with the people involved enrolling the physical and conceptual tools available to them in a specific natural, social, and cultural environment. The revelation that scientific knowledge was shaped by the social exigencies of its production opened space for the development of sociological accounts of science.

With Kuhn's (1962) work as its foundation, the sociology of scientific knowledge (SSK), under the umbrella of Barry Barnes' and David Bloor's strong programme, emerged as a field that studies how collective scientific beliefs are distributed and the factors that influence their construction (Bloor, 1976/1991). As described in section 3.1, SSK is relativist and perspectival, it sets aside questions relating to the phenomena of the natural world and looks instead at the formation of perspectives about these phenomena. Likewise, social constructivist theories of technology like the social construction of technology (SCOT) were advanced. These views emphasized the design of technology as a product of complex human action, rejecting simplistic claims that technology was value-neutral or that it was simply an extension of instrumental rationalities of science and modernity (e.g., Ellul, 1964).

Within STS, however, some of these original social constructivist arguments opened up a quandary about the relation between epistemology and ontology, knowledge about the world and the world itself. The emphasis on developing sociological accounts of science had stimulated a small number of focused ethnographic and participant observational accounts of science and technology in practice, especially in laboratories (Woolgar, 1982). These accounts started to link science and technology to practices in a way that complicated the idea that knowledge generation was a matter of perspective, of culture, or an overarching interpretive framework to be revealed. They turned to science in action, signaling an

interest in patterned activities rather than rules, in speech and discourse rather than language as a structure, in questions about the use of instruments or ideas in a particular location and situation rather than in universal knowledge, in production and intervention rather than

representation, and in science as a mode of working and doing things in and to the world rather than as a system of propositions arranged into theories. (Amsterdamska, 2007, p. 206)

These practice-oriented studies aimed to ground discussions of scientific knowledge in rich empirical accounts of the day-to-day goings on of science. This aim is not in itself incongruent with early social constructivism like SSK, however, a major rift started to form as people attempted to sort out what form these studies should take, what exactly they were able to say, and what it meant to be reflexive while undertaking social study.

Steve Woolgar stimulated a number of these debates. As Woolgar (1982) points out, ethnographies of scientific practice “as it happens” allow analysts to see science first-hand, preserving its “craft character” (p. 484). One can understand the scientist’s work at the bench in the lab rather than rely only on the representations of their work they might provide in interviews. However, he argues further that while it is tempting to champion ethnography for its ability to offer a more precise picture of scientific work than analysis of second-hand accounts, there is more to the story. Ethnography, like any other method, can offer only a partial explanation. Woolgar finds that some ethnographers ignore this fact, and use their accounts instrumentally to “produce news” to discredit the formal, authoritative, positivist picture of science by revealing science in practice as mundane and thoroughly social (Woolgar, 1982, p. 484). Reflexive ethnography on the other hand, takes on an anthropological curiosity. Beyond reporting on what things are “really like,” it instead takes up the question of our “ability to relate perceptively to one another” (Woolgar, 1982, p. 484), which, especially in science studies, is largely a question of practical reasoning. Woolgar challenged STS scholars to ask what we can learn about reasoning in general by studying scientists.

This push for reflexivity was aimed squarely at SSK and the strong programme, which had spawned a number of these instrumental ethnographies. While reflexivity was a tenet of the strong programme, many accounts tended to lean on interest-based analysis, the idea that “change in or involvement with the content of scientific knowledge, the relationship between the social and knowledge products, is to be explained or understood in terms of the ‘social and/or cognitive interests’ of participants” (Woolgar, 1981, p. 367). Interest-based explanations allowed sociologists of science to draw on a

social theory toolbox to relate scientists' actions to overarching social structures, forces, and ideologies (Woolgar, 1981). While proponents of SSK argued that their work was reflexive in that they applied the same social theoretical tools to their own work (Bloor, 1976/1991), others asked if perhaps these tools were just like those of science— that is, constructed and contingent (Woolgar, 1981). The problem, then, was that the social study of sciences treated knowledge about the natural world differently than knowledge about the social world.

In short, these ethnographical differences raised two questions for STS to grapple with: (a) What can we learn about the nature of inquiry in general from observing scientists? and (b) How can we treat the natural and social worlds in symmetrical ways (or justify their asymmetrical treatment) (Sismondo, 2004)? These questions are taken up in Latour and Woolgar's (1979/1986) pivotal book *Laboratory Life: The Construction of a Scientific Fact*.¹³ In this text, Latour and Woolgar take an anthropological approach to following the construction of fact in the laboratory. Like other social constructivist work, they aim to demystify scientific knowledge and dispel the positivist notion of demarcation (the idea that the products of science are transcendent or distinct from non-science because they are born out of the formal application of a methodology). In this exercise, however, Latour and Woolgar attempt to depart from the usual character of such accounts of science which attempt to describe the social interferences (like the "social and cognitive interests" that Woolgar (1981) finds suspect) in scientists' otherwise technical endeavours. Rather, they note that this distinction between the technical and the social is one of the conceptual resources with which scientists work. So, in trend-bucking fashion, Latour and Woolgar commit themselves to not draw on the technical/social divide as an explanatory resource, and to look at it instead as a phenomenon to be explained. Accordingly, they also refuse to draw on overarching explanatory tools of social theory, attempting to approach the ethnographic setting with the tabula rasa of an anthropologist investigating an alien culture. The product that Latour and Woolgar arrive at is the idea that not only facts, but reality itself is constructed in the laboratory: "scientific activity is not *about* nature, it is a fierce fight to construct reality" (p. 243, emphasis in original). Scientists create order out of disorder, but in doing so they need to enroll and link together numerous

¹³ Note that the 1979 subtitle was "The social construction of a scientific fact" but in the 2nd 1986 edition, "social" was pointedly removed.

heterogeneous elements – skills, instruments, routines, materials, concepts, texts, institutional structures, etc. When these links become well-established, they form the network that constitutes a new order, a new piece of reality.

What Latour and Woolgar (1979/1986) advanced (with the help of many others) was a new kind of constructivism, one that has been central to STS work from the publication of their work until the present day. In a nutshell, it is the idea that the activities of science constituted not only a construction of knowledge, but also a construction of the world itself. This shift reframes epistemological concerns (how we know the world) as ontological concerns (how we make the world) (Mol, 2002).¹⁴ Nature and the social aren't causal mechanisms that science and social study unveil, rather they are themselves caused; reality is “secreted” by the activities that create order out of disorder (Latour & Woolgar, 1979/1986, p. 243). The [fragmented] shift towards this sort of constructivism over the last 40 years in STS – under the various labels of actor-network theory, material semiotics, ecologies, posthumanism, sociomateriality – has been characterized as the ontological turn or the turn to practice. The term “sociomaterial practice,” while not an “-ism”, is useful for capturing both that the social and material are co-constitutive and that they emerge out of activity.¹⁵

Perhaps the simplest way to describe this turn is using the *subject / object schema*. Indeed, this is the resource employed by two leaders of opposite camps in this turn, David Bloor and Bruno Latour, in a back and forth beginning with Bloor's (1999) *Anti-Latour* and Latour's (1999) response *For David Bloor... and Beyond*. The notion of the subject / object

¹⁴ As Woolgar (2013) points out, “the history of STS complicates any simplistic distinction (or transition) between ontology and epistemology. Contrary to those who see in ‘constructivism’ a programme focused on the investigation of ideational and discursive forms (see, for instance, Coole and Frost, 2010), the field has long advanced an analytical programme that foregrounds the instrumental, performative and material dimensions implied in the making of facts and artefacts (cf. Hacking, 1983; Haraway, 1991; Latour, 1988).” This is a weakness in how I've presented the 3 theoretical paradigms introduced in Chapter 2 as if they were distinct phases in a 3 phase progression.

¹⁵ Note that the turn to practice in STS has a number of antecedents in social theory, perhaps especially in Marxist theorizations of the practical and material. Marx saw philosophy as reflective of social problems in the real-world, problems which philosophy dealt with in abstraction (Feenberg, 2014). Progress in the realm of knowledge and theory, then, required practical change. It required a process of world-making through the constructive capacities of humankind (Feenberg, 2014). In this way, Marx blurred the distinction between epistemology and ontology in a similar way to theorists of the turn to practice.

schema, however, goes back to Plato and is central to the modern understanding of the human relation to the world of experience. The idea is that there is a fundamental division between the human and the non-human, or the knowing subject and the object that is known. We humans, as knowing and social minds live our lives in interaction with an external nature. The aim of the positivist sciences, then, is to formalize this interaction in such a way that we might come to thoroughly know and master the objective world. The original social constructivist argument, here, is that such a formalization is mediated by cognitive and social interferences, specific practices, instruments and thus will only ever be partial, one interpretation out of many. Both of these paradigms fundamentally rely on this division for their explanations.

However, as Latour and Woolgar (1979/1987) point out, we can think of this subject / object division as an open question . Like other conceptual frameworks, it is a resource which scientists and social scientists alike draw upon. What we have to do, then, is find ways to treat human and non-human actors symmetrically. This has two important effects for the social study of science. The first is that the material world is allowed to matter in way that might be anathema to previous social constructivist work. Earlier social constructivism was reluctant to involve the material world in explanations, because if indeed the material world really matters in the creation of knowledge, this seems to bring back the very problematic question of correspondence between the material world and our knowledge of it. It seems to say that the world might then be described in terms that are more or less true, bringing back all of the old problems of positivist realism that social constructivist relativism sought to escape. The turn to practices return to realism, however, is of a relativist sort. Since there is no presupposed outside object, there can be no “correspondence”. Rather, the material world is brought into being in the active relations amongst things and people. For example, we might think of the atom as a thing that does not exist outside of the laboratories, microscopes, cathode rays, physicists, technicians, models, theories, etc. with which it relates. And, since relations are themselves contingent and context specific, we might see reality itself as relativist – we act out only particular configurations and coordinations of relational networks, when many others are perfectly possible.

This leads to the second effect of dissolving the subject/object dichotomy: action is foregrounded. The subject/object schema resonates well with a static, spatial understanding of the world. We can freeze either nature or the social into models, structures, frameworks that, in a way, exist outside the passage of time. When we conceive reality as dependent on relations, however, things are brought into being and sustained through ongoing activity across time. This relational activity is generally referred to as *enactment* in STS literature. Woolgar (2013) documents how these approaches use the concept of enactment to refigure existing social scientific analysis. Enactment “implies a refusal to draw on ‘context’ as an explanatory or descriptive tool” and “emphasizes the generative power of the practices involved in the constitution of reality” (Woolgar, 2013, p. 323). Context is not so much a backdrop to front stage events as it is the active construction of reality. Objects are not embedded in a social context, they are created in this “context in action” where “objects are brought into being, they are *realized* in the course of practical activity” (Woolgar, 2013, p. 324, emphasis in original). Again, enactment talk signals a move away from the idea that the world is a concrete referent that humans come to know through experience and form various worldviews about. The world does not exist, what exists is instead a constant process of world-*making*.

2.4.2. What has Changed?

It’s worth stepping back here, and asking – how have the ways that we understand and study scientific knowledge changed over the course of the turn to practice? It is worth noting the fragmented character of what I refer to here simply as a turn. Turn to practice is a narrative tool that I and others use to bring together a complex of interlinked changes that have occurred largely within the field of STS, but also in exchange with other fields (notably, anthropology and feminist studies). In this section, I try to offer more of an exploded view of the changes that are encompassed within this turn, with an eye to specific premises that have changed and what they mean for doing social studies of science today.

Practices as Situated Action

In the previous section, I described how the change brought about by the ontological turn was one where material things were now allowed to matter and they came

to do so in the course of practical action. This leaves the analyst with the job of following this action and relating it to the emergence of concretized things. Suchman (1987/2007) frames this shift as moving away from a “cognitivist” understanding of the world, where it is presumed that human behaviour follows from “mental states” (prior knowledge, belief systems, plans, logics) that mediate the experience of the natural world (p. 37). In its strongest form, cognitivism sees human activity as computational, as essentially the running of a highly responsive code that takes sensory experience as an input and subsequently outputs a calculated behavioural response (Suchman, 1987/2007). Cognitivism and positivisms are clearly complementary, however, cognitivism is also a fundamental element of social constructivism. If we recall that the focus of social constructivism is on the mediating influences that are wedged between the natural world and our knowledge of it, it is clear to see that many such influences would have to be cognitive. From the social constructivist viewpoint, social orders, conceptual frameworks, and inherited assumptions must to some degree be programmed into cognition before manifesting in behaviour.

Suchman (1987/2007) makes the argument for a rejection of cognitivism in favour of a theory of situated action. Her claim is that the notion of cognition (or what she calls *plans*) is itself a construction. Plans are merely a resource to bring coherence, significance, and intention to situations of action. The true activity of everyday life is instead situated action: “actions taken in the context of particular, concrete circumstances” (Suchman, 1987/2007, p. 26). Suchman argues that human action is always practical and ad hoc, tied to the shifting material and social circumstances of the immediate situation. The plans that we relate action to, that present action as the coherent result of a cognitive order, are post-hoc reconstructions that “systematically filter out precisely the particularity of detail that characterizes situated action, in favour of those aspects of actions that can be seen to accord with the plan” (p. 26). These plans, as after-the-fact reconstructions, would include both cognitive scientific logic as well as sociological structures.

The question, then, is how do we account for continuity? It would, of course, be an absurd proposition to suggest that action proceeds without reference to any prior experience or social conditioning – so what about all of the seemingly enduring determinants of action: “prescriptive representations, past experience, future

considerations, received identities, entrenched social relations, established procedures, built environments, material constraints” (Suchman, 1987/2007, p. 27)? Suchman’s argument is basically that the way that these prior forms come to play a role in a situation and the way that they are reproduced is always underdetermined. They are themselves enacted within practices, among shifting relations with heterogeneous actors: “the point in the end is... to identify the materialization of subjects, objects, and the relations between them as an *effect*, more and less durable and contestable, of ongoing sociomaterial practices” (Suchman, 1987/2007, p. 286, emphasis in original). In social constructivism, practices and material/technical entities were simply another manifestation of pre-existing social forms, the social constructivist analysis attempted to access the social that was manifest or underwritten in them. After the turn to practice, the analysis becomes the study of interactions, the creation and maintenance of associations between heterogeneous things. This has notable methodological implications, pointing to the need for empirical accounts of action (apart from, for example, interview accounts). And since action is where reality and knowledge are made, it makes sense to look at knowledge not only as something that is known but as something that is done. In studying action, we study the intertwined ontological and epistemological process.

Partial Perspective and Situated Knowledges

Donna Haraway (1988) extends the argument for understanding action and knowledge as situated. She argues for what she describes as a “feminist objectivity” – or situated knowledge – in which we give up the myth of a “view from nowhere” (and its equally mythical counterpart –the transcendent view offered by the hyper-technologically-enhanced) and embrace the “view from somewhere” (p. 590). For Haraway, the “objective” view must admit its partiality; it must attend to its embodiment, “always a complex, contradictory, structured, and structuring body” which means that a claim about the world must be qualified through an interrogation of the vision mediated by an interaction between a particular self, a particular social environment and history, and particular technologies. Whereas traditional objectivity demands replicability for knowledge to be accountable, feminist objectivity demands locatability (Haraway, 1988).

This emphasis on tying knowledge to its local mode of production may seem to suggest that all knowledge is relative. However, Haraway (1988) is uninterested in making

an assertion for realism or relativism in any way. The realism/relativism debate is itself an argument for a decision on what knowledge *is* – and for Haraway, arguing about what things are is beside the point. Rather, what is interesting is the way things come to be and what things do. She wants to track the “resonances” of each incomplete, underdetermined decision affecting knowledge production (Haraway, 1988). By decision, here, I refer to the translation, interpretations, or partial renderings of an ambiguous world that artificially resolve it. Such decisions might be embedded in a technology, method, or gender that form the machinery of objectification – the sum of these decisions, or their combined force, determine the final decision as to what reality becomes. So Haraway is asking – what decisions should count? What do each of those smaller decisions do to their final product?

It is important to note, here, that for Haraway (1988) decision is not solely a social act. She would disagree with the idea that truths are a cognitive construction of humans. Indeed it is not difficult to see how the affordances and constraints of an object (in relation to other actors) might affect how it is decided. One might have difficulty, for example, deciding one’s coffee cup as a mode of transportation. However, Haraway’s argument extends beyond this difficulty: why should we think that we have the right to decide the world? And what effects does that assumption have on our knowledge of it? Always attentive to the privileging of position, she doesn’t afford the human a specially privileged position in the make-up of the world. She insists upon the agency and recalcitrance of things, a thing is to be taken as an “active subject, not as a resource to be mapped and appropriated” (p. 593). The logic of research is not to discover the secrets of a passive and external nature but to create a “power-charged social relation of ‘conversation’” (p. 593). What Haraway means by this is that when we take research as conversation, we submit that we are not in control, we can never definitively know our conversant’s mind, and through this submission we allow ourselves to be ready for the unexpected, we can (to some extent, but never totally) prepare ourselves for response, redirection, and failure: “The Coyote or Trickster, as embodied in southwest Native American accounts, suggests the situation we are in when we give up mastery but keep searching for fidelity, knowing all the while that we will be hoodwinked” (p. 594).

Complexity

Science brings order out of disorder. It takes an apparently chaotic world and makes it fit equations, models, pictures, stories, graphs, theories, probabilities, and facts. The narratives of social studies of science do the same. They explain, they give reasons, they reveal backstories, and social forces at play. When this is done, things are left behind and suppressed, only a minority of actors make it into the lab report or the journal article:

The texts that carry academic stories tend to organize phenomena bewildering in their layered complexity into clean overviews. They make smooth schemes that are more or less linear, with a demonstrative or an argumentative logic in which each event follows the one that came before. What may originally have been surprising is explained and is therefore no longer surprising or disturbing. Academic texts may talk about strange things, but their tone is almost always calm. (Mol & Law, 2002, p.3)

Complexity is the everything else that overflows the boxes in which we attempt to put the action of reality when we give it order. It is something that positivist work (which wishes to claim that its explanations are total, or at least approach totality) attempts to ignore. This line of critique (that positivists simplify, reduce, do violence to their objects) is somewhat of a trope of social constructivism (Mol & Law, 2002, p. 6). It provides an initial justification for doing rigorous qualitative work, for producing what Geertz (1994) refers to as “thick descriptions” of phenomena to overcome the thin ones offered by the positivist sciences. But, of course, even thick descriptions leave complexities behind. The challenge, then, is to find ways to respect complexity, which entails, as Mol & Law (2002) argue, attention to “what happens to complexities when simplifications are made” (p. 6). Doing research after the turn to practice entails not simply a critique of reification, but tracing the resonances of the reified. It means looking carefully at how things – texts, representations, labels, assumptions, intuitions, methods, technologies – resonate in and structure their environments (Mol & Law, 2002). Again, the concern is less what things truly are (for that question is irresolvable), but about what they do.¹⁶

¹⁶ I try to observe this point in my writing in this thesis (though it is admittedly difficult!). For example, rather than speak of what positivism *is*, I attempt to articulate it as a product/producer of activities – what it does, how it has been done - and try to make transparent my forced simplification of it as a singular concept.

Multiplicity

Traditional social constructivism allowed for a multiplicity of perspectives, but it assumed, like science, that these perspectives related to one concrete referent object. For practice-oriented research, this is no longer the case. Rather, since things are enacted and sustained in the forming and reforming of relations with other people and things, we might see them as only local productions. Our modern language and understanding of the world, however, is in general not attentive to this localism. Annemarie Mol has produced perhaps the clearest account of multiplicity in her 2002 book *The Body Multiple: Ontology in Medical Practice*. Taking the disease atherosclerosis as her example, she shows how it is brought into existence, performed, or enacted by the many different experts and many different tools and techniques that the medical world has to offer. In the physician's examining room, atherosclerosis might be pain after walking a specific distance or a poor ankle/arm index (the measured pressure differential between arm and foot). In the pathology lab it is a microscopically enlarged thickening of the vessel wall. On an angiogram, it is an observed percentage lumen loss while on a duplex ultrasound it is a certain ratio of blood velocities. In the surgery theatre, it is the vessel wall visible to the naked eye. And at every site where Mol observed the enactment of an atherosclerosis, people were not the only actors. Blood vessels, pens, techniques, words, forms, patient records, insurance systems, stethoscopes, fluorescent lights, classification systems – a veritable web of heterogeneous objects participate in the making of a medical diagnosis (Mol, 2002).

Mol's (2002) storytelling shows the reader how to abandon the very comfortable, intuitive idea that there is a single atherosclerosis, an objectively present disease that is simply being interpreted in diverging ways, and to see atherosclerosis instead as multiple – as different performances involving very different configurations of people and things. Moreover, she shows how the singularity of atherosclerosis is something that is achieved, multiple performances are made to “hang together” as one (p. 5). In this way, her analysis is a strikingly situated one. It works explicitly and meticulously to trace the origins of the abstractions she sees practitioners making, to investigate and disassemble links that are otherwise taken for granted.

Ecology

Mol's atherosclerosis is enacted in various worlds of practice, composed of many interacting heterogeneous parts. How might these worlds be studied? Star (1995) calls for an *ecological* understanding of science, which means "trying to understand the systemic properties of science by analogy with an ecosystem, and equally important, all the components that constitute the system" and "refusing social/natural and social/technical dichotomies and inventing systematic and dialectical units of analysis" (Star, 1995, p. 2). The change advocated by Star has everything to do with what can and should be topicalized in social study, it means leaving open the question of what is important to a particular situation. This requires a dissolving of traditional notions of social study that, for example, might enter with preconceptions of how activity is being structured (recall the medicalization literature) or that denies the meaningful participation of material things and the concrete settings of practice, or that forgets or ignores the complexities of the seemingly mundane (e.g., forms, infrastructures, door-closers). Importantly, the notion of organizational or analytical scale disintegrates here; if all of the components of a situation might be equally offered the opportunity to matter, then the role of the electron, notepad, calibration, professional hierarchy, institutional mandate, or the capitalist commodity form can never be assumed or slotted within a hierarchy of micro and macro influences (Star, 1995). As Suchman (1987/2007) argues, even for enduring cultural, historical, and social orders which one might consider to have a structuring, inertial, or determinative effect and which we might pre-emptively fit into dichotomies (of the micro/macro, local/global), all survive and are reproduced in daily everyday action: "it is only through their everyday enactment and reiteration that institutions are reproduced and rules of conduct realized" (p. 16). Thus, ecologies are always emerging, and our understanding of them is more precise if it follows this emergence empirically, tracing action as a process of structuring rather than as a process of structures being revealed.¹⁷

Reflexivity and the Role of the Analyst

Steve Woolgar has led the charge for a re-evaluation of the role of the analyst in science studies (see also section 2.4.1). Prior sociological work provided the analyst with

¹⁷ This is the central argument advanced in Latour's (2005) *Reassembling the Social*.

the privileged position of representing the field that they studied and the people within it, gathering inside information from informants. Their role was to apply a different kind of expertise to the analysis of the situation, they were engaged in a “scientific” social science – one that brought to light the relevant, causal social relations at work in any particular setting. For Woolgar (1995), this standpoint makes little sense: if our aim is to understand a scientific culture that fundamentally leans on the notion of representation (phenomena of the natural world can be more or less accurately represented), then why adopt that notion in our own study? Why not make that notion itself an object of study? Again, as Star (1995) argues, we might expand the domain of analysis to even the most basic theoretical assumptions that underlie inquiry.

Next, in expanding this domain, why not expand it to ourselves as the analysts? Might our role be relevant? As Woolgar (1995) argues, if we are to critique scientists for their authoritative explanations of a passive world, then who are we to authoritatively explain passive scientists? The most immediate implication of critically examining our own role is the recognition of the paternalism, pretension, and power inherent in the assumption that the social analyst knows best which elements are important to the situation under study. As Callon (1986) argues, sociologists have a tendency to censor attempts by the scientists they study to comment on social structures. This censorship forecloses on what might be an extremely valuable insight into what matters in a situation. If the analyst is looking for controversies, crises, instabilities, or contingencies, why ignore the indicating signs of the actors embroiled in them? Why instead pick a unit of analysis that is most familiar and impose alternative explanations from the sociological toolbox?

2.4.3. Critiques

The turn to practice brings together questions of knowledge creation and reality, and correspondingly, sociological empiricism and philosophy. It is perhaps unsurprising, then, that it comes under attack from both of these camps. In this section I’ll point to some of the many objections advanced by critics. My goal is to outline the contours of some of these debates, and point to some reasons why I think these critiques fall short of devastating. An exhaustive engagement with them is a career’s work (seemingly that of Bruno Latour’s).

Too Idealist

First, I'll introduce an objection that is regularly raised against this new constructivism, though I believe it mostly to be a misunderstanding. Many perceive a practice-oriented ontology as suggesting that things are simply "how we do them." Amsterdamska (1990), in her critique of Latour's (1987) *Science in Action*, argues that such a claim means that if a group of people thinks and acts as if the tram is faster than the bus, then this somehow makes the tram actually faster than the bus. Or, more concerning, that this claim "allows us to say that when the South African government's belief that Blacks are inferior serves as the basis for the policy of apartheid, by this very fact it somehow becomes 'more right'" (Amsterdamska, 1990, p. 499).

I think the confusion centers around one point: Amsterdamska (1990) and others retain the subject/object schema in their critique of the turn to practice. For example, Amsterdamska's problem is that action guided by a certain fact makes that fact "more right". However, her interpretation here of "more right" is something like "closer to how things really are." The fact, for her, is a subjective representation of an objective reality. It is easy to see how the notion that representation somehow causes reality to change would be disagreeable. But this is not what Latour and others are arguing.¹⁸ For the theorists of the turn to practice, the fact is simply the contingent product of the particular machineries that make and sustain it (the actions of human/non-human actors involved). It cannot be right separate from the particular circumstances of its production. Examining the claim that the tram is faster than the bus, for Latour, would not be a question of "she acts as if it is so, so it is so" but of following the actors, actions, and resulting associations that are required to make that claim: the conceptual frameworks for space and time, watches, tram and bus trips, calibrations, rules, maybe a controlled experiment, maybe average velocity calculations, etc.

¹⁸ Amsterdamska appears to be interpreting *Science in Action* as neo-Kantian constructivism, the theory that representation gives rise to the object. Her argument is not necessarily misplaced – in earlier work Latour and Woolgar often slipped into explicit representationalist expression. Critiques like Amsterdamska's have likely ensured that in future work they would take more care!

Too Realist

Ironically, another vein of critique makes the opposite claim to the first that was mentioned. Levied primarily by the SSK camp in STS, this critique argues that the new constructivists, in taking seriously the role of the material world in knowledge creation, are regressing towards positivism, giving credence once again to the notion that some claims might be more objectively true than others (see, for example, Bloor, 1999). This critique stems from SSK's commitment to not say anything about the things-in-themselves which, as the social constructivist insight goes, can only ever be accessed via problematic mediation.

Again, this critique does little damage because it relies on its own presumption that the subject/object division exists and is not worth examining as a phenomenon itself. Latour (1999) addresses this presumption at length in his response to Bloor's (1999) article *Anti-Latour*. Latour's primary critique of Bloor's position is that he denies the ability of the material world to have an effect on society, to "make a difference" in our accounts of the world (Latour, 1999, p. 117). Such a position is anti-empirical in that it sees the constructions of scientists as being manifestations of social convention. When applied also to social science, it creates a dynamic of "bootstrapping", where the analyst must make reference to social convention to explain how all knowledge is the product of social convention (p. 118). On the charge that the new constructivism might tend towards a return to realism and absolutism, the debate remains somewhat open in STS (Sismondo, 2004), but it seems implausible to construct a discipline on the self-referential ground of social convention. It makes sense to be anti-realist only because realism indicates a realm that is untouched by the mediating influence of the social (where the social refers to the mediating influence of human interpretation). The social for constructivists after the turn to practice, however, is not about interpretation but about relation, it isn't an influence as much as it is the fabric of reality. Thus, the objects that receive treatment under methods like actor-network theory (ANT) are not taken as asocial (the fear of SSK-ers), but as contingent on relations that are always intrinsically social in a different way. This shift in understanding the meaning of the social is why Latour (1990) suggests that "a little bit of

constructivism takes you far away from realism, a complete constructivism brings you back to it” (p. 71).¹⁹

Ethnography vs. Philosophy

Winner (1993) asks the question, “Where does one go to learn what one needs to know to write confidently about philosophy and technology?” (p. 363). Constructivists after the turn to practice (and social constructivists before them) argue for fine-grained empirical analyses, usually via in situ ethnographic accounts of the actors, artifacts and activities that might be relevant to a particular question. They pride themselves in accounting for detail, nuance, and complexity of their explanations. Winner (1993), however, is concerned about larger questions: (a) the downstream social consequences of technical choice, (b) social groups that are unattended to, and (c) the basic underlying conditions of structure and culture. Winner (1993) feels these questions are left out of constructivist accounts in favour of a focus on the process of construction and the contingent origins of scientific knowledge or technology (the opening of the black box). Winner sees the constructivist approach as fruitful, but ultimately too narrow. Latour (2005) frames this debate as “critical distance” (of philosophy) versus “critical proximity” (of ethnography) (p. 253).

Winner’s (1993) first concern that constructivists seem unconcerned about the social consequences of technical choice has, at least since 1993, proven to be untrue. With the rise in interest in science and technology as sociomaterial practice, constructivism that was previously more interested in revealing mediation, contingency, and underdetermination tends now to be more concerned with the impacts of facts or technologies (things that are ripe for ethnographic, practice-oriented study).

Winner’s (1993) second concern is that precise analyses of relevant social actors does not problematize who the actors are. It doesn’t consider non-actors, non-present solutions and this imbues it with an implicit conservatism: it attends only to the needs of what already exists. I think that this is a very strong point, and one that constructivists must be attentive to. Feenberg (1999) adds to this critique, arguing for a “symmetry of

¹⁹ Sismondo (1996) gives this question a full treatment.

program and anti-program” (p. 119), that is, ensuring that the analysis of the status quo accounts equally for what is absent or suppressed. The question is, however, who is best positioned to recognize absence? The philosopher or people doing work on the ground? I think there is a practical orientation to the conservatism of attending to what exists in that alternatives can’t take root in nothing, they must interrupt and emerge from the status quo. Similarly, normativity isn’t given, but rather emerges in the situated activity of the researcher (Jensen, 2007a). The program of practice orientation is to first recognize differences, alternatives, frictions, then to articulate them in as rich of terms as possible, and widen the interstices of how things might be done. We need to show how they might work, give them what resources and attention we can, and get buy in from current players.

Winner’s (1993) final argument is that constructivist approaches remain ignorant of macro social forces (e.g., class, technological rationality) at play in a given situation. Latour’s (2005) *Reassembling the Social* is devoted to refuting this argument. His and others’ central argument is that to introduce these macro social forces a priori is to impose order from nowhere (Haraway, 1988). This isn’t to say that they don’t exist, but rather that they should be located empirically in the goings on of the situation under study, where they will be uniquely expressed. Also, it is only with proximity that an analyst can see how such forces may matter, determine if indeed they matter more than other concerns, and locate potentialities for how they might be overcome:

With respect to the Total, there is nothing to do except to genuflect before it, or worse, to dream of occupying the place of complete power. I think it would be much safer to claim that action is possible only in a territory that has been opened up, flattened down, and cut down to size in a place where formats, structures, globalization, and totalities circulate inside tiny conduits, and where for each of their applications they need to rely on masses of hidden potentialities. If this is not possible, then there is no politics. No battle has ever been won without resorting to new combinations and surprising events. One’s own actions make a difference *only in a world made of differences*. (Latour, 2005, p. 252-253, emphasis in original)

Latour’s (2005) point is that pitting ourselves at the outset against the presupposed heavy machinery that underpins all activity is unproductive. We might rather map the territory, find frictions, infiltrate networks, learn the levers that might be pulled, explore the space

between fact and fiction. Rather than goddesses, seeing and proclaiming from on high, we might be cyborgs (Haraway, 1991).

However, as Haraway (2004) argues, there is a risk inherent in the rejection of traditional social explanations. It is very easy for accounts of practice, in their desire to be empirical, to flatten, and to reject reference to “old social ghosts” (p. 116), to abandon questions of how societal inequalities are done in practice. An overeager obsession with the local and immediate can engender a blindness to the fact that practice is taking place in a built environment of discourses and technologies. If practice is to be the focus of inquiry, there needs to be intense attention to how it bleeds beyond the immediate interaction of people and their machines. Latour’s (1995) concept of “delegation” may be useful here. Delegation refers to how artifacts take the place of human action and shape or constrain settings of practice, and prescribe power, values, morals, and ethics (Latour, 1995). Haraway’s (2004) point is that too often accounts of practice forget this delegation.

Politics

The shift from philosophy to ethnography does raise questions as to how politics has been transformed and what implications this transformation might have for social struggles for justice. Proponents of constructivism after the turn to practice are hopeful. Shifting from the understanding of a singular world as the referent for competing worldviews to multiple worlds that are created moves politics out of the discursive realm (politics as battle of ideas and argument) into the action realm (politics as world-making). As Woolgar (2013) describes, the turn to practice allows for a move from “cosmopolitan irony,” the idea that we can ever achieve approximate rationality (e.g., achieving Habermas’s ideal speech situation), to “cosmopolitical choices..... in which world would you like to live and what can you do to bring such a world into being?” (p. 326). Latour (2005) picks up on this point, arguing that political philosophy has long been accustomed to diagnosing and treating the social conditions that enable democracy, that we know how to “assemble relevant parties, authorize them to contract, to discover ideal speech conditions, to detect legitimate closure” (p. 6), yet we continue to ignore the objects that have brought everyone to the table. Latour sees politics as a positive project, one that seeks to reveal potentials, rather than a negative one:

Dispersion, destruction, and deconstruction are not the goals to be achieved but what needs to be overcome. It's much more important to check what are the new institutions, procedures, and concepts able to collect and to reconnect the social. (Latour, 2005, p. 11)

Mol (2002) describes this as a shift from a "politics of who" (who decides what should be done?) to a "politics of what" (what is the thing about which a decision must be made? What should be done?) (p. 166).

These theorists argue for the need to develop rich accounts of the sociomaterial practice. They point to how our current explanations of things are impoverished when we assume their singularity, their objectivity, or their distinct technical and social dimensions. The political, then, is not about the act of arguing for one worldview over another, but of populating and nurturing worlds. Instead of being an ideological position, it is the action of showing how things could be otherwise, of producing difference. And if we might define domination as the control of difference, then the act of producing difference is, as Holbraad, Pedersen, and Viverios de Castro (2014) characterize it, "constitutively anti-authoritarian" (para. 13).

There remains, however, concern that an operationalism is replacing a moral imperative for change after the turn to practice (Feenberg, 2002). Analysis focused on what empirically exists empowers the dominant actors and activities that make up this reality. And if politics is taken as only fostering openness to alternatives, it takes away the ability of the marginalized to stake their case on a notion of justice. They must instead work to articulate their ontology as one alongside more stable or established ontologies. Again, the concern is that analysis at close proximity may not account for alternative ways of being. The response of theorists like Mol to this concern is that understandings of "the good" are found in local contestations and are not acted out or fought for in a straightforward or risk-free way (Mol, 2002, ch. 6). Rather, the good is multiple and uncertain, and its achievement requires circumstantial action – tapping into potentialities, jumping on opportunities, preparing for surprises. In this way, operationalism doesn't suggest a total absence of normative commitment, it means rather that normative positions emerge from and are situated in particular unfolding circumstances. Practice-oriented inquiry simply suspends normative commitment (e.g., it may choose to neither assume an a priori alliance with technical experts or a lay public) so that emergent

normativity might be evaluated in context. However, the situated researcher must take care also to avoid strictly delimiting what an active context can be. If preoccupied with proximity, we may neglect the structuring action that happens at a distance (say, in the design of a computer system that is now in use or the crafting of a mandate for an institution).

2.4.4. A Caveat

My aim in this thesis is not to argue that the subject / object ontology or the positivist or social constructivist ways of working be abandoned. The turn to practice is instead a new method, ontology, and line of critique to be added to others. It provides a new way to frame, conceptualize and explore questions. It also undermines other methods by introducing activity as a new criteria by which they might be scrutinized. Where positivists might say they have minimized bias, practice points to the ways in which a bias of a different kind is inscribed in the methods used. The clinical trial, for example, creates knowledge only via particular configurations of sociomaterial practices. The trial happens in specific locations with specific patient groups. It uses specific forms, rubrics, or classificatory systems. Its patients are evaluated in specific ways and only specific indicators of wellbeing are measured. Does this suggest that the clinical trial should be discarded as a method? Should it be replaced by ethnographies of experimental drugs? Certainly not, and it may be unlikely that a practice-oriented ontology could produce a construction as elegant and effective as the clinical trial, or achieve the benefits it has to offer. But we can bring doubt and introspection into the process by attending to how the clinical trial shapes its object, the ways in which it gives order to disorder, and what the implications of this ordering are: What uncertainties does it gloss over? Who is left out? How is the trial different from everyday care? We can locate the information produced by a clinical trial to its origins in practices and we can open up the question of how things might be done better or otherwise.

Likewise, we might reconsider some of the longstanding epistemological critiques offered by social constructivism. We can poke at some assumptions: How do we know this or that social interest is dominant for this situation? Are there major players that are missing from our accounts? In what ways do our accounts of others enact them? But

there is, of course, still room for social constructivist work. Indeed, social constructivism has opened up considerable space for understanding the world in different ways – and it has achieved mainstream traction. Referencing society and social forces, factors, or dimensions remains a powerful and intuitive way to bring attention to contingency and to bring forward alternative renderings of what is possible, especially in modern societies, where the coordination of activities rarely takes place in one site. For instance, if we want to understand the proliferation of medication use, where do we look? Which things and practices matter? Certainly, observing physicians in consultation will offer some insight. But at the same time physicians are attending all-expenses-paid meetings hosted by drug companies, medical journals are taking in advertising revenues, drug companies are suppressing trial results and quietly negotiating legal battles, pharmacists are trying to meet dispensing quotas; people are self-diagnosing via the internet. Policy, copyright, profit margins, insurance schemes, economic ideologies, and cultural norms are at work. Is the solution to bring sociologists into the boardrooms, have them sit in on the sales pitches, go to the courts, or go home with patients? The idea is intriguing and could be extraordinarily fruitful, however, it's also impractical. We might find ourselves lost and disoriented by fragmented partial accounts, and, engrossed in the fine grained inspection of individual pixels of activity, we might miss a bigger picture. Here, we might turn again to well-developed analytical avenues of social theory. We might follow the money and consider how relations of production play an undoubtedly powerful role in widespread pharmaceutical use. We might consider how class, consumerism, privatization, specialization, conceptions of risk, or scientific management might structure the action on the ground. We might even tell stories of how medical hubris, narratives of progress and domination, or technological fetishization factor in.

Theorists like Latour (2005) have offered impassioned arguments against these supposed shortcuts of social constructivist theory and method. However, practice-oriented work doesn't escape this concern, and indeed, deserves skepticism as an analytical category that appears to offer universal explanatory power. Gad & Jensen (2005) argue that practice as a conceptual tool can be taken up like a "magical charm" (p. 705), that guarantees a more accurate or novel analysis because the activity that it describes is taken as unmediated empirical data that is "simply 'found'" (p. 699). Here, I argue that the researcher's choice of ontology or method must also be situated, attend to

practicalities and particularities: What type of analysis is best for the question at hand? What type of analysis is feasible? When industry develops a new drug, let's turn to clinical trials to detect small differences between the new product and the current standard. When the production and control of essential drugs is left to a US\$300B industry (World Health Organization, 2016), we might turn to political economy to see how power is wielded, who is exploited, and who is left out.

To close her account of ontological multiplicity in medicine, Mol (2002) states that “presenting the *body multiple* as the reality we live with is not a solution to a problem but a way of changing a host of intellectual reflexes” (p. 184, emphasis-in-original). Reflexes are actions that are done without thought; they are habitual, easy, and predictable. In bringing attention to them, we expand possibilities. Mol's goal (and mine) is not to circumscribe new boundaries that disqualify ways of knowing and doing the world, but to stretch those boundaries to include much more.

2.4.5. Doing Medicine

How might an understanding of action as situated and objects as enacted in practice change our understandings of how medicine is done? How does it change the way that we undertake the social study of medicine? As described in section 2.2.1, the last several decades have seen a major shift towards research-based interventions medical practice. This shift has redefined what it means to do medicine well (emphasizing the application of research findings) and, along with a growing number of financial, legal, and administrative demands, engendered new demands for clinicians to account for their activities (account both in the sense that they are held answerable and they are required to extensively document their activities). This is not a bad thing in itself, however, it has meant that formal conceptions of how medicine should be done (often from the standpoint of researchers, managers, lawyers, or policy-makers) have increasingly been prioritized over practice.

In this environment, perhaps the most significant aspect of a practice-oriented ontology is that it fundamentally re-prioritizes the activities of medical care. Planned understandings of medical work – and the normative assumptions that are embedded

within them – are taken not as transcendent or unquestionable, but as contingent objects whose effects in practice need to be explored. For example, several STS theorists in healthcare have examined the effects of ICTs in healthcare which are often enthusiastically adopted with the presumptions that their benefits are self-evident or that their implementation will be unproblematic so long as they are technically sound. As well, the field of computer supported cooperative work has started to expand traditional understandings of how information technology is designed. But the objects of medicine extend beyond physical objects like medical technologies – researchers might take an interest in diseases or diagnoses (e.g., Mol, 2002); information infrastructures (e.g., Star & Bowker, 2000); clinical guidelines (e.g., Berg, 1997; Zuiderent-Jerak, 2007); normative conceptions of care, safety, accountability (e.g., Jerak-Zuiderent, 2012; Jerak-Zuiderent, 2015); knowledge translations (e.g., Jensen, 2007b); clinical data (e.g., Balka & Schuurman, 2009); or the normative orientation of evidence-based medicine (e.g., Timmermans & Berg, 2003; Timmermans & Mauck, 2005).

Given these examples, it is clear that one consequence of the turn to practices is that it opens up the domain of inquiry in the social study of medicine. Previously such study confined itself to examining the social side of medical objects like disease (i.e. illness and stigma), and left the technical side to the expert physicians, surgeons, bioscientists, and engineers (see section 2.3.1). Social researchers were often attracted to sexier or more politicized issues and big questions within medicine, like “access to care, health inequality, medical hubris, reproductive technologies, HIV-AIDS, or genetics” (Timmermans & Berg, 2003, p. 106). Or, as Mol (2002) argues, ethicists and social scientists have focused their attention only to the “pivotal points” of decision-making in care (p. 169), like the moment in a physician/patient consultation about whether to undergo an operation.²⁰ However, this is not the only moment of contingency, there are countless others that are involved in this decision-making that are not present in the deciding moment designated pivotal (Mol, 2002). As Timmermans and Berg (2003) point out in the article *The Practice of Medical Technology*, there is perhaps more to learn from

²⁰ There is another point here that the “pivotal points” are often chosen because they are moments whose contingency appears to be based entirely on a human agency. In the “social/technical” divide, these moments are of a greater potency, of greater meaning to epistemology and change, than a moment of interaction involving one or more material things. Latour (1988) addresses this issue in *The Pasteurization of France*.

the study of “the seemingly mundane, ‘infrastructural’ technologies – such as records, information systems, standards, small home-care technologies, clinical research guidelines” (p. 108). These are the technologies that are ubiquitous, that concretely structure medical worlds and patient lives, and due to their very ordinariness escape scrutiny. Only fine-grained analyses of practice can capture the quiet but often radically restructuring influence of technologies on day-to-day activity (Timmermans & Berg, 2003).

This attention to structures as they emerge shifts the normative character of social studies of medicine, which might have previously started from a commitment to critiquing medicine as a positivist or technocratic enterprise. Certainly these tendencies remain worthy of study, but instead of being taken a priori as faulty underlying mechanisms, they are taken as the specific actors and activities that comprise them – as “people doing things together” (Becker, 1986) to particular effect. Brives (2013) offers an account of clinical trials that richly exemplifies this empirical and practice-oriented way of carrying out social study in medicine that is still critical. She points to how the rigidity of scientific understandings of clinical trials, and the failure of sociological analyses of clinical trials to “apprehend the subject in terms of their very adherence to the trial and practices making up the trial,” are manifestations of the social/technical divide (Brives, 2013, p. 398). In either the social or the technical literatures, the actual practices of the clinical trial were an “unquestioned premise” (p. 397). In contrast, her account provides a rich narrative of the action of a clinical trial, the ways it figures patients as scientific subjects, and the translation of the personal and clinical interactions involved in patient health into quantitative terms and a ruling of efficacy. In this way, Brives counters the notion that technical activities have a transcendent or even coherent character, a notion that even critical literatures attribute them in reifying them as one category opposed to an organic other (Haraway, 1991). What emerges is a challenge to the idea that medicine is, or ever could be, a coherent whole: “it is, rather, an amalgam of thoughts, a mixture of habits, an assemblage of techniques.... a heterogeneous coalition of ways of handling bodies, studying pictures, making numbers, conducting conversations (Berg & Mol, 1998, p.3). This challenge is not only against the simplifications of the medico-scientific practitioner, but also the social analyst. The macro-structures, theories, or lenses of the social are tempting to apply to the world of medicine, yet may fit poorly or lack the necessary granularity that would offer

insight into the complex decision-making and technologically mediated practices of the clinical environment (Berg & Mol, 1998, Timmermans & Berg, 2003).

Taking an interest in fine-grained analyses of practice means that particular methodologies are prioritized, especially those capable of foregrounding materialities and practicalities in detail. Such methods have frequently been grouped under the general heading of ethnomethodology, which combines grounded theory, immersive participation and observation in communities of practice, and concern with action and sense-making (Have, 2008). Ethnography is usually central to such approaches, attempting to bring to light both human activity and the material circumstances under which humans act. Mol (2002) suggests that after the turn to practice, ethnography might be better be termed “praxiography” (p. 32). As well, interdisciplinary and collaborative approaches to research like action research, participatory design, or workplace studies are seen as particularly fruitful points of intervention.

As researchers become more attuned to the practical struggles of the physicians, nurses, pharmacists, engineers, and managers that they work with, opportunity is opened for them to bring careful analytical attention to frictions that already exist: technological frustrations, ‘uptake’ failures, collaborative breaks, blunt protocols, bureaucratic demands, professional hierarchies, competing definitions, value conflicts. This requires new modes of entry into research collaborations, and demands that the researcher take on new roles further from “neutral observer” than ever before; they are themselves entering into a set of relations that enact them in particular ways and their action too is practical and situated (Boulus, 2010, Suchman, 1987/2007). Timmermans and Berg (2003) suggest that by reconsidering the role of the researcher in this way (from external analyst to situated collaborator), the social scientist might engage in a dialogue with medical practitioners and medical worlds, where the previous subjects of research become partners, articulating their own accounts of contested terrain on their own terms and the qualitative researcher can make their stories explicit and visible. In this interdisciplinary dialogue, participants can learn from each other and co-develop the richest accounts possible of the worlds they inhabit.

The actions of the researcher, then, are not necessarily about inquiry, but are also about intervention: “knowledge is a practice that interferes with other practices (Mol, 2002, p. 153).²¹ The interventionist attitude (and notions of pragmatism, utility, and relevance that accompany it) is one that has been embraced both enthusiastically and uneasily by practice-oriented researchers (Zuiderent-Jerak & Jensen, 2007). There is enthusiasm for a social research that is against antagonism, that brings about concrete change, that leaves the ivory tower and makes itself relevant. Berg and Timmermans (2003) characterize this phenomenon with some cheekiness: “the fall of disciplinary boundaries allows us to enter adjacent fields and escape the occasionally insular environment of sociologists speaking to each other about how to be politically relevant” (p. 114). But there is also concern that such an orientation leaves behind valuable disciplinary insights, claims more relevance and influence than it really brings, or (intentionally or unintentionally) submits to or enables politics and change that are about implementation and not inquiry (e.g., instrumental initiatives to improve cost-effectiveness or efficiency) (Gad & Jensen, 2014).

This brings us finally to the question as to what exactly practice-based research is interested in achieving in medicine. As Mol (2002) points out, the turn to practice means that the prior orientation of research – to reveal an objective reality – is reconfigured into the normative question of “is this practice good for the subjects (human or otherwise) involved in it?” (p. 165). In the prior configuration, fact and value were separate: find out what exists, then choose a path forward. When what exists is underdetermined, however, when values are shown to “reside within facts” (Mol, 2002, p. 173), the very act of doing research is disentangling the various normativities embodied in the way things are done. Determining what action is good becomes a question of carefully considering the directions that certain practical configurations take us, the goals they seek to realize, and their possible risks and side effects (Mol, 2002). Like a good physician’s assessment of how to treat a patient, action is not a matter of matching up a diagnosed problem with a corresponding medication. Rather it involves a complex judgment about what might be

²¹ As Jensen (2009) observes, this is one way to consider and evaluate varying types of social research – what are the differences between how a philosopher (like Winner, for example) and an ethnographer enact their objects? What actors and activities are involved and to what effect? What do these enactments do?

considered good for this patient's needs and circumstances at this time, linking up considerations of the patient's goals, side-effects, possible complications, past experience, what's doable, and more.

2.5. Conclusion

Research is a practice that is like any other in that it involves the situated activity of doing things with others. The ways that it can be done, however, can be radically different and lead to radically different outcomes. Complexity will always be left behind and particular aspects of practice will be amplified or erased. Problems will be shaped and treated in unique ways that exclude other approaches. This thesis is an argument for a sensitivity to how research treats the practices it intervenes in and what its effects might be, a sensitivity that I think can be found in the turn to practice in STS.

In this chapter I have laid out two of the better established ways that research treats its problems. I do this to provide an overview account of the way that research is currently done and to situate the turn to practice, which is emerging from and in dialogue with other styles. I do this because I think that to truly understand what the turn to practice does and why it is compelling, one must contrast it with the precursors and alternatives. As well, exploring positivism and social constructivism not only as epistemology but as practice helps to establish how an ontology of sociomaterial practice might be plausible, and how other styles might be expressed in its terms.

I have shown that positivism and social constructivism share a concern with the ways in which an outside material world is represented in research. Positivism claims that we can model the world with relative certainty and coherence, and that our action can follow accordingly. Social constructivism calls attention to the human involvement in doing this, which means that representations are always contingent on mediating social influence. Drawing on the work of Steve Woolgar, Bruno Latour, Lucy Suchman, Donna Haraway, Annemarie Mol, John Law, and Susan Leigh Star, I have described the historical roots of STS in this conversation and how the turn to practice problematized the foundational tenets of these other styles.

My aim has been to reveal differences between how research might conceptualize medicine versus how medicine is done in practice. As excitement grows for the systematic collection of electronic clinical data that facilitates frequent and farther-reaching quantitative study, it is necessary now to re-articulate information as practiced: a moment in a process, something that is locally made in the context of care, and the product of a series of translations involving diverse human and non-human elements in the clinical environment. Sociological approaches are required that are empirically open and can attune to these activities, finding frictions and locating ways in which intervention might be able to offer an always uncertain improvement. The challenge is to develop situated ways of knowing and designing in and for the clinical environment. That is, to lash down our understandings of the objects of medicine – like an adverse drug event, a diagnosis, a disease or data – to the worlds in which they are produced, to their ontological origins in unique configurations of people, things, and practices. In this chapter I hope to have offered a theoretical resource to make the challenge offered by the turn to practice more tangible and plausible. In what follows, I will try to show how it might be done in research, how an empirical account might further make clear how medical practice might be treated as sociomaterial, and the value of this approach.

Chapter 3.

Case and Methods

Method? What we're dealing with here is not, of course, just method. It is not just a set of techniques. It is not just a philosophy of method, a methodology. It is not even simply about the kinds of realities that we want to recognise or the kinds of worlds we might hope to make. It is also, and most fundamentally, about a way of being. It is about what kinds of social science we want to practise. And then, and as a part of this, it is about the kinds of people that we want to be, and about how we should live (Addelson 1994). Method goes with work, and ways of working, and ways of being. I would like us to work as happily, creatively and generously as possible in social science. And to reflect on what it is to work well. (Law, 2004, p. 2)

3.1. Introduction

In the previous chapter I explained the different styles that one might employ in doing research in medicine, and advanced an argument for reimagining research after the turn to practice in STS. In the following 2 chapters, I try to bring these insights to a case study that makes up a part of the Pill Talk project, an interdisciplinary undertaking that has as its objective the participatory design of an electronic reporting tool for the communication of adverse drug event data across healthcare settings in BC. I refrain from commenting on the entire process of this project, and instead draw on my personal experience and involvement, primarily in ethnographic fieldwork I undertook with clinical pharmacists in emergency departments. My rationale for bringing in a case study is that I can demonstrate the theoretical orientation described in the previous chapter through an empirical account. I can show how my involvement in action research created a different type of medical intervention than would come from traditional positivist or social constructivist approaches that tend to try to operate from conceptualizations formed at a distance from the activity of care.

This chapter is concerned with explaining the context of the case study, the action research approach of my project team, and the methods that were employed. In the next section, I provide an overview of the problem which Pill Talk seeks to address and in doing so I draw attention to some of the political, institutional, and discursive milieus into which

it is situated. In subsequent sections, I describe my involvement with the project. I then outline and explain the action research approach which characterizes our team's work with Pill Talk (Section 3.3), and I explain the rationale for and process of doing participatory observation (Section 3.4). Finally, in (Section 3.5).I speak to my ethnographic process – the rendering of our collective data along with my memory, experience, and judgements into a particular and partial account.

This chapter is chiefly about transitioning from a theoretical case to an empirical case. I demonstrate some of the ways in which this project is (a) situated in a particular active sociomaterial milieu and problem and (b) organized to respond to this milieu given the recognition of the importance of understanding it as unfolding in action. My goal is to take seriously, translate, and respond to the tools and challenges introduced by the turn to practice. As such, I've tried to consider how my own work is situated, a reflexive construction of something new within particular circumstances – circumstances as mundane as the page limit of this paper, the time frame of my Master's program, my anxiety to finish my thesis, or the number of occasions I had to make observations. In what follows I try to draw out some of the detail that might otherwise be left behind in a formal account of method including some of the day-to-day struggles, compromises, simplifications, and translations that have gone into the production of this thesis. Doing this helps me demonstrate how the theoretical assumptions that I've introduced in Chapter 2 can be brought into method, and sets the stage for the empirical analysis that I offer in Chapter 4.

3.2. The Pill Talk ADE Reporting Project

3.2.1. ADEs and Pharmacovigilance

My work centers on the participatory design of a clinical intervention. In January 2014, I started working as part of an interdisciplinary team on the Pill Talk project, which aims to innovate the systems and practices related to the reporting of adverse drug events (ADEs). Over the next two years, our team's design process entailed a systematic review of adverse drug event reporting systems worldwide, extensive participatory observation, and design oriented focus groups / workshops with various health provider groups, all of

which shaped the development of this thesis and provided its empirical base. During the course of this work, I occupied an office in the Centre for Clinical Epidemiology & Evaluation (C2E2) in Vancouver Coastal Health Authority's Research Institute, on the top floor of the building next to the Vancouver General Hospital emergency department. Here, I was able to attend weekly rounds and build a working knowledge of both the textbook methods and on-the-ground practice of qualitative and quantitative approaches used in health research. Seven floors and a 45 second walk away was the emergency department in which I did the bulk of my observational work.

Our team's project relates to a specific type of drug safety apparatus: adverse drug event reports. Definitions of ADEs are varied and contested, but for explanatory purposes at the moment, it suffices to use the broad definition that ADEs are "injuries resulting from drug-related medical interventions," and can refer to everything from a relatively minor reaction or side effect to a more serious event like a congenital defect, permanent disability, or death (Office of Disease Prevention and Health Promotion, 2015, para. 1). ADEs became a major concern after the Thalidomide disaster in the late 1950s, when the medical community and the public too slowly came to the realization that the drug Thalidomide, when taken in early pregnancy, led to severe birth defects. With no well-coordinated post-market oversight of drugs in place at the time, the drug led to the death of an estimated 2,000 children and left some 10,000 more deformed before its adverse effects were recognized and it was removed from circulation. The catastrophe stirred calls for a more rigorous drug approval process and a more formal surveillance of medications already on the market (World Health Organization, 2002). It was the beginnings of what is now known as the field of pharmacovigilance (or drug safety science): "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" (World Health Organization, 2002, p.5). As well, the Thalidomide disaster propelled a shift in drug management from an era dominated by professional control to one of centralized government regulation (Daemmrich, 2007).

Prior to the Thalidomide disaster, post-market surveillance of drugs involved medical associations and journals collecting, reviewing and comparing reports. By 1970, most western countries had created national pharmacovigilance centres and drug safety

agencies, implemented standardized reporting forms for adverse drug events, and signed on to share information with a pilot project by the World Health Organization (See Figure 5).²² The priority of these systems was to gather precise quantitative data, and standardized terminology was developed by agencies like the U.S. Food and Drugs Administration (FDA) so that reports could be codified and compared using statistical methods (Daemmrich, 2007). Indeed, Daemmrich (2007) suggests that the FDA's authority was based on a "regime of numbers" (p. 67), speculating that such a quantitative approach allowed the FDA to make their drug safety efforts more tangible to the government and the public. In the 1990s, national reporting programs had become a mainstay in drug regulation and developments in information technology enabled statistical methods to analyze very large reporting datasets, offering scientific methodology that was a compromise between expensive, time-consuming, and narrow-scope clinical trials and single case reports that were considered to be anecdotal and unreliable (Daemmrich, 2007). Reporting was expanded from only physicians to other medical professionals and then to patients, and many systems moved online (Daemmrich, 2007). Very recently, some institutions, like Veteran Affairs hospitals in the U.S., have started to integrate reporting into clinical information systems (Emmendorfer et al., 2012).

The analysis of ADE reports is the primary tool for the post-market surveillance of drugs (Meyboom, Egberts, Gribnau, & Hekster, 1999). The methodology of ADE reporting is supposed to work as follows:

1. A Patient has an adverse event that a provider suspects may be related a medication.
2. A provider submits a report documenting the event using the paper or online forms offered by their national pharmacovigilance program.
3. Databases containing thousands of reports are analyzed by researchers using data mining tools and statistical techniques to identify signals, patterns of related events that might indicate a problem with a specific drug.
4. The detection of a signal initiates further targeted investigation, the dissemination of warnings to health providers, or, in some cases, immediate recall of the drug.

²² Later to become the International Drug Monitoring Programme.

In practice, however, this process is complicated in many ways. One of the most significant issues is that clinicians consistently underreport ADEs. Health Canada likely receives reports for less than 1% of ADEs,²³ a figure supported by several studies of reporting rates in European countries (Shakir & Hazell, 2006). To jump ahead a little, in our 350 hours of observations, despite observing around 70 possible ADEs, not a single report to Health Canada was observed. Interestingly, the failure to report ADEs was identified as early as the 1960s, when it was suggested that as few as 2% of physicians in the U.S. had reported an event (The Suspect and the Innocent, 1966; Daemrich, 2007). This shortcoming has frustrated many in the research and policy worlds, and spurred research into ways to foster the active and reliable production of ADE data. Some initiatives focus on changing clinician attitudes and behaviours –through training, mandatory or incentivized reporting, or assistance (Lopez-Gonzalez, Herdeiro, & Figueiras (2009) review 50 such studies). The seven deadly sins of underreporting (later expanded to ten), (e.g., ignorance, lethargy, complacency, guilt) which were outlined in a 1976 report are often referred to or used as a framework when reporting findings from studies undertaken in an effort to address under-reporting of ADEs (Inman, 1980). Most such studies are questionnaire-based studies. Others attempt to take the clinician out of the equation, by focussing on mining data from administrative records (Bates, et al. (2003) review 25 such studies). Neither approach has met with significant success. Underreporting remains a fundamental problem world-wide, and research has found that data-mining techniques lack the sensitivity and specificity to detect ADEs effectively (Hohl et al., 2013; Bates, et al., 2003).

Another problem is related to the complexity of ADE diagnosis and documentation. ADEs are particularly complex experiences, and the establishment of a causal link between a specific medication and a patient's experience is a fraught process – an event can occur over varying time periods after a medication was administered, the patient may be taking numerous other medications, the patient may have other underlying conditions

²³ Calculated as follows: There are ~10.3M ED admissions per year (Canadian Institute for Health Information, 2014). Studies have found that approximately 12% of ED admissions are ADE-related (Zed, Abu-Laban, & Balen, 2008). $0.12 \times 10.3M = \sim 1.24M$ ADEs annually. Health Canada received approximately 9004 reports in 2014. $9004 \text{ Reports} / 1.24M \text{ Events} = 0.72\%$ reporting rate. It is likely that this is a conservative estimate considering it only accounts for ADEs resulting in ED admission.

that are contributory, etc. These complexities also complicate the translation of an ADE into documentable terms. Complex health events don't lend themselves to easy quantification. How might one quantify a rash? Dizziness? An ulcer? Certainly there are ways, and indeed there are many in health care that shrug off or ignore this difficulty. Nonetheless, the abstraction of the event into neat categories or numeric representations has always been problematic for providers (Daemmrlich, 2007).

Considering these limitations and others (e.g., uncertainty related to the number of people taking a drug, reporting bias, report quality, duplication of reports), there is a strong case to be made that post-market surveillance via ADE reporting is ineffective in its current form. From a scientific standpoint, the uncontrolled nature of data collection and the presence of descriptive evidence make reporting systems of low scientific value in the evidence hierarchy compared to cohort studies or clinical trials that are more insulated from bias (Evans, 2003). However, despite its limitations the method has many strengths and has at times been effective in detecting previously unknown ADEs (Aagaard & Hansen, 2009). ADE reporting offers insight into how drugs may be affecting people over the long term and under complex real world conditions (Lexchin, 2006). It is a rapid, ongoing, and comparatively cheap method and is one of very few established tools that regulatory bodies have to monitor drug safety (Meyboom et al., 1999). Further, reporting systems for other types of events (e.g., medical device incidents, child abuse, aviation incidents), where underreporting is less of an issue, are upheld as highly successful.

The question today is – what to do now? Medication use has risen dramatically since the 1950s, so it is perhaps unsurprising that today ADEs are extremely frequent and pose a massive challenge to the healthcare system (Dumit, 2012). ADEs have become a leading cause of ambulatory and emergency department visits, and of unplanned admissions – prompting some in the medical literature to refer to them as the “silent epidemic” (Lazarou & Cory, 1998; Nebeker, Barach, & Samore, 2004; Budnitz, Lovegrove, Shehab, & Richards, 2011; Zed, Abu-Laban, & Balen, 2008). Some of these events are related to unknown or unexpected reactions associated with a drug, but interestingly, studies from a variety of care settings suggest that many, if not most, of all ADEs are preventable and are more likely related to human error. They may, for example, be related to provider error (the wrong drug or dose is prescribed, a drug that has previously caused

an ADE is represcribed) or patient non-adherence to their medication regimen (Gurwitz, et al., 2003; Classen, Pestotnik, Evans, Lloyd, & Burke, 1997, Zhang et al., 2007). Whatever the cause(s) of ADEs, they persist.

These trends raise another problem with the current pharmacovigilance approach. The challenge posed by ADEs needs to be addressed not only by drug surveillance research, but by better documentation and communication of medication and ADE information between care providers and across healthcare settings (Van der Linden, et al., 2010; Van der Linden, et al., 2006). The focus on routing out the “bad” drugs may miss the perhaps more urgent issues to be addressed related to medication overuse, misuse, and mismanagement. Moreover, the quest for certainty around medication use may be misguided, and instead medicine might find ways to best “live with” the uncertainties inherent in widespread medication use (Jerak-Zuiderent, 2012). These are issues that arise not from the medication as a technical entity, but from its embeddedness in networks of dynamic and complex social relations. As Cohen et al. (2001) argue, the tendency to understand medications as merely technical entities that might be rationally used has shown itself to be inadequate, and we might instead understand medications as social phenomena having “complex life cycles, with diverse actors, social systems, and institutions determining who uses what medications, how, when and why” (p. 441).

ADE reporting in its current form is a good example of how a narrowly defined approach to safety can fail to bring meaningful change for providers and patients. It’s clear that reporting is not enough to address the problems that ADEs pose to patients and the healthcare system. Yet, little imagination has gone into how the practice of reporting might be reworked. Indeed the forms that are in use today are not radically different from those introduced 50 years ago. Very few studies concerned with ADE reporting system designs have questioned the data-centric orientation of reporting systems or proposed ways that reporting might be designed to work for clinical care providers and their patients as well as meet research needs.²⁴ And reporting remains oriented almost exclusively to the needs of research and regulatory worlds. It’s not useful for patient care and it isn’t amenable to the communication of dynamic, complex events in day-to-day practice –

²⁴ Van der Linden, et al. (2010) and Bates et al. (2003) are notable exceptions.

possibly major reasons why clinicians are not motivated to report. In short, the worlds of plans (research/regulation) and practice (dealing with ADEs in clinical settings) find themselves at odds. The empirical work in this thesis and the Pill Talk project that I have undertaken with the team at C2E2 (described in section 3.2.3) are both attempts to bridge what is often a gap between the planned activities of ADE reporting (designed to meet the needs of regulators and researchers), and the situated actions of clinicians in practice settings.

3.2.2. Political, Discursive, and Institutional Situation

As I elaborated in Chapter 2, research intervenes in a situation that is ongoing. The researcher enters into relations with an existing sociomaterial milieu, which they are constrained by, try to flesh out, act in response to, and change. In the prior section, I started to explore some of the circumstances that define how my work and the Pill Talk project are situated. This section continues this situating, by pointing to three examples of the political, discursive, and institutional frames that currently have an effect on activities related to drug safety in research in clinical practice. There are, of course, many more than these three things at work, however, the examples that I have chosen either seemed exemplary of a body of others or were significant developments at the time of my research. In the order I discuss them below, they are (1) The U.S. Institution of Medicine's report *To Err is Human*; (2) the passage of "Vanessa's Law" through Canadian parliament; and (3) CBC Marketplace's hidden-camera investigation into pharmacy practice. These were items that repeatedly came up in the literature and/or in conversations with practitioners, and were instrumental in stimulating action by researchers and clinicians related to ADEs (indeed, they played a role in bringing momentum to our project). I include them because they have oriented and come to bear upon action.

To Err is Human

It is common for the introductory paragraphs of journal articles on ADEs and pharmacovigilance efforts to reference the 1999 report *To Err is Human: Building a Safer Health System* by the U.S. Institute of Medicine (IOM) (whose authors are Kohn, Corrigan, & Donaldson). The report extrapolated the results of two large-sample studies of hospital admissions in New York and Utah/Colorado to the 33.6 million hospital admissions to U.S.

hospitals in 1997, to estimate that 44,000-98,000 Americans die each year in hospital due to medical errors (Kohn, Corrigan, & Donaldson, 2000, p. 26). That's 2-4% of all deaths in the U.S. per year – more than car accidents, breast cancer, or AIDS, even by conservative estimates (Kohn, Corrigan, & Donaldson, 2000, p. 26). Medication-related errors were among the most common type of error observed and the report featured a thorough overview of studies into ADE prevalence and the seriousness of their implications for the health system (Kohn, Corrigan, & Donaldson, 2000, p.30-35). One of the first impacts that the report had was to initiate a wave of similar studies of health care systems around the world that arrived at similar conclusions to the IOM report (Croskerry, 2010). In Canada, a 2004 study into preventable adverse events suggested that 9,000-24,000 deaths had occurred in 2000 as a result of potentially preventable adverse events (that's 4-11% of all deaths that year) (Baker, et al., 2004).²⁵ The alarming numbers advanced by *To Err is Human* and follow-up studies didn't go unquestioned, but they quickly transformed patient safety into an urgent issue of public and political concern (Jensen, 2007).

The IOM report aimed to break the silence on the issue of medical errors, but also to end what it referred to as the “cycle of inaction” that continually sidelined patient safety (Kohn, Corrigan, & Donaldson, 2000, p.3). It argued that the problem of medical errors was systemic and that the path to improvement thus demanded systemic change, as opposed to blaming or punishing individuals. As Jensen (2007) points out, the main innovation of this report, next to indicating the seriousness of patient safety issues, was this framing of health care as a system. The report drew on sociological systems theory to articulate this frame, however, the way that systems theory was taken up in the report was specific. It figured patient safety as a matter of identifying and evaluating deficiencies, and “designing in” new properties and controls to stop the gaps:

All adverse events resulting in serious injury or death should be evaluated to assess whether improvements in the delivery system can be made to reduce the likelihood of similar events occurring in the future. Errors that do not result in harm also represent an important opportunity to identify systems improvements having the potential to prevent adverse events. Preventing error means designing the health system at all levels to make it safer. Building safety into processes of care is a more effective way to

²⁵ As calculated out of 218,062 deaths in Canada in year 2000 (Statistics Canada, 2009).

reduce errors than blaming individuals....The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. (Kohn, Corrigan, & Donaldson, 2000, p. 5)

The assumption, here, was that designers operate outside of the system, making adjustments based on the analysis of feedback. In this context, the word system stood in for a delimited segment of practice – that of clinical care.

The authors of the IOM report advance a science of safety and a notion of culture change that ultimately frame error as a preventable flaw introduced by human faults (Kohn, Corrigan, & Donaldson, 2000). Indeed, the report defines error as a matter of either deficient knowledge or poor execution, error is “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim” (Kohn, Corrigan, & Donaldson, 2000, p. 1). Jensen (2007) argues that this interpretation is quite the opposite of the sociological systems theory that the report draws upon, and jokes that it arrives at the conclusion “to err is human, but errors can be prevented” (p. 318). The *To Err is Human* report simultaneously reveals the complexity of care and articulates a path forward based on a specific mechanistic model of care-in-practice. Uncertainty, the unexpected, and error were presented as occurring only because there were still gaps in knowledge and safe practice, gaps that could be systematically identified and filled (Jerak-Zuiderent, 2012). In concert with EBM and standardization regimes, the report advanced the notion of that patient safety was a matter of implementing general solutions (Jensen, 2007).

The decade after the publication of the *To Err is Human* report saw the establishment of committees, conferences, research initiatives, fellowships and chairs, institutes, and officers devoted to patient safety (Croskerry, 2010). The report’s recommendations have been entrenched in Canadian policy, beginning with Canada’s 2002 National Steering Committee on Patient Safety’s report *Building a Safer System*, which – as one might imagine given its title – leaned very heavily on the IOM report (which was subtitled *Building a Safer Health System*). The Canadian report’s 19 recommendations outlined the creation of the Canadian Patient Safety Institute and a strategy for improving patient safety that has shaped the structure of health care in Canada until today (National Steering Committee on Patient Safety, 2002). Notably, closely following the IOM report, these recommendations again were oriented primarily

around the science of safety and implementing general solutions. They highlighted evidence-based medicine, measurement and evaluation via surveillance and reporting, education and training, standardization, and information technology as the chief avenues to improve patient safety in Canada (National Steering Committee on Patient Safety, 2002, p. 10-23). The research I undertake in this case study aims to test this conceptualization of drug safety, which draws heavily on the positivist model of medicine that I described in section 2.2.1. I will show how practice-oriented research is valuable here for examining how this framework unfolds in practice, what its limitations and blindspots may be, and what opportunities for progressive intervention it misses.

Vanessa's Law

On November 6th, 2014, the Canadian government introduced amendments to the Food and Drugs Act through Bill C-17, *Vanessa's Law / Protecting Canadians from Unsafe Drugs Act* (Health Canada, 2015). The Bill was introduced by Terence Young, Member of Parliament from Oakville. He named it after his daughter Vanessa Young who died from a possible adverse drug event in 2000. The amendments awarded the Minister of Health several new authorities including the capacity to (i) require information, tests, and studies on suspected high-risk therapeutic products; (ii) require a label change; and (iii) recall therapeutic products. Of specific relevance to ADE reporting, however, is the requirement for *mandatory* reporting of serious ADRs and medical device incidents directly to Health Canada. Section 21.8 of the amendment states,

A prescribed healthcare institution shall provide the Minister, within the prescribed time and in the prescribed manner, with the prescribed information that is in its control about a serious adverse drug reaction that involves a therapeutic product or a medical device incident that involves a therapeutic product. (Health Canada, 2015, section 21.8)

It has not yet been specified what the prescribed scope of time, the manner, or the required information will be, or which healthcare institutions fall within this legislation, and the terms serious adverse drug reaction or medical device incident are still to be defined. As a result, the bill has put mandatory reporting on the agenda for policy-makers and health care institutions but left questions relating to implementation of Bill C-17 extremely open.

It is perhaps unsurprising that the call for mandatory reporting is in line with the chief recommendations of the *To Err is Human* report, which argues that mandatory reporting

will ensure a response to specific reports of serious injury, hold health care organizations and providers accountable for maintaining safety, provide incentives to organizations to implement internal safety systems that reduce the likelihood of errors occurring, and respond to the public's right to know about patient safety. (Kohn, Corrigan, & Donaldson, 2000, p. 3).

However, this strategy, while laudable for its aim of increasing accountability and transparency in patient safety, is limited in many ways when it comes to post-market drug surveillance. First, it fails to address the inadequacy of the current reporting infrastructures that capture only a fraction of events. Additionally, there is little evidence that mandating institutional reporting will remedy this issue (Leape, 2002; Barach & Small, 2000; Chen, et al., 1994). Various reports conducted by Canadian health authorities, along with evidence presented during Bill C-17's Senate Committee review have revealed that many of Canada's most experienced health providers reserve serious doubts as to the efficacy of mandatory reporting (Health Canada, 2005; Standing Senate Committee on Social Affairs, Science, and Technology, 2013; Standing Committee on Health, 2008a; Canadian Medical Association, 2005; Standing Committee on Health, 2008b).²⁶ Objections to mandatory reporting have been made on several grounds, which have included that it would lead to an avalanche of data that is not necessarily novel or useful; it would increase an already strained provider workload; it would introduce new bureaucratic burdens related to monitoring and enforcement, and it would fail to address the already significant limitations of current reporting systems (Standing Committee on Health, 2008b). The measure alone does not address the weaknesses of reporting surveillance or attend to the complexities inherent to identifying and documenting these events in clinical practice. Notably, many experts in Canada argue for an innovative re-

²⁶ Objections have been raised by members from Health Canada, the Standing Senate Committee on Social Affairs, Science and Technology, the Standing Senate Committee on Health, the Canadian Medical Association, Canadian Society of Hospital Pharmacists, the Canadian Pharmacist's Association, and the National Association of Pharmacy Regulatory Authorities.

evaluation of reporting and its redesign to be useful at the point-of-care and to provide higher quality data as opposed to higher quantity (Standing Committee on Health, 2008b).

Second, depending on how serious adverse drug reaction comes to be defined, the amendment may do nothing to address the majority of adverse drug events that patients experience – even if those events are endemic. It appears that, at best, the Bill C-17 amendments could increase reporting rates of a minority of adverse drug events, which may enhance a minority of regulatory decisions to investigate drugs or withdraw them from the market. As it stands, however, it will not address the alarmingly high volume of ADEs that are experienced on a day-to-day basis. Thus, given its questionable approach and ambiguous language, Bill C-17 remains a peculiar administrative grey area hanging over Canadian providers.

Bill C-17 is an example of an intervention that is designed at a distance from care, around the positivist conceptualization of how safety happens. Like the IOM report, it takes the problem of drug safety as something that can be designed into clinical care (if only providers would take the time to provide the necessary data to researchers and regulators). The bill is also exemplary of a large body of research around reporting that frames the provider failure to report as a behavioural problem that must be corrected (in the case of Bill C-17, by enforcement). What is interesting at this point is how the Bill will be implemented and to what effect. I suggest that accounts of ADEs and drug safety in practice may offer some direction for this implementation and give a sense as to how mandatory reporting will fit into the current action of care.

CBC Marketplace's Hidden-camera investigation

On October 6, 2014, CBC news' Go Public published an exposé entitled "Pharmacists' failure to check drug risks leads to 'horrible' death" which detailed the accidental death of a woman who was prescribed and dispensed two drugs that interacted and resulted in the shutdown of her immune system (Tomlinson, 2014). The drug interaction was known, but was overlooked by the dispensing pharmacist, who also ignored an automated alert by the pharmacy's information system (Tomlinson, 2014). The article raised a number of issues: professional roles and responsibilities (the prescribing physician assigned blame to the dispensing pharmacist), pharmacist overwork and

attentiveness (the dispensing pharmacist ignored an automated alert to the possible drug interaction), and IT system design problems (pharmacists get desensitized to the constant alerts raised by the system, leading to 'alert fatigue') (Tomlinson, 2014).

A few months later, CBC Marketplace broadcast their investigative series *Pharmacy Error: Dispensing Danger*. The introduction went as follows:

We rely on pharmacists when we're sick. But what happens if they make a mistake? We're investigating pharmacy errors, taking hidden cameras into 50 Canadian pharmacies in the largest test of its kind in Canada. Do pharmacists dispense the right advice and catch potentially dangerous drug interactions? And who's tracking the mistakes that happen? (CBC Marketplace, 2015)

In the investigation, secret shoppers went into 50 pharmacies in 9 Canadian cities and requested drugs (like Tylenol Codeine) that were known to carry a risk of interaction with other drugs. In 27 cases, no advice was given; and in zero cases did the pharmacists advise of a possible interaction. The program certainly implied that the problem was related to pharmacist apathy, but also suggested other causes for concern: the unrealistic performance demands of chain drugstore managements trying to cut costs and maximize profits, and the lack of any mandatory reporting system for pharmacy errors.

The CBC marketplace investigation is interesting first because it placed an enormous level of public scrutiny on pharmacists' practice, which has generally been uncontroversial. In my observational work with pharmacists, the program was raised often, sometimes positively (it brought some much needed attention to some of the unrealistic demands placed on pharmacists) and sometimes with frustration (it leaned on explanations that were seen as too simplistic). I think it is noteworthy that the investigation explored some of the practical difficulties of drug management: fatigue, the demands of calling GPs to check problematic prescriptions, time pressures, automatic alert overuse, limited information, and the constant uncertainty of working within such constraints. Arguably, the video accounts and interviews in the program created a more textured account of practice than is sometimes produced in research. However, as one might expect, the program fell short of analyzing its accounts in full, leaning on the two major narratives that locate the problem with drugstore management and a lack of error

reporting.²⁷ My observational work undertaken as part of the Pill Talk project picks up where this analysis falls short, especially with respect to provider-provider communication.

3.2.3. The Pill Talk Approach

To recap, the alarmingly high rate of ADEs poses a massive and likely growing challenge to the provision of good medical care. The primary oversight and prevention method for these events – spontaneous reporting – has gone virtually unchanged over the last 50 years. This approach has severe limitations, including that it is underutilized, ill-designed for the complexities of ADE identification and diagnosis, and is used more for the quantitative detection of rare or unknown side effects – a minority of ADEs – than for more frequent ADEs like those related to patient adherence, medication errors, or dosage issues. Despite evidence to suggest that many ADEs are preventable or recurrent, there is only fragmented communication across care settings around medication issues and ADEs. In terms of solutions, the general policy approach to patient safety since 2000 has been explicitly system-oriented, employing measurement and evaluation via surveillance and reporting, education and training, standardization, and information technology as the chief avenues to improve patient safety in Canada. Bill C-17 exemplifies this approach, affirming Canada’s commitment to reporting structures by mandating the reporting of severe ADRs, but its implementation remains an open question. Meanwhile, some of the persistent, on-the-ground challenges related to drug safety are starting to emerge and be subjected to scrutiny both in Canada and around the world.

ADEs are very common events, but currently, there is limited communication about them across care settings and providers. This puts patients at risk of being re-prescribed or dispensed drugs that have been harmful to them in the past and limits the opportunity for care providers to learn about how certain drugs may be harming their patients. Traditional ADE reporting systems such as Canada’s MedEffect (Canada’s national ADE reporting program) are in place, however, these systems are designed only for the collection of data about a minority of ADEs for drug safety research and regulatory purposes. They do very little to improve the day-to-day decision-making around

²⁷ I’d venture to assume that this narrow interpretation is at least partially due to the fact that automated alerts in clinical information systems don’t make for intriguing television!

medication prescribing for specific patients. For this reason and others, reporting in these systems is extremely low, leading to limited data related to post-market drug safety. These are the concerns highlighted in Pill Talk's project proposal, which put forward a plan for the participatory design of an electronic reporting tool for the communication of ADE data across all care settings in British Columbia. The tool would be integrated into B.C.'s widely used medication information database Pharmanet, in which almost all dispensed medications are recorded for each citizen, and, importantly, a key resource used by pharmacists to screen patients for potential drug risks (e.g., interactions with other drugs they are on, early or late refills on drugs indicating non-adherence). Every time a drug is dispensed in a pharmacy, it is recorded under a patient's profile in PharmaNet. Pill Talk would enable providers to also enter information about ADEs into this profile, where it could be stored and viewed by future providers who could adjust their prescribing practices accordingly to avoid recurrent events (See Figure 6). Ideally, an automatic alert would draw attention to the ADE if a provider attempted to re-prescribe or dispense a drug that a patient has previously had a problem with.

In sum, where previously an ADE report would be sent only to Health Canada, now it would also be made available to the patient's providers in all care settings. Reporting would not only serve the data collection needs of researchers, it would also serve the communication needs of providers and their patients. Our theory was if we could create a reporting system that was designed by and for providers that are encountering ADEs on a daily basis, it would be used more, improve provider communication and patient care, *and* generate better data.

It is unconventional for project teams in the health sciences to contain a single member with a social sciences background. It was my good fortune to land on one that contained three, along with a clinician researcher, an epidemiologist, a pharmacology post-doc, and a clinical pharmacist. This diversity meant that we could approach the practical problem of redesigning adverse drug event communication using methods and insights drawn from fields like communication studies, STS, computer supported cooperative work (CSCW), or medical anthropology while also benefitting from the medical and experiential knowledge of health researchers and practitioners. We aimed to be explicitly and methodologically attentive to the real-world practice of medicine and to work

in close collaboration with clinicians for the dual purpose of research and the design of a practical intervention in care work. Pill Talk involves 4 primary methods overlapping with the iterative design of the platform:

1. A systematic review to identify all existing reporting systems internationally and understand what information is collected in each, and how it is collected (e.g., on paper or using a computer);
2. Participatory observation with clinicians (physicians, pharmacists, and nurses) in the care settings where ADEs are frequent and drug prescribing and dispensing decisions are made;
3. Interactive focus groups with clinicians to inform and refine the reporting platform's design;
4. Pilot-testing of a paper-based version of the new reporting platform using "lightweight" ethnography. (Randall, Rouncefield, & Harper, 2015)

These methods reflect our position that research and design processes in medicine and elsewhere should find ways to be methodologically bottom up as opposed to conducted or implemented by an external managerial or technical team (e.g., see Zuiderent-Jerak, 2007). As one collaborating clinician noted referring to an upcoming policy decision concerning ADE management: "They're taking the same approach that they've taken everywhere and for all time – they get a bunch of people into a boardroom that have never stepped inside the clinical setting to make decisions about what's best to do in the clinical setting!"

My Role in Pill Talk

As a research assistant on this project for 2 years, I was involved in a number of activities outside of these 4 formal-ish methodological steps, including regularly reviewing medical, health informatics, and health sociological literature; creating and revising form mock-ups with clinicians; organizing and discussing findings, and deliberating in team meetings; attending conferences and presenting our work to both healthcare and STS audiences; writing manuscripts; and attending weekly research rounds at the Centre for Clinical Epidemiology and Evaluation (C2E2), where my office was located. The papers I read, the discussions I had, the feedback and ideas I received from clinicians, the presentations that I've given and listened to – they've all been part of a learning process that is in itself an empirical base for this work. So while my discussion in this thesis focuses

around the participatory observation component of the work, it is necessary to highlight that these methods were really just one part of a greater action research and ethnographic experience. Certainly, I believe that my findings would be different if I hadn't been able to benefit from such an immersion in these worlds of health care and close collaboration with both the health care researchers and care providers.

3.3. Action Research

If the traditional view of method is that it allows us to hold the world still for a moment, to capture, briefly, the maelstrom of reality in graphs, tables, stories, and findings sections, then perhaps action research might be seen as subversive, or maybe not as method at all. Indeed, action research is described by many authors not as method but as an approach, an orientation, a process, an agenda, or even a period of inquiry (Reason & Bradbury, 2006; Meyer, 2000; Kemmis & McTaggart, 2003). I think that action research is method – just in the reflexive sense that method is less the principled application of a set of formal techniques to create knowledge than it is a messy process of thoughtful intervening, with others, in a particular state of affairs. As Reason & Bradbury (2006) describe it, action research is “a way of being and doing in the world” (p. xxviii). To be more specific, action research is an approach to research that has the dual aim of generating insight into a practice setting while contributing to practical change (Reason & Bradbury, 2006; Meyer, 2000). It is often participatory – incorporating the active involvement in the field, close collaboration with practitioners, and a democratic bent that allows participants to take an active role in research, design or implementation projects (Meyer, 2000).²⁸ Accordingly, it is often interdisciplinary and practitioner-initiated or driven, and it incorporates qualitative methods that bring out the practices and perspectives of participants such as observation, interviews, or focus groups (Meyer, 2000). These methods are not prescribed, but are rather selected by the practitioners involved based on their particular research problem, circumstances, and setting (Reason & Bradbury, 2006).

²⁸ There are non-participatory forms of action research, which is why some prefer the more explicit “participatory action research” or PAR label. In this thesis, when I refer to action research, it is to the participatory type.

Action research is used in wide range of disciplines, however, it is particularly suited to negotiating the research/practice boundary in healthcare (Hart & Bond, 1995). Hughes (2008) argues that health and healthcare demands a holistic understanding (along the lines of Star's (1995) ecologies, described in Section 2.4.2) that action research is capable of offering. Intervening in health requires attention to many dimensions of health and what constitutes good care in complex interdependent systems of human and non-human elements (Hughes, 2008). As well, action research mobilizes a different sense of knowledge than many traditional approaches to research:

For me it is really a quest for life, to understand life and to create what I call living knowledge – knowledge which is valid for the people with whom I work and for myself. (Marja Liisa Swantz, in Reason, 1996, p.6)

Living knowledge, here is congruent with Haraway's (1988) situated knowledge; action research is the practice of mobilizing knowledge that has a particular location within an ecology of practice, and it does so in a way that is attentive to the question of who does the mobilizing and what its consequences will be. Note that this requires the social sciences analyst to shift their role from one of ready critique (of, for example, positivist orientations) to one of modest collaboration, "aiming to learn, instead of itching to instruct" (Ashmore, Mulkay, & Pinch, 1989, p. 195).

The Pill Talk project's action research approach also incorporates elements of participatory design, which – drawing on the action research tradition – is specifically oriented to improving information technology design as a means of improving work (Simonsen & Robertson, 2013). Simonsen and Robertson (2013) explain that participatory design is based on two foundational arguments. The first is political: workers should have the right to be involved in decisions that shape their workplace (Simonsen & Robertson, 2013). The second is pragmatic: collaboration between experts/managers and workers (the people who will be affected) creates the opportunity for "mutual learning" and consequently better design (Simonsen & Robertson, 2013, p. 27). As well, in contrast to traditional approaches to information technology design which are carried out at a distance from use and reflect assumed work practices rather than actual or situated work practices (Suchman, 1987/2007), participatory design requires its practitioners to gain access to

work / practice settings in order to appreciate the complex phenomena that are the focus of change (Balka, 2005).

It is within the broad programs of action research and participatory design that the Pill Talk project was conceived. I was not involved in its original proposal, but from the beginning it has been a flexible and responsive programme, stemming from a practical problem that our clinician lead investigator was continually observing in clinical practice: the alarming prevalence of ADEs and the inadequacy of current solutions. Pill Talk has taken action research and participatory design commitments seriously, combining multiple methods – systematic review, participatory observation, focus groups, and pilot-testing – with iterative system design among an interdisciplinary team. Notably, this approach is a departure from many initiatives in health ICT design, especially in ADE reporting – which has been traditionally implemented in a top down manner, aiming to meet the data needs of the research, administration, and regulatory stratum, rather than the needs of the clinicians who diagnose, treat, and document ADEs (or their patients).

Is Action Research “research”?

The turn to practice and new approaches to research that are attentive to the practices of doing research and not just its planned character raise new questions about what exactly counts as research and method. First, there are familiar critiques from positivists, who argue that action research lacks objectivity and scientific rigour (Reason & Bradbury, 2006; Kemmis & McTaggart, 2003). This argument, of course, runs up against the theoretical premises of action research – that knowledge is never objective, that research is more a process of intervening than of discovering, and that this process is never simply neutral, but rather advances particular normative directions. Evaluation of action research, then, must center on whether and to what degree it is able to observe its commitments to practicality, flexibility, reflexivity, attention to context, and a participatory/democratic orientation.

These commitments, however, may also be disagreeable to some traditional social constructivists, who question foremost whether practicality and participation are appropriate commitments for a practice that would claim the label of research. Gingras (1995), for example, argues that the sociologist should act “at arm’s length” from the

communities they study, creating enduring, sociologically informed, and critical theories of how people in these communities act (p.123). This critique is weak in the face of Woolgar's and others' arguments for a reflexive social study. Again, taking up an analytical standpoint that immediately posits people as objects of study and creates categories and models (however reflectively) to explain them and their actions is hardly critical, it's positivistic science in sheep's clothing – it's perhaps more problematic because the reality to be studied, here, is made up of people.

Perhaps a better way of framing how method and research are understood within an action research framework is the idea that action research is attentive to an “extended epistemology” (Wicks, Reason, & Bradbury, 2008, pp. 14-31). That is, the traditional conception of knowledge (and especially academic or scientific knowledge) artificially delineates between theoretical and practical/experiential/folk ways of knowing the world (in line with other forced divides between thinking/acting, epistemological/ontological, and subject/object). Action research operates without such a distinction, and thus leans on an epistemology that extends beyond theoretical propositional knowledge – knowledge *about* things. Rather, knowledge is always about living and relating to the world in the myriad ways that humans do, and research is about detecting, resonating with, and amplifying patterns in these relations (Law, 2004).

3.4. Methods

3.4.1. Rationale

Beyond our overarching action research and participatory design approach, there were several other considerations which influenced research design. Our objective was to create an ADE reporting system that people will use and that will improve patient care. Our research design, then, had to first consider the limitations and shortfalls of the more than fifty years of work that have gone into existing systems. It is notable that existing ADE reporting systems have been designed at a distance from use, with limited clinician end-user input, and have focused on the data needs of organizations engaged in medication safety surveillance, rather than the information needs of clinical care providers who diagnose and treat patients with ADEs. Interestingly, however, this data-centric

orientation has been constantly preserved in efforts to innovate current systems. As mentioned in section 3.2.1, the solutions that have been proposed tend to focus on changing provider behavior, attributing shortcomings to poor user knowledge, attitudes, workplace culture, professional priorities, incentives, and media influence (Shakir & Hazell, 2006; Lopez-Gonzalez, Herdeiro, & Figueiras, 2009), or attempt to bypass users by analyzing clinical and administrative data created by their activities (Bates, et al., 2003; Forster et al., 2012). Others have pointed to the value of expanding the role of reporting to patients, yet there has been little formal evaluation of patient reporting and reporting rates among patients remain low (Margraff & Bertram, 2014; Hunsel et al., 2012). Studies on underreporting or initiatives to improve reporting rarely examine systems issues and instead focus on the users. And notably, these studies are almost all questionnaire based. Studies have generally failed to examine system shortcomings or propose ways to re-design reporting so that it may complement and facilitate components of clinical care in addition to meeting the data needs of external organizations.

In the medical literature, where synthesis of available robust research evidence (typically meaning systematic review of randomized control trials concerned with a narrowly defined research question) is considered the standard prior to changes in clinical care delivery (Timmermans & Berg, 2003), there has been little or no discussion about what, if any, research evidence should be used to inform the design of information technology systems that may have a profound impact on health services delivery. The use of qualitative observational data, including information from end-user engagement in designing information technologies has gained popularity in the last 25 years in computer and information sciences (Berg, 2001). Yet, despite the promise such approaches hold, their uptake in medical communities has been slow (Greenhalgh & Swinglehurst, 2011). The lag is likely related to assumptions that frame the design of health information technologies as an exclusively technical problem (Greenhalgh & Swinglehurst, 2011; Pratt et al., 2004; Star & Bowker, 2000). Often the claims for technologies like electronic medical records (EMRs), automated decision support, or computerized physician order entry – that they will increase efficiency, support decision-making, reduce errors, and standardize information – are taken as self-evident. Benefits are presumed to follow logically from implementation (Greenhalgh & Swinglehurst, 2011). Coupled with this

assumption is the notion that staff and clinical practices will simply adapt to new technology (Berg, 2001).

In the situation in which the Pill Talk project intervenes, there has long been a methodological blindspot with respect to recognizing the sociotechnical complexities of clinical practice and achieving meaningful clinician engagement. So in contrast to previous studies and prior interventions attempting to address underreporting, Pill Talk starts from the premise that it is not the end users that need to be fixed through more education, enticement or enforcement. Their conscious work cannot be replaced by analyzing traces of data left as documentation in medical records that were not specifically intended to capture robust ADE data. In contrast to previous work, we tried to rethink the rationale and systems designed for reporting. If clinicians are going to supply the information that reporting systems seek to capture, we might prioritize the design of systems so that they work for clinicians, and enable clinicians to meet their care delivery goals of safer and more efficient care for patients.

The central question, then, is how to approach the design of such a system. In practice, the success of new technology often hinges on how well it is integrated into organizational and clinical practice and how well it meets end-user need, so methods are needed to bring rigor, robustness, and accountability to the design process (Greenhalgh & Swinglehurst, 2011; Berg, 2001). Importantly, these methods must allow for meaningful engagement with clinician-users in the design, evaluation and implementation phases, and should include observational methods to identify differences between actual and perceived work practices. Methods must be useful in developing a rich understanding of the sociotechnical hospital environment and the clinical practices in which such a platform would intervene.

For Pill Talk, we chose to use participant observation and focus group methods to develop an understanding of the sociotechnical milieu of the environments we seek to change. It is important, however, to mention why other methods were rejected. Our goals – to understand the sociotechnical environment, capture situated action, and give voice to practitioners in our design and research processes – made some methods easy to exclude. Questionnaires, for example, are the dominant method used for studying

underreporting (Lopez-Gonzalez, Herdeiro, & Figueiras, 2009), but offer little in terms of meeting these goals because they are so removed from action. They rely on imagined or recollected accounts and offer only the weakest form of participation to the people whose work is the focus of study.

The analysis of video recordings of action offers a more promising alternative. Suchman (1987/2007) argues that video analysis is preferable to observational or interview accounts because it captures detail about the phenomenon of study without presupposing what is relevant, or how things are playing a part in the unfolding of events. Observations, on the other hand, unavoidably involve the observer constructing a partial account – one that carries in it preconceptions, structures, and the innumerable little decisions about what the observer thinks is relevant or important at any given moment (Suchman, 1987/2007). Unlike video, observational notes offer no “recourse to a record of the action and its circumstances, independent of [the observer’s] analysis” (Suchman, 1987/2007, p. 121). I believe Suchman is correct in this assessment, however, the choice of methods is itself an action that needs to attend to local circumstances. Care providers are on the move: they visit patients in different areas, look for charts, discuss with other providers, access various computers – all in sometimes chaotic healthcare settings like the emergency department. The difficulties of filming in this environment are combined with the problem of consenting every patient and provider that is encountered (who may not appreciate being filmed while they navigate a traumatic health event or their care provision, respectively) and the handling of sensitive personal health information. While video recording was a very viable option for Suchman’s (1987/2007) study of an “expert help system” built into a (very stationary) photocopier machine, it was impractical for Pill Talk’s more complicated environment.

One-on-one qualitative interviews offer another viable alternative method that can offer insight into how care providers make meaning in their worlds. However, much of the benefit of this method is captured through unstructured interviewing during participant observation and focus group discussions. Moreover, in these methods care providers can develop their input in concert with their colleagues (focus groups) and with reference to their ongoing work activity (interviews during observation) or the prompts offered by Pill Talk’s team members (interviews in situ and focus groups).

3.4.2. Participant Observation

For this thesis, the primary method for achieving my results was participant observation. Participant observation is an ethnographic field method in which the researcher acts as a participant in the community or culture that they are studying (Tedlock, 2005). Initially, participant observation was taken up as a technique to “try on” the research subject’s perspective to bring more depth to ethnographic accounts (Tedlock, 2005, p. 467). Participant observation today, however, considers itself more critically, especially within more reflexive research streams in feminist studies, anthropology, STS, and action research. The researcher has a responsibility to interrogate what it means to be an “outsider within” (Star, 1995, p.1), and to shed the notion that participation might offer a somehow less problematic account of the activities of the cultural other. This means that participant observation includes practicing autoethnography, a critical reflexivity which Tedlock (2005) characterizes as an attempt “to heal the split between public and private realms by connecting the autobiographical impulse (the gaze inward) with the ethnographic impulse (the gaze outward)” (p. 467). The same emphasis is seen, for example, in the work of Woolgar (1982) or Suchman (1987/2007) who argue for a move away from constructing representations of participants. The first reason for this is to honour an ethical commitment: to avoid subjugating research participants to the models and categories of the researcher, framing them as mere objects of study. The second is to honour an epistemological commitment: recognizing the contingency, partiality and situatedness of even the researcher’s claims. Overall, participant observation is a shift from the sometimes one-directional activities of ethnography, where the observer reports on an alien culture, to a two way exchange, emphasizing “relational versus autonomous patterns, interconnectedness over independence, translucence over transparency, and dialogue and performance over monologue and reading” (Tedlock, 2005, p. 467).

Participant observation (and ethnography in general) is also valuable in that it involves the researcher immersing themselves in a social situation, enabling them to create a more fine-grained, detailed, and situated account of action. Clifford Geertz’s term “thick description” is often invoked in reference to ethnography, an alternative to the comparably thin (reductive and context-free) accounts of action offered by positivistic science (Geertz, 1994). In workplace studies, for example, observations methodically

detail and reflect on collaborative work, as well as explicit and tacit or taken-for-granted elements of work. As Suchman (1987/2007) suggests, “one objective in studying situated action is to consider just those fleeting circumstances that our interpretations of action systematically rely on, but which our accounts of action routinely ignore” (p. 118). This detail is valuable in that it reveals how planned work activities differ from action on the ground (e.g., in the case of Pill Talk: complexities in diagnosing ADEs, spontaneous problem-solving) and deters reductive accounts of the complexity and spontaneity of work, showing how practitioners don’t simply complete a series of discrete tasks or “apply” knowledge but instead are constantly engaged in a “continuous stream of knowing and acting” (Jerak-Zuiderent, 2012, p. 732). Ethnography also reveals actors and artefacts that may have otherwise gone unnoticed. In the Pill Talk project, for example, we were able to account for the wide array of people, tools, and practices enrolled in information gathering and medication management decisions related to ADEs (e.g., clerks, nurses, family members, clinical information systems, internet resources, paper and online forms).

In Pill Talk, participant observation was used to examine the practices of clinicians identifying, diagnosing, and documenting ADEs. Four other researchers and I (all familiar with qualitative investigation) conducted observations in three hospitals in British Columbia: the Vancouver General Hospital, North Vancouver’s Lion’s Gate Hospital, and Victoria’s Royal Jubilee Hospital. The majority of these observations were carried out in emergency departments and hospital wards where we shadowed clinical pharmacists, nurses and physicians for 3-8 hour shifts at varying times of the day and days of the week to account for changing levels of activity and work procedures. I also did observations in three community pharmacies. I undertook ten of our collective fifty observation shifts.

Study participants included a convenience sample that we recruited through the contacts of the practicing clinicians on our team. Our observations were unstructured; we attempted to capture as much detail about all elements of the situation as possible, but with some focus on elements such as

- a.) the setting,
- b.) patient presentations in which ADEs are suspected, worked up, managed, and documented,

c.) artifacts that mediate the work (e.g., medication reconciliation forms, Pharmanet – a provincial pharmacy dispensing record, pre-printed orders),

d.) activities that constitute work (e.g., obtaining a patient's medical history, reviewing bloodwork, etc.), and

e.) the flow of information between clinicians over time.

Doing Participant Observation

In general, I would meet with the provider that I would be shadowing that day and, if we weren't already familiar, give a brief introduction of myself and our project, have them sign off on ethical clearance if required (e.g., if they have not already been consented by a team member), and then they would immediately begin their work. As they went about their activities, I tried to capture as much detail as possible about what was happening on a notepad that I carried, along with my own personal reflections or observations. To keep up with the amount of detail, I often used shorthand or jot notes that could remind me about something that happened later. Some providers would treat me like a student or a partner, walking me through all of their activities and sharing their thoughts and opinions: what they were doing on the computer, why they were looking at certain documents, what they were thinking about a patient, what issues/frustrations they had, etc. Other providers that I shadowed were more indifferent to my presence and tried to carry out their work in the same way and at the same pace that they would if I wasn't there. There was no shortage of moments when I felt awkward or out of place, and tried with varying degrees of success to blend in. Depending on the person I was shadowing and how busy they were, I would often ask questions and carry on a dialogue about their activities. In this way, observations were sometimes like an unstructured interview carried out over the course of activity. Conversation ranged from more mundane topics like what tabs they clicked on in the electronic medical record to more complicated or involved questions like "Do you think this [patient event] would qualify as an ADE?" or "When would you report an ADE?" As well, I would often establish a friendly relationship with the provider I was working with and our conversation would sometimes stray into personal life (which, of course, I didn't record).

In some cases, it seemed clear to me that my presence had a significant impact on the provider's activity. This partly related to the demands of being accompanied and

explaining their work. As one provider noted, she would normally see triple the amount of patients compared to when I was there. I also noted that it seemed like some providers felt accountable to me – as if I was evaluating their work and the decisions that they made. I feel like some would have conducted their work differently if I hadn't been there. For example, they might have been less thorough with a patient, or would have been less likely to approach a physician about something they suspected (some pharmacists appeared nervous about approaching or interrupting physicians).

After each observation shift, I would either immediately retreat to my office to type up my notes or type them up in the following days. In this time, I would draw on my notes and my memory to create cleaner, more detailed recollections of the shift's events. In total, our team generated field notes from over 350 hours of observations. Another researcher and I independently coded these notes in *NVivo 10* as they were collected, iteratively reviewing them with attention to emerging trends and concepts, which were temporarily recorded in memos. Upon the initial review, the team used these memos to develop a formal coding structure. As coding progressed, we discussed emerging conclusions in team meetings and used analytic exercises such as workflow diagrams, information flow maps, and event summaries to help us explore our data more deeply and synthesize findings. We initially refrained from formalizing theories or hypotheses to be tested and rather attempted to generate and examine new ideas through an earnest engagement with the accounts that we experienced or reviewed. For me, this was quite easy, as at the outset of the project I knew very little about the clinical environment and was skeptical of some of the simplistic accounts I was reading in both the medical and sociological literature (e.g., clinicians are stubborn and don't want to change their practice). What I found was usually a far more varied and complex picture.

In this thesis, I have chosen to write about only events that I personally observed, which allows me to draw on my own memory to bring detail and reflection to what I saw. I also present only a few arguments and observations of the many that were drawn out of the Pill Talk work. Most of my results (presented in Chapter 4) don't stem immediately from our formal analysis but emerged out of memos that I recorded at various times over the course of my work on the project: while typing up a day's observations, while coding

or analyzing field notes, after provocative discussions or meetings, while reading related literature, or while writing.

3.4.3. Writing this Thesis

There is an obvious contradiction in writing about a shift from conceptualization to practice, as writing an account is itself an activity that conceptualizes, simplifies, and reduces the action and complexity of the real world. The organization, flow, argument, and style of a piece of writing is detached from the mess of practices responsible for its construction. The last two years of my research didn't neatly divide themselves into distinct sections like theory, methods, and case study. Nor did my writing proceed linearly from analytical categories under which I sorted field notes in *NVivo*. There was a lot of activity in between writing: in the emergency department watching, walking and talking with providers, listening to patient interviews, furiously writing shorthand notes; in the office at C2E2 transcribing, recalling and adding details from memory, reacting to what I observed, importing into *NVivo*, highlighting sections of text and dragging them to my chosen nodes, writing memos, searching the library and reading pdfs of papers, discussing findings and design with the team. Every description I offer in this thesis is a partial rendering enabled by that work, and I will highlight only a sliver of the actors and activity involved in my research. The majority of my qualitative work will not be seen by anyone but me – if indeed qualitative work can be neatly separated from my other experiences over the last two years!

I am also concerned with what exactly my account will do. For I operate with the assumption that general themes find their way into action as a weak resource more than their nuanced theorizations (Suchman, 1987/2007). When we do or talk about science for example, it is far easier to reference the simple maxim “minimize bias” than to act based on a strict observance of Popper’s theory of falsifiability. Or when we critique and offer alternatives to science, it is much easier to act with a maxim “knowledge is mediated.” Both are translations and simplifications, and my thesis is also. So if I am to practice what I preach, if I am to advocate for situatedness, then I must try to research and write in a situated way and be honest about the translation. I do this by citing sources, adding caveats, avoiding generalizations, writing this section about writing. I try to leave traces

of what I've done and how I've done it. I also am sensitive to how my work might be taken up – that is, of course, if it were to be read by more than my thesis committee. I hope it introduces a sensitivity to the implications of studying and doing medicine in certain ways (e.g., the erasures that come with positivist or even social constructivist work). I hope also that it demonstrates a modest attempt at how research attentive to situated action might be done, how situated or living knowledges might be created (Haraway, 1988; Swantz, 2016).

3.5. Conclusion

My argument for practice-oriented research in medicine is strengthened and extended by showing how such research can be done. This is the work that I have done in this chapter, first by situating my case study and then by offering a concrete account of methods that resonate with the turn to practice (action research and participant observation). In positivist research, giving context and outlining methods is generally for the purpose of providing a backdrop to the front stage events of inquiry and for showing how the account that the researcher is going to offer is, to the best of their efforts, an objective one. In social constructivist research, method is about bringing forward an unarticulated social, and providing context (or at least a certain version of it, drawing upon the categories of social theory) is everything. Context is where the researcher reveals positivist explanations to be lacking. After the turn to practice, however, the aim of a chapter on context and method, like the one that I provide here, is to offer an account of the ecology into which the researcher enters, with attention to some of the frictions or crises that are worth following in action (as deployed by people on the ground), and to show how the researcher is going to intervene, how they are going to create living knowledge. As Latour (2005) puts it, method is just a pompous way of asking “Where to travel?” and “What is worth seeing there?” (p. 17).

I have described how I am entering into the action of drug safety in Canada. In Canada and internationally, ADEs are a constant harm to patients, and the dominant drug safety method of adverse drug event reporting is likely unable to change this fact significantly. Patient safety as it has been advanced by national institutions in the U.S and Canada focuses on the activities of quantitative data collection and data-informed

intervention via education, standardization, and new ICTs. Policy in Canada is following suit, with Bill C-17 making some ADE reporting mandatory. This approach is not necessarily bad, but it has conspicuously little to say about the practice of clinical care delivery and the action that goes into drug safety on the ground. In any event, it has been flagged by clinicians as a problem. This is where the action research project that I am involved with, Pill Talk, looks to intervene, employing a number of techniques to bring forward ways in which ADEs are dealt with in practice. Pill Talk is positioned as a different form of intervention than those just mentioned, in that it aims to capitalize on the communicative issues relating to sharing drug safety information for individual patient care, prioritizing this function over the collection of data. My empirical work has been embedded in the activities of Pill Talk and in this chapter I have tried to make clear the practices that have gone into the production of my findings, which I now present in Chapter 4.

Chapter 4.

Situated Drug Safety

Let us, somehow, share the doctoring. Let us experiment, experience and tinker together – practically. This is far from easy. Shared doctoring requires that everyone concerned should take each other's contributions seriously and at the same time attune to what bodies, machines, foodstuff, and other relevant entities are doing. Those who share doctoring must respect each other's experiences, while engaging in inventive, careful experiments. They must attune all variable variables to each other, while attending to everyone's strengths and limitations. They must change whatever it takes, including themselves. Shared doctoring requires us to take nothing for granted or as given, but to seek what can be done to improve the way in which we live with our diseases. And remember that failure is inevitable and death the only security we have. (Mol, 2008, p.56)

4.1. Introduction

As I described in Chapter 3, adverse drug events pose an extraordinary and growing challenge to the worlds of medicine. Since the thalidomide disaster in the 1960s, entire new fields of research have developed to guard against the harms of drugs. Before our drugs reach the market, clinical trials try to ensure they are effective and seek to identify early, frequent, or severe adverse effects they may bring. Once drugs are in distribution, surveillance through spontaneous reporting schemes tries to ensure that any adverse effects that have been missed are caught. Patient safety and quality initiatives try to locate contributing factors and causes of risk in the use of drugs through medication incident and near-miss reports and introduce interventions related to medication management, error prevention, and patient adherence.

These fields have been integrally shaped by their co-emergence with particular conceptualizations of how medical research and practice is done and should be done. With the rise of evidence-based medicine and the standardization imperative, improving care has become more a matter of proving – proving certain practices right or wrong (e.g., via clinical trials) (Mol, 2006). And care has become about doing the right things right (applying the evidence) (Mol, 2006). Jerak-Zuiderent (2015) argues further that implicit in

this assumption are two more: proving what is right is separate and distinct from doing it (i.e. research and knowledge creation are distinct from the practice of care) and that the doing of right things is accountable to the proof that they are indeed right (i.e. the practice of care is accountable to research).

In setting apart and defining the roles of worlds of research and practice in this way, a very specific form of drug safety has been enacted. Research, policy, and protocol are designed to better enable a control feedback optimization of health care as a system. The task of research is to take system outputs (usually in the form of clinical, administrative, or reported data), analyze them to identify problems, design solutions that alleviate these problems, then implement them as an intervention into the system. The post-market surveillance of drugs via adverse drug event reporting is one example of this process. As I have shown in section 3.2, the ADE reporting method attempts to adhere to a sort of feedback control model. Clinical data is extracted from submitted reports (or possibly entries into electronic medical records and administrative systems). It is analyzed using statistical techniques to identify signals (patterns of related events that might indicate a problem with a specific drug). The detection of a signal initiates further targeted investigation, the dissemination of warnings to health providers, or, in some cases, immediate recall of the drug. The process is ongoing, hopefully resulting in an optimized set of more or less safe drugs remaining in circulation. This appears to be quite a sensible approach and it has been effective in identifying many previously unknown ADEs. However, it is only one of many ways of undertaking study or improving care, and it comes with serious shortcomings. Efforts to combat underreporting that have focused on either compelling clinicians to report (e.g. Bill C-17) or bypassing them by analyzing data from electronic records have generally failed.

What I argue has happened, is that we've so dedicated ourselves to a certain conceptualization of ADEs and a model for how they might be prevented, that we've failed to look beyond our model to what is actually happening in day-to-day care. The problem of ADEs has continuously been examined at a distance from care itself, preserving the division between research and care, from the standpoint of policy-makers, administrators, and data-oriented researchers. And, further, we've failed to adequately understand what medication use looks like in practice.

What's more is that in this distancing of research and care worlds we constrain ourselves to rely on only one bridge between the two – data. Data appears to be an uncontaminated, value-neutral snapshot of what is happening in the care system. It is clean and quantitative and can be standardized for analysis and comparison. Data, however, is something that's been made, a momentary translation that is done by someone, within constraints, and takes a very particular form. Questions about this translation – when it is done, how it is done, what people and things and practices are involved, what the situations are that are being translated, and what is getting left behind – are generally left out of research literature itself and are discussed only on the margins.

In this case study, I attempt to make these questions central – to examine adverse drug events and drug safety as things that are enacted (or done) in clinical care, and are best studied ethnographically if we are to break from the mechanistic notions advanced by positivist research. I found that the adverse drug event that I went into these environments to observe was not a clear-cut phenomenon but rather an extremely nebulous and contested thing. The ways that ADEs were understood, explained, worked up, and documented varied, and they were dealt with as one aspect of a complex of activities surrounding patients and their medications. I found that drug safety was bound up in practical concerns – practical in the sense that it required attention to circumstance, speculative reasoning about the future, and judgement and action without certainty. I found there was often an interweaving of care and documentation processes that are usually taken as distinct. I found professional differences. I heard that pharmacists over-call and physicians under-call events, and read studies citing both as ignorant, complacent, lethargic, and insecure, neglecting their duty to report and contribute to research and drug safety. Above all, however, I observed a process where clinicians were making links between various activities occurring in varying times and places that as an assemblage enact a particular version of what good care would entail (Mol, 1998).

So far in this thesis, I have argued for a research orientation that is attuned to practice and I have started to show how this kind of research can be done. This chapter demonstrates an analysis, grounded in action research and ethnography and informed by the theoretical assumptions of the turn to practice, that explores drug safety as situated activity. I suggest that by attending to situated activity, we might reveal other ways of

understanding and doing drug safety that are responsive to the “various viscous variables” (Mol, 2008, p. 83) that inevitably crop up in clinical care, instead of trying to generate universalisms and enforce fixed and linear care practices. Mol (2008) calls this situated approach to care “shared doctoring” (p. 56), one where we (as patients, providers, administrators, etc.) don’t expect to be able to stand outside the system evaluating outputs and adjusting the controls, but rather see ourselves as constrained and active participants, interacting and collaborating across time. Such an alternative approach to improving medicine may not be objectively better – there’s no such thing. But it might bring attention to ways of caring that currently receive too little attention, and might be weighed and considered alongside the more positivist approaches that have tended to dominate medical discourse and organization.

4.2. Clarifying ADEs

Before getting into the action of ADEs, there is the seemingly simple question of what ADEs are said to be. This is worth looking at to show the messiness, tensions, and complications in even formal accounts of how ADEs might be identified, classified, documented, and reported (of which there are a wide variety of versions and interpretations in circulation). Most research articles (including those produced by our Pill Talk team) begin with a cursory definition then quickly move on to their study. Some articles will expand further on precise definitions and event evaluation procedures used in their methods. Some will take the identification of ADEs as unproblematic. Attributing the label ADE (or ADR for adverse drug reaction, a specific form of ADE where the event occurred under appropriate use) to a patient’s event, however, can be highly complex.

What follows is based on one of the best accounts of how ADEs can be understood that I’ve come across in the literature, an article by clinicians Nebeker, Barach, & Samore (2004), *Clarifying Adverse Drug Events: A Clinician’s Guide to Terminology, Documentation, and Reporting*. This article offers a careful look at terminological difficulties and, using examples from clinical practice, attempts to sort these difficulties out. They make reference to four general variables that give some order to the terminological confusion relevant to categorizing an event. These variables are causality, appropriateness, expectedness, and harm. Below, I explore each of them, in order to

familiarize the reader with some of the basic elements of ADE identification. This framework provides a vocabulary to understand and analyze the ethnographic accounts that follow this section.

Causality refers to the ability of a clinician to attribute the cause of a patient's adverse event to a drug. Drug safety science stipulates a few major criteria for evaluating causality: time between drug administration and event onset, pathophysiology of the event (whether the drug and the event can be related mechanistically – laboratory evidence is often necessary), competing causes (whether the event might be attributed to another cause like an underlying condition), response to dechallenge (whether the patient improves after discontinuing the drug), and response to rechallenge (whether the patient reacts when exposed to the drug again) (Nebeker, Barach, & Samore, 2004). Based on these kinds of indicators, a clinician has to make a judgement as to their certainty regarding causality. In general, events where certainty is higher are expected to be documented and reported and shift towards a categorization as an ADE or an ADR as opposed to a generic adverse event. However, there is considerable variability as to what is expected regarding certainty when classifying events for both research and regulatory purposes. To attempt to quantify and standardize certainty, scales have been developed (e.g., distinguishing rules for categories like 'unlikely', 'possible', 'probable', 'definite').

Appropriateness refers to whether the use of the drug in practice proceeded in the right way. This has to do with human error, either by the provider or the patient. If a drug is prescribed, dispensed, or administered in a way that deviates from what might be considered best practice, then this is considered inappropriate. This can refer to things like a patient missing a dose or increasing it, or a physician choosing the wrong unit for their patient's dosage (e.g., mg instead of μg). Sometimes this is clear-cut and sometimes not – again, this comes down to a judgement call on the part of the clinician assessing the event. Of course, determining if the drug was used under "right" practice can be extremely complicated – patient medication regimens are often based on fluctuating dosages or include new drugs and dosages they are trying out, and what's right for an individual patient prescription may depart from conceptions of best practice. If the clinician treating the adverse event decides that a drug was used appropriately, this shifts the event's classification towards an ADR – a specific form of ADE where the problem has to do with

the drug and not the circumstances surrounding how it was used. Interestingly, our systematic review found that the majority of reporting systems (around 86%) are only concerned with ADRs, which indicates a specific form of drug safety – one of routing out the bad drugs distinct from their use in practice.

Expectedness refers to whether the patient's event and its severity could have been reasonably anticipated prior to administering the drug. For example, side effects that are listed in the product information or labeling are sometimes considered to be expected. Alternatively, an event might be reasonable to expect if it follows from the drug's principal therapeutic effect (e.g., perhaps a patient's blood pressure dips too low after being administered a diuretic medication). Some drug safety agencies will specify that they are not interested in these events, and –especially when the event is common – clinicians may be less likely to document or report expected events, taking them as a normal consequence of a medication's use. More recently, the international drug safety community has recognized this as a problem, in that expected events go unaddressed or unreported and consequently downplay the injurious effects of some drugs (Nebeker, Barach, & Samore, 2004). For this reason, usage of the term side effect has been discouraged by some (Nebeker, Barach, & Samore, 2004).

Finally, there is the question of harm. Harm refers to the severity (the intensity) and/or seriousness (the outcome) of an event. There are formal indicators of severity and seriousness. For example, if an event is life-threatening or results in hospitalization, it can be classified as serious (Nebeker, Barach, & Samore, 2004). However, determination of severity and seriousness usually requires a judgement call on the part of the clinician. If little or no harm was caused, the event is less likely to be categorized as an ADE or ADR and is less likely to be deemed worth documenting or reporting. Events can be categorized as medication errors even if no harm has occurred.

In sum, a formal account of how an event might be termed an ADE is dependent on a combination of clinical judgements regarding at least four often ambiguous variables: causality, appropriateness, expectedness, and harm. Within each of these variables are embedded other criteria, evaluation processes, complicating considerations, and judgements. Then there is an overarching judgment to be made regarding which variables

deserve the most weight for a given event. For example, if an event has a very serious outcome for a patient, then perhaps a definite ruling on causality is less necessary to warrant documentation or reporting. In general, it is clear that even formalized notions of ADEs and the decisions that need to be made around identifying, documenting, and reporting them are often not clear cut. They come down to clinical judgements, not the straightforward application of criteria, where the clinician has to make tentative links between different types of evidence and considerations and attempt to match them up to available (and non-standard) terminology.

This is important to note because, judging from the way that ADEs or ADRs are referred to in some of the research literature, it may appear that ADEs and ADRs are as unproblematic to identify as a gunshot wound. Studies using clinical data, for example, rely on how providers have coded these events in their electronic medical records, without attention to the difficulties and intricacies that might be involved in how this is done. In Pill Talk's workshops with providers, we often used case examples from practice to orient discussion. We tried to pick more straightforward ADEs to avoid derailing conversation, but these examples often triggered intense discussion about how to classify and deal with the event. We also saw clinicians navigate these difficulties constantly in practice. But to complicate things further, clinicians aren't referencing an article on terminology and decision-making as they work, and they are not undertaking an isolated and exhaustive study of a patient with a complaint that may or may not be related to drugs. They are making expedited, practical decisions relating to the specific circumstances and available information about an event to improve a patient's situation.

4.3. Doing ADEs

The description above shows how ADEs can be quite a complex diagnosis to make. Their identification, documentation, and reporting involves gathering information about and making a series of judgements regarding a given state of affairs surrounding a patient's medication use. This is a description of what an ADE is. But, of course, my aim is not to show simply what an ADE is but how it is done. The ADE is not a state of affairs, an objective reality waiting to be discovered by an attentive clinician, but something that emerges over time, a process, a construction. One that is often uncertain, in flux, and is

dealt with in a practical way. In what follows, I offer 2 stories from practice and one from the literature to bring out this distinction and what implications it has for care.

4.3.1. Situated Care - Ms. Jacks' Side Effect

Consider the case of Ms. Jacks, who has been admitted to the emergency department at Hospital A. I observed a clinical pharmacist who assessed Ms. Jacks.

Lindsay introduces us to Ms. Jacks then, in a friendly but efficient way, starts confirming medications. She asks about vitamins, over the counters, and prescription drugs. She asks about the colour of pills, and how much and how often Ms. Jacks takes them. She listens and makes notes on Ms. Jacks' medication reconciliation form. She asks if Ms. Jacks has completed her course of antibiotics for her pneumonia. Ms. Jacks responds yes, but complains of being plagued by a dry cough, which Lindsay informs her is a side effect of one of her medications, ramipril. It affects around 10% of people. Lindsay says that she will pass on a message to Ms. Jacks' GP to follow up on this. Ms. Jacks notes that her GP – who she thinks is wonderful – is on maternity leave, and that sometimes she will see someone else in her clinic if they have room, but otherwise they tell her to go to a walk-in.

We leave Ms. Jacks' room and Lindsay writes up a note on her assessment of Ms. Jacks, telling me that she'll write a fax to Ms. Jacks' GP to get her to follow up. She explains that Ms. Jacks' case isn't cut-and-dried and shows me on Lexicomp (a drug information resource often used by pharmacists) that 7-12% of patients get the side effect of chronic dry / tickling cough from ramipril (confirming her earlier guess of 10%). I ask her if she would report this as an ADE to MedEffect if she were more certain. She starts to say "in a perfect world-" then trails off, going to photocopy her note. She returns and tells me that she has changed her mind: if Ms. Jacks' GP is on maternity leave, she may not have access to good follow up care and it may be best to switch her off of Ramipril here and now. Lindsay finds Ms. Jacks' physician in the nurses' area and explains the situation. He agrees to the change and they briefly discuss the replacement medication (candesartan) and an appropriate dosage – I hear him suggest a low dose because "she's a little old lady." I'm impressed by how he and Lindsay work together, their discussion is

efficient, friendly, and respectful. Lindsay goes back to her desk, revises the note she had started earlier, and affixes a patient sticker.

We go to see Ms. Jacks and Lindsay reintroduces herself. She explains to Ms. Jacks that her physician has decided to replace ramipril with candesartan to see if it will help the dry cough. Ms. Jacks asks what is different about candesartan and Lindsay explains that it is a different class of drug but, like ramipril, it will help decrease blood pressure. Lindsay advises Ms. Jacks to monitor her blood pressure, as they are putting her on a conservative dosage to avoid her blood pressure dropping too low, and she may need to increase the dosage. Lindsay notes that Ramipril is the white and red pill and instructs Ms. Jacks to stop taking it today and start candesartan tomorrow.

Later in her shift, Lindsay pulls up the 'ADE screening GP fax form' from her e-mail, prints it, affixes a patient ID sticker, and writes a brief note that Ms. Jacks had a chronic cough, it was unclear if this was related to ramipril, and that the emergency department physician has replaced ramipril with candesartan. She look GP's fax number, then goes to the fax machine and sends it.

Listening to Ms. Jacks' account of a dry cough and reviewing her drug list, Lindsay makes a link between the cough and information she's previously seen about the side effects of Ramipril (abstracted from physician reports on patients participating in Ramipril's clinical trials) that make this a possible ADE. It seems that there is no further evidence that she can gather at this point to make this link more certain, besides maybe obtaining agreement from Ms. Jacks' physician that it is worth considering. She recognizes, however, that Ms. Jacks' GP would be in a better position to assess the need to replace ramipril, and, if it was replaced, to follow up to see if Ms. Jacks' cough subsided and her blood pressure was okay. If ramipril was removed and Ms. Jacks found that her cough subsided, this would greatly bolster the link between the cough and the drug and consequently, the cough's status as an ADE. The best action at first, then, seems to be to notify the patient's GP of this possible ADE. However, there is another element of the story that Ms. Jacks brings to bear – her GP is on maternity leave and she must sometimes go to walk-in clinics. Lindsay says it is for this reason she decides to replace Ms. Jacks' ramipril with candesartan in hospital.

The possible ADE here requires construction over time (to determine if the cough subsides with the change in drug, which would suggest that the cough is a side effect), across settings (acute care to general practice), and will involve various providers (pharmacist in hospital, emergency physician and general practitioner). It will involve a confluence of diagnostic, care, and documentation activities. If it is confirmed to be an ADE, it will likely be because Ms. Jacks visits her GP down the road, where perhaps she remembers the medication change or her GP notices the fax from Lindsay in Ms. Jacks' file and inquires about it. Maybe Ms. Jacks' cough will have subsided, in which case Ms. Jacks and her GP may decide this as an ADE and avoid ramipril. Whatever the outcome, the ADE will remain ambivalent and unstable for a while. Like Mol's (2002) observations of atherosclerosis, disease is something that is done, it is the holding together of various distributed activities that enact the thing that we know as atherosclerosis or ADE.

This story draws out the uncertainty surrounding some ADEs and shows diagnosis, care, and documentation as intertwined processes. The clinicians had to act on only partial understandings of what the patient was experiencing, responding in the best way they could to the specific circumstances of an event. Action does not proceed linearly after a diagnosis is made, rather actions of diagnosing and treating are intertwined. Likewise, documentation activity isn't necessarily a separate, after-the-fact account – it can be functional, it can do work to solidify a diagnosis or improve a patient's care. In this clinical care setting, different forms of documentation – in the medical record, the clinical note, and the medication reconciliation form – are practiced and orient practices in unique ways. As Berg (1996) reminds us with respect to clinician note-taking, documentation is not simply a representation of events, it is an active artifact where links are made between disparate activities, to hold together a patient's case or disease across time and space and orient action.

Looking over the shoulder of a physician during a patient in-take exam: [the physician] creates an overview, distilling and reconstructing information from different times and places, different relevancies, and different sources into a single frame, in such a way that the bits of information he jots down mutually elaborate each other, and form a clear case.....Each entry is a transformation of disparate cues into one which strongly directs the line of action to take. (Berg 1996, p. 505)

Whether it is Lindsay's clinical note that she adds to the patient's chart or in the fax to the GP, documentation is a part of the care she provides to Ms. Jacks. Ms. Jacks' record will be constantly updated, revised, and acted upon over the course of her stay in the hospital and possibly beyond.

But while documentation constitutes an important part of diagnosis and care, it remains subordinate to the demands and contingencies of practice (Berg, 1996). Different ADEs will require different documentation depending on what the provider aims to achieve by documenting. After Ms. Jacks' event, Lindsay explained to me that she would be very hesitant to enter this as an ADE into an outpatient record for Ms. Jacks (one that could be seen by providers such as a community pharmacist). For one, whenever Ms. Jacks visits a community pharmacist, they might end up asking her about this ADE. It is possible that, down the road, Ms. Jacks will need ramipril (regardless of the cough) and an ADE report in an electronic record may influence a provider to not prescribe it. Part of the problem, here, is that Lindsay wants only to have this event documented in the patient's chart (her note) and in the fax to the GP – that will alert Ms. Jacks' next providers that the ADE is a possibility and should be considered in Ms. Jacks future medication regimens. This concern for the future interpretation of a shared report was very common in our observations. Clinicians worry about how their note will live on past its usefulness, or shape action in unnecessary or harmful ways. Most significantly, it was often the concern that documentation might at some point prevent a patient from getting a medication that they required which sometimes deterred care providers from documenting an ADE. It's notable that in such cases, care providers' concern is not about whether their note is a true representation of the facts as much as it is a concern that future providers won't be sensitive to the circumstances of the event.

When I asked Lindsay about whether she would report this event to MedEffect (Canada's national ADE reporting program), she says "in a perfect world" then goes back to her work preparing her clinical note. Based on my experience with her and other providers, what she means when she says this is that reporting to MedEffect would be nice to do, but it isn't a priority for her practice. It will do nothing to help improve the care of Ms. Jacks or Lindsay's other patients. Likely, her uncertainty around the event and its low severity mean she doesn't think it would be particularly valuable to drug safety

researchers either. The decision not to report is a judgement which involves weighing the particular demands of care against the formal demands of research and regulation. Each side has its advocates, with some clinicians arguing that reporting is not a valuable use of their time and researchers and regulators charging them of neglecting their duties to contribute to general drug safety knowledge. Certainly, both sides can enact good care in different ways. One shouldn't, for example, suggest that attention to the particulars of a situation always supercedes the benefits of general knowledge. I note that in this example, it was a general fact about ramipril's side effects that provided Lindsay with the first indication that Ms. Jacks' cough and the medication could be related. This shows the value of facts – they can allow stories to travel. During ramipril's clinical trials, there were a number of patients that experienced a dry cough. These patient's accounts were translated into reports, which when analyzed translated into a note on ramipril's monograph that there is 7-12% risk of experiencing dry cough as a side effect. Such translations (along with previous experience observing that side effect) allow Lindsay to quickly make a tentative link between those coughing patients in the clinical trial and Ms. Jacks.

It's not possible to say that this is objectively good care. While Lindsay may have relieved Ms. Jacks of a chronic cough, the new candesartan prescription may bring new side effects, new risks. Other providers would undoubtedly have acted differently. Some may have viewed the cough as minor and not warranting time that could be devoted to other patients or the risk to Ms. Jacks of a new medication. Some may have chosen only to document the event in the chart or to document it in Pharmanet so that other pharmacists would be aware. Some may have reported it to MedEffect. Some may have printed out information for Ms. Jacks about why the medication was switched. Some may have identified a different problem altogether. There are a multitude of possible trajectories that might constitute good care – each carrying their respective normative priorities (e.g., seeing as many patients as possible, establishing continuity of care, informing large-scale drug safety research, enabling patient autonomy). Each trajectory starts from small decisions, often imperceptible if one is removed from practice, and each is uncertain. As researchers in medicine, we might pick up on these various trajectories and take care to develop and enable them.

Jerak-Zuiderent (2012) argues that good care proceeds under lived and located judgements. In what ways were goods of care enacted in Lindsay's activities with Ms. Jacks? How was drug safety done? Perhaps most simply, Lindsay talks to Ms. Jacks, she listens to what she has to say and is friendly. Lindsay reviews all of Ms. Jacks medications with her, noting what they look like and how they need to be taken. She is able to work from a record of Ms. Jacks' prescriptions to make sure that she is thorough. This careful review can catch both outstanding issues and potential future issues with Ms. Jacks' regimen and the way that she follows it. Lindsay notices a potential issue and takes action to communicate it to Ms. Jacks' physician in the emergency department, her subsequent providers in the hospital who might read the clinical note, and her GP. Her attention to Ms. Jacks' comment about not having access to a regular GP immediately may save Ms. Jacks from months of coughing. When Lindsay and Ms. Jacks' physician decide to switch her to candesartan, they do so with a cautious dose to avoid lowering her blood pressure too much. Lindsay explains clearly to Ms. Jacks (noting things like the colour of the pills) how she should discontinue Ramipril today, and start Candesartan tomorrow. Some of these little decisions and comments may prevent another medication issue.

These actions (and the many in between that didn't make it into my story) may constitute good care or drug safety for Ms. Jacks. They are care that is attentive to the many particulars of Ms. Jacks' situation – to Ms. Jacks herself, her words, her list of medications and her knowledge of them, her current situation with her GP, her size and her age and measurements of her blood pressure. They are also attentive to how ADE documentation might mislead community pharmacists, how uncertain the cause of Ms. Jack' cough is, how candesartan and ramipril do more or less the same thing. While elements of Lindsay's work on Ms. Jacks are routine or standard (for example, it is common practice to do a medication reconciliation, the step by step medication review using a pre-printed medication list), there is no formal protocol that could best handle Ms. Jacks' case. Rather, it was Lindsay's responding – her in-the-moment, practical action – that enacted drug safety. What we see in this story with Lindsay and Ms. Jacks is the situated practice of care and drug safety. Ms. Jacks' case is unique, uncertain, and unfolding over time and space. Lindsay's work is practical and collaborative, and can't be

clearly divided into diagnostic, treatment, and documentation phases. It is about small situated activities that bring about uncertain improvement.

4.3.2. Situated Care - Ms. Hart's Non-Adherence

In our observations, ADEs related to patient adherence were among the most frequent events. A patient is deemed non-compliant, non-adherent, or self-managing when they do not take their medications as prescribed (e.g., with the correct timing, frequency, dosage, duration).²⁹ This has been highlighted as a serious problem for health care provision, with studies finding that less than half of patients are adherent to long-term therapies, compromising the effectiveness of treatments and increasing the likelihood of ADEs (Brown & Bussel, 2011). A 2003 report from the World Health Organization argues that “increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments” (Sabaté, 2003, p. 11).

ADEs related to patient adherence are generally not the object of drug safety surveillance efforts. These are events where the patient is using a drug in a way deemed wrong, and thus they cannot offer insight into the safety of the drug itself because they introduce a significant confounder. A researcher wouldn't be able to tell if a problem was associated with the drug (used as prescribed) or with the patient's incorrect use of the drug. Efforts to improve adherence, however, often follow the same feedback control model of drug safety science. For example, RCT methods are used to evaluate novel interventions (like counseling/education programmes, self-monitoring and feedback technologies, or electronic reminders), in an effort to correlate an intervention with a measure of adherence or health outcome (Mistry, et al., 2015). In a systematic review of studies like this, Mistry et al. (2015) found that no single intervention could greatly improve adherence, and that the interventions that made at least a little improvement were complex, and involved “combinations of more convenient care, information, reminders,

²⁹ There is interesting controversy over which of these terms is appropriate, with non-compliant and non-adherent implying a passive patient and exaggerating physician control (Brown & Bussell, 2011). Brown & Bussell (2011) point out that no single term can capture the complexities involved in taking medication for chronic conditions.

self-monitoring, reinforcement, counseling, family therapy, psychological therapy, crisis intervention, manual telephone follow-up, and supportive care” (Mistry et al., 2015). What this perhaps suggests is the need for more attention to the ecology of actors and activities, the networks of support over time, and the particularities of patient situations that bring about good medication use.³⁰ The following instance offers an account of a non-adherent patient admitted to the emergency department, and helps empirically ground this discussion:

It's 4pm and I'm nearing the end of my shift in the emergency department at Hospital A with the clinical pharmacist, Jane. Jane is at the charting area reviewing a physician's notes and a nursing assessment for the next patient she will see – they've been admitted for very low blood pressure and dizziness. We find the patient, Ms. Hart, in room 9. She is an older woman, accompanied by a friend (also an older woman) and a young man that she explains is her grandson. Jane chats with them briefly then starts asking the usual questions: Who looks after medications? Can you remember them? When and how often do you take them? When did this dosage switch? Ms. Hart answers these questions readily, though at one point she says what she is "supposed to be taking." Jane clarifies she needs to know what Ms. Hart is taking. Ms. Hart revises her account, noting that she occasionally misses a dose. Jane asks how often she misses her doses and Ms. Hart responds 2 times a week, and she forgot yesterday. She says normally she takes them but she is sometimes late. She explains how she went to see her GP today and he just sent her to the emergency department because her blood pressure was so low. Jane jokes that it was a good day to see her GP and Ms. Hart laughs and agrees.

We leave Ms. Hart and go to the charting area. Jane quietly tells me that Ms. Hart is pretty good about her meds but not perfect – she guesses that Ms. Hart is maybe missing a dose per week. Jane goes to a nearby computer and opens Pharmanet (BC's patient medication registry). On Ms. Hart's profile she can see the dates when prescriptions were filled and the amounts dispensed. On a scrap piece of paper she adds up how many pills

³⁰ By “good medication use” I do not mean simply compliant with physician orders. Indeed, many patients find ways to self-manage their medication regimens that involve tailoring to what makes them feel best, is most convenient with their life, is most effective for them, and so on. Some of these self-managing practices certainly do enact “good medication use” despite deviating from the doctor's orders.

Ms. Hart's prescription calls for versus how many she has been dispensed over the last few months. She googles calendar and calculates the days on her phone - Ms. Hart is 26 days behind. The amount dispensed is not near sufficient for her to be taking a regular dosage.

Jane says that she will return to see Ms. Hart, but she thinks that Ms. Hart may be more open about her adherence without me in the room. She notes that it is already difficult with Ms. Hart's friend and grandson there. Ms. Hart may not want to say the truth in front of them.

I wait at the charting area while Jane talks to Ms. Hart. When she returns, she explains that it sounds like Ms. Hart has been very irregular with her medications this week because she was distracted with an issue with her foot. Ms. Hart also admitted that she has difficulty remembering if she has already taken her medication on any given day – she currently gets her drugs in bottles so she can't track whether she's already taken her dose for the day. Often she opts not to take them because she doesn't want to risk a double dose. Jane suggested Ms. Hart try a dosette (a plastic box with separate compartments for each pill) so that she can track her medications day by day. Jane notes that a dosette is more appropriate than a blister pack (medications are prepackaged in labeled packets at the pharmacy) in this situation because the patient knows her meds quite well.

Jane tells me her concern that Ms. Hart is not managing, that what really needs to happen is for her to try the daily dosette, then have a follow up consultation with a pharmacist or GP and if she's still having trouble, switch to a blister pack. Jane explains that she wishes she had the ability to outline a plan like this in some kind of patient record –then, once the plan has been done (say, the follow up check has occurred) then the entry could be easily removed.

She explains to me that, if Ms. Hart is First Nations (which she appears to be) and had any experience with residential schools, then her non-adherence could be due to the discomfort of being in a facility surrounded by white-coat authority figures. Jane recounts a story of attending to a First Nations patient with a Saudi Arabian physician who was confused by his patient's indifference to anything he told them. Jane had said something

to him like 'if you have a moment, let me tell you a story about the tragedy of residential schools.'

Jane is writing a note explaining her concerns for Ms. Hart. She tells me she will fax Ms. Hart's GP but, looking at Pharmanet, realizes that the prescribing physician appears to be different from Ms. Hart's usual GP. She isn't sure who to send the information to for follow up. Jane quickly checks with Ms. Hart, who says that today she saw a walk-in clinic doctor because her GP was unavailable. We leave and Jane faxes her note to Ms. Hart's GP. She sees Ms. Hart's physician and tells him about the fax she sent to the GP. The physician tells Jane that Ms. Hart will go home and that he thinks he will have her start using blister packs.

Jane's work has involved carefully piecing together of an ADE due to non-adherence. It has involved reading physician and nurse notes that translate accounts of Ms. Hart's blood pressure and dizziness from prior tests and interviews. It has involved listening – Jane noticed how Ms. Hart referred to what she was “supposed to be taking,” which cued her to ask more about Ms. Hart's blood pressure medications. It has involved using Pharmanet to check records that the staff at Ms. Hart's pharmacy have entered, and making calculations with a notepad and a smartphone to compare what was prescribed to what was filled. It has involved creating a more comfortable setting for Ms. Hart to talk to her, one without a large man with an ID badge scribbling on a clipboard at her side (me). In these actions, she has created a textured and particular understanding of Ms. Hart's non-adherence: one that links the reading of Ms. Hart's blood pressure, her complaint of dizziness, her knowledgeable recounting of her medications, her admission of forgetfulness, her inability to access her usual GP, and her navigation as a First Nations woman of a health care system that is dominated by settlers.

Other information may, of course, be missing (both from my account and Jane's assessment). I heard nothing about an underlying reason for Ms. Hart's low blood pressure, or what exactly the problem was with Ms. Hart's foot that distracted her from taking her medications as usual. Perhaps Ms. Hart's medication makes her feel sick or not herself, but she was reluctant to say so. Perhaps she was holding back important information because of the presence of her friend and her grandson. Perhaps she was

saying what she needed to because she was sick of being in the emergency department. The reality is that Jane must act with an only ever partial understanding of Ms. Hart's situation. She has to intervene at one point in what is an unfolding process of the ADE. Her treatment of Ms. Hart's ADE is based on a concern for Ms. Hart down the road: it includes trying to make for a comfortable conversation with Ms. Hart, the recommendation of a dosette, and a fax to the GP. She expresses the desire to outline a plan, which she currently is only able to do in the fax to the GP. With a plan, Jane could add some dynamism to her treatment of Ms. Hart. She could make note of contingencies and future actions. As she told me later, the problem with communicating via forms is that there is nowhere to put your "ifs, ands, or buts."

What this account illustrates is again that care unfolds in response to particular circumstances, and is made up of many efforts to enact an uncertain good. Jane's decisions about how to care (and at the same time, how to document) come down to her recognition of what is doable and might improve Ms. Hart's life. Such practical considerations might again influence the way we look at drug safety or non-adherence: there is no solve-all intervention, no reality out there to be revealed and fixed. Rather we might open up space and create tools for people to improvise, re-organize, plan, and react as situations unfold. Achieving this requires a recognition that drugs are not simply technical entities that can be straightforwardly or objectively used, that we cannot just study and intervene until one day providers and patients prescribe and take medications rationally.

The current orientation of drug safety is towards routing out drugs that harbour unknown but harmful effects: a surprising toxicity, a hidden side-effect, a rare allergy trigger. And of course, knowing about these risks is necessary for good care. However, these lead to only a minority of events. A significant proportion of adverse drug events (as reported in the literature and as observed in the Pill Talk fieldwork) are related to the challenges of medication use in practice. It's evident from the stories of Ms. Hart, Ms. Jacks, and from the rest of our qualitative work that there are many areas that can be improved related to medication use in practice that may seriously contribute to drug safety but are not likely to be fixed with a simple intervention like a technology, a best practice, or a protocol. Access to a good GP or consistent patient contact with care providers who

are familiar with their medical history, provider communication and continuity of care across settings and over time, collaboration within settings (e.g., pharmacist and physicians in the emergency department), provider sensitivity and attentiveness in patient interviews – all might be areas where improvement might take root.

One thing that these potential points of improvement have in common is that they demand that care be local – local in the sense that the patient and providers are connected, communicating, and, ideally, familiar. Improvement through the fostering of local care, however, is something that cannot be recognized or achieved by a control feedback system approach, as local issues are poorly expressed in clinical and administrative data. At the same time, local care can make the more general normative frames from philosophy and sociology clumsy. For example, it is not clear cut how a lay / expert relationship should unfold, how natural healing figures against a technical medicine, or how the complexity of patient experience should be preserved in the short time that a provider has to see a patient. Making care local requires understanding each patient interaction with healthcare providers as one moment in their care trajectory and their life, and attending to frictions and problems while making best judgements about the modes of good care that can be enabled for the time being.

4.3.3. Translations - The Case of Paroxetine

In the account of Ms. Hart's non-adherence and Ms. Jacks' side effect and on frequent other occasions in our observations, we see how important the patient interview can be in revealing the circumstances of an event. Notably, there is a tension that arises between dealing with the patient as a medical case and as a person, and this tension relates to a larger and very important question about what is relevant, what gets to matter about a particular patient's event. On the one hand, you have the patient as a medical case (I use the word "case" here because this is often how providers refer to patient events and construct a narrative of formal information about a patient). Providers can rattle off details relating to demographics, chief complaint, medical history, symptoms, lab values, physical exam, medications, possible diagnoses, etc. at a speed that is baffling to a lay

person.³¹ Clinicians on the Pill Talk project used the same form of narrative to present cases to our focus groups with providers. These narratives create sorts of information puzzles, where the provider must take the disordered information provided and give it order in the form of a coherent diagnosis and treatment path. Clinicians are exceptionally good at this and it can be an incredibly effective way of working. The situation is similar with an ADE report. The report is where various pieces of information are aggregated to create a picture of an event that can stand alone enough that researchers might be able to recognize it as an ADE, assess the likelihood of causality, and group it together with other reported events.

These cases, narratives, and reports, however, offer only a very partial account. The information that gets to be included in the puzzle is of great importance. Let's remember again that information is something that has been done, thus these narratives determine what activities get to matter in decisions about what to do, they enact one among many configurations of an event and particular avenues of treatment. These information puzzles are where distributed actions –bloodwork testing, the physical examination, the triage nurse's interview note-taking, dispensing of medications, etc. – are linked together within a single frame. The forms that these cases take often exclude, among other things, detailed information about the patient's story. Sometimes, we observed how what the patient was saying was given less weight than what the provider could learn from other information sources. Some providers constructed an ADE before they even spoke to the patient, using information from medication lists, lab values, and chart data. In discussions about which data fields were relevant in an ADE reporting platform, not a single field referred to the patient experience (except, interestingly, a little tick box to indicate non-adherent). This eschewal of the patient's input is not necessarily the norm nor is it necessarily bad, but it does show how a patient can sometimes be reified as a health state. This reification can be exacerbated by ICTs in health, which are more adept for the representation of quantitative information than qualitative. As shown in the

³¹ This is a technique in which clinicians are trained – to be able to recount relevant information about a patient's event as quickly as possible to others. As well, cases are recognized for their usefulness in medical decision-making, they serve as a resource for clinicians to refer to when deciding how to respond to a patient's situation, especially under pressure (Mol, 2015).

examples above, patients provide nuanced information that can often have a significant impact on their care that would not generally make it into a formal account of their event.

A fascinating example of the translation of patient accounts into medical terms is a set of studies by Medawar et al. (2002, 2003/2004) (expanded on in a set of editorials in the *Prescrire* journal) around the reporting of ADEs to paroxetine, an antidepressant selective serotonin re-uptake inhibitor (SSRI). In these studies, the authors compare reports submitted by British clinicians to several thousand accounts collected in written e-mails by patients who had experienced an ADE with the drug. Upon withdrawal of paroxetine, patients variously accounted experiencing something that felt like “an electric head sensation, associated with sensations of whistling and dizziness” which were “alarming and incapacitating” and “made it difficult or impossible to stop paroxetine” (Prescrire Editorial Staff, 2004, p. 234). In the clinician’s reports, however, this was coded as “paresthesia,” which is associated with a much more mild experience like pins and needles, and investigations based on reports concluded that “withdrawal symptoms are relatively mild and do not have features of a physical drug dependency syndrome” (see Figure 7) (Medawar et al., 2002, p. 167). Medawar et al. (2002) found a number of other discrepancies between the clinician’s and patient’s reports, especially those relating to qualitative experiences, which could not be numerically analyzed very well.

On one hand, this example can be taken as a matter of patient versus expert, a neglected social experience in an increasingly technical enterprise. While this approach may be productive, it artificially sets apart the social and technical domains. What may be more fruitful is to look at the practices and artifacts of translation that are necessary to take a patient’s account or event and abstract it into a report and ultimately into a set of values in a database. For example, the choices available to a clinician in coding a patient’s withdrawal experience for a report are limited. While the clinician may have recognized something more serious than pins and needles, paresthesia was the only selectable code. The coding structure (we might assume that it was the international classification of diseases or ICD system) is not the product of the science of medicine, but of many competing medical, epidemiological, financial, administrative, and industrial demands, and – while imperfect – is part of an ongoing activity of negotiation, contestation, and compromise (Star & Bowker, 1999). What is necessary, then, is a sensitivity to these

various activities and how the translation of events into data leaves behind uncertainty and ambiguity, sometimes in significant ways. This sensitivity needs to happen not only with respect to the translation of a patient's event into information, but with all information translations. Bloodwork values, for example, are created via specific artifacts and practices, and are referenced to ranges of normal/abnormal that have their own origin in practices. Coordinating practice well requires an understanding of where these values and thresholds are coming from, what they really indicate, and what limitations exist.

Schuurman and Balka (2009) highlight this problem in clinical data generation. While interest in evidence-based medicine has grown and considerable investment has gone into the technical infrastructure to enable data-driven research and policy-making, the local conventions of practice entailed in the making of data have been largely ignored (p. 84). Often, the automation of data collection in electronic medical records or electronic reporting platforms only serves to further obfuscate the ontological activity of data collection as data collection activities assume the role of "de facto status as infrastructure" (p.94). The consequences of this can be inappropriate interpretations, comparisons, and aggregations of datasets sourced from different contexts. Information becomes a view from nowhere (Haraway, 1988).

The ontological context of data can refer to the simplest who-what-why-when-hows of data collection, but Schuurman and Balka (2009) argue that data collection remains problematic even in thoroughly standardized infrastructures. Specifically, they draw attention to the semantic heterogeneity of various concepts – suggesting that even uniform language is open to wide interpretation across different communities of discourse. Things that we like to assume are ontologically singular – suicide, ER wait time, atherosclerosis, adverse drug event, paresthesia – are multiple. They are enacted as distinctly different things across various sites of practice.

Following from this, a new question arises. How can we engender sensitivity to translations? With respect to patient's experiences, Medawar et al. (2002) suggest the

ability to link patient reports to clinician reports.³² Alternatively, many clinicians that we observed and spoke with suggested the need for free text entry so they can enter more nuanced descriptions. Within the pharmacovigilance world, some have pointed to the limitations of quantitative analysis of reports, advocating for proactive explorations of reporting data and follow ups with patients and providers.³³ Schuurman and Balka (2009) suggest adding “context-based metadata (data about data)” to databases. For any unique database or dataset, one might perform an ethnography of the collection and stewardship practices, especially those practices that might otherwise remain tacit (p. 100). All of these solutions introduce new complications of course, but they offer directions for experimentation that might serve to engender recognition of information ontologies in the age of evidence-based medicine and health ICT boosterism.

4.3.4. Managing Medications

One of the goals of doing participatory observation for the Pill Talk project was to understand clinician workflow. Prior to doing observations, I envisioned creating diagrams, maps, and sequences illustrating the order of how work was done. In practice, however, a generalizable order to the activities of care was difficult to pin down. As Suchman (1987/2007) points out, plans serve as only a weak resource to action, especially in complex settings like healthcare. Certainly I could extract a very general order of activities, very general routines that exist in, for example, processes of identifying patients at risk of ADEs or in lines of questioning that were common in clinician/patient interview. However, to extract these general orders would not necessarily be useful or instructive. A perhaps rather obvious reason for this is that clinicians – to varying degrees

³² University of Washington Medicine has piloted an innovative venture incorporating the patient experience. The *OpenNotes* movement gives patients access to the electronic clinical notes entered by their clinicians, allows them to add their own notes or to build the note together face-to-face with their physician (Leventhal, 2015).

³³ While most pharmacovigilance analysis today uses automated statistical methods to analyze databases of ADE or ADR reports, it is interesting to look back to what existed before such computer capabilities existed. For example, in the 1970s Canadian Dr. Ed Napke developed a system of “pigeon holes” – essentially a shelving unit that served as a physical database – in which he attached coloured tabs to reports to help track patterns. Some refer to this as an example of a “primitive” form of the statistical techniques that are now used, but others point to how spending a few hours in the pigeonhole room was a highly effective way to synthesize signals. Older drug safety experts are sceptical of the “uncritical” uptake of sophisticated new statistical programs, which leave assumptions unchecked (Finney, 2003, p.xxvii).

and in varying ways – are nearly always engaged in a process of managing medications as a part of their delivery of care. I use the term managing here to try to capture the broad range of activities and actors that are involved in helping improve patients' health situations with medications. Using medications involves more than straightforward diagnosis, prescription, dispensation, and subsequent patient health improvement. It involves referencing research, following best practices, trying out, adding or removing drugs, adjusting dosages, collaborating with the patient, navigating patient non-adherence, and, of course, dealing with adverse events. In this process there can be a multitude of relevant human and non-human actors: the patient, care providers of various kinds (clinical pharmacists, admitting clerks, specialists, internists, GPs, nurses, etc.), insurance policies, drug availability, drug costs, research. Some activities have nothing to do with any single patient, but rather have to do with general troubleshooting and contributing to an environment that is more conducive to drug safety. For example, we observed clinical pharmacists devote considerable time to activities like tracking down staff who are completing medication lists erroneously or helping clerks make sure they put the right print-outs into patient charts. Clinicians rarely even had the opportunity to complete one patient at a time. They are frequently moving between multiple patients at one time, being interrupted by other providers seeking assistance and being drawn into other patient's cases. Indeed, one of the main ways that pharmacists found patients that needed assistance was through listening to other providers talking in the charting area and offering to help.

It's important to note the connotations related to casting these activities as managing. As Mol (2008) points out, managing suggests a straightforward collecting of facts, growing certainty towards a diagnosis, then an informed patient choice between courses of action. Sometimes, care does approximately follow this trajectory. More often, however, achieving good care is a process "of trying, tinkering, struggling, failing, trying again" (Mol, 2002, p. 177). For this reason, Mol (2006, 2008) argues that notions of managing should be replaced with doctoring, tinkering, or nursing: "the creative calibrating of elements that make up a situation, until they somehow fit – and work" (Mol, 2006, p. 411). Indeed, following the clinicians in their work was less about observing how they complete the discrete tasks of identification, diagnosis, and documentation of ADEs, nor

about how they straightforwardly optimize people's medication regimens, but about following them through a care process that is about making things work for the time being.

4.4. Intervening

In the previous sections, I have tried to reveal the complexities behind simplistic formulations of ADEs, drug safety, and care. But what can complexities tell us about what to do, how to intervene, how to improve? I think that most importantly, they force us to consider that good care can take many different forms beyond the application of best evidence, contributions to general knowledge, or reference to an overarching normative frame. They inform us about the myriad other ways that the negotiated and uncertain goods of care are enacted, different ways of acting that we might empower: "We seek those ruled by partial sight and limited voice – not partiality for its own sake but, rather, for the sake of the connections and unexpected openings situated knowledges make possible" (Haraway, 1988, p. 590). The Pill Talk project taps into this potential and is worth exploring as an example of what might be a situated intervention in the activity of clinical care (Zuiderent-Jerak, 2015).

Central to Lindsay and Jane's care was the communicating of the circumstances of their patients' visit to the emergency department that day to outpatient providers that their patients might see in the future. This was done by sending faxes to their GPs. It is likely, however, that GPs do not always see these faxes (and some admit to giving them little attention). Improving drug safety, then, might take the form of opening up this line of communication via a platform such as Pill Talk. First, we learned from our observations and work with clinicians that documentation and care processes need not be taken as separate. Pill Talk is about trying to repurpose ADE reporting to be about provider-provider communication. It is about integrating reporting into the practical activity of care, seeing documentation as an act of care, rather than as a separate process to enable research that clinicians must be constantly harangued to do. We hope providers will be motivated to report because reporting matters to their individual patients in that by communicating to GPs and community dispensing pharmacies that are responsible for dispensing drugs, it is in itself a form of providing care. Second, ADEs (and health in general) are not states of being, but rather come together over time and space, and include

multiple people. Pill Talk, then, might consider making the ADE report a “living document” that would allow for multiple providers to easily edit, update, and remove the report. In Ms. Jacks’ case for example, Lindsay could open a report suggesting a possible ADE to ramipril. If Ms. Jacks’ cough has receded when she makes her next visit to her GP, then the GP might choose to update the report, confirming that it was indeed likely that Ramipril caused the dry cough. Third, different documentation practices are required for different events. Rather than attempt to standardize or mandate which events are reported, give providers the flexibility to make judgements as to what is safe or necessary for a particular patient. This will avoid documentation that could endanger the safety of a patient (e.g., if reporting an event might prevent a patient from getting a medication they will later need). Fourth, documentation is a constrained constructive process in which a limited set of distributed activities are brought together in one frame, some activities will be left out. One way of providing practitioners with a degree of flexibility in entry is to allow free text entry of information into the platform, so that, for example, Jane could enter into the form that Ms. Hart is trialling a dosette, but if it fails, she should be put on a blisterpack. Finally, the Pill Talk platform is an opportunity for a different type of drug safety learning, in that it enables providers to receive feedback on their decisions, with detail regarding the circumstances of their patients. Regular use of the platform combined with local analytics about how it is being used can create a learning-through-practice environment with feedback, collaboration, and shared expertise.

While the Pill Talk platform may expand a space for better care to be enacted, it also creates new harms. Like a medication to treat an illness, interventions to solve problems in health care work are never without hazard. They have side effects, risks, adverse events. They boost certain elements of a situation and they suppress others. They give freedom and they constrain. They have unpredictable ripple effects in the ways that people in a setting relate to their world. We can only speculate as to what these effects may be, experiment, and make judgements, but we cannot be certain that an intervention is improvement. Our observations and focus groups made clear some of the issues that will arise with the Pill Talk platform, which might be further understood using ethnography after the platform is in place. First, time spent documenting is always time that could be spent doing other activities of care. The question that will be at the fore for providers is: is the trade-off worth it? Documentation work, even when it is quick, is more

time in front of a screen and less time with patients. Second, as Latour (1995) points out, a new actor in a network –say, a technology like Pill Talk – takes the place of a previous network that performed a certain action or dealt with a particular problem. Current practices of communicating around ADEs – practices that have been in place for a long time like faxes, phone calls, face-to-face conversations, reporting – these may fall away under Pill Talk. Even modes of medication management, say, a complete review of a patient’s medications, could possibly be replaced by a more superficial ADE check. Third, Pill Talk may also introduce new punitive social and legal implications. For example, a provider’s error might be circulated via the platform instead of being dealt with through confidential reporting to oversight bodies. Fourth, it introduces new risks of misinterpretation, and patients may end up not getting medications that they need – people might suffer or die as a consequence of Pill Talk.

As I’ve laid out earlier, the traditional approach to intervention in care is generally uncritical. New technologies, protocols, plans are rolled out because their benefit – whether it be reducing errors, increasing efficiency, standardizing practice, saving money – is taken as given. The electronic medical record, for example, is seen by many as an urgent and unquestionably necessary step towards health care improvement, boosted by the allure of automating what was previously done by mere humans and primitive paper and pen. In some cases, interventions that have intuitive value are put to the test, with researchers using RCT methods to evaluate their effectiveness. But even these tests offer only a glimpse of what the impact of an intervention may be. Like RCTs with drugs, they are limited by the fact that they only measure specific outcomes, in specific ways, under specific circumstances. Taking the form of the control feedback system, intervention today is, as Haraway (1991) writes, about “the translation of the world into a problem of coding, a search for a common language in which all resistance to instrumental control disappears and all heterogeneity can be submitted to disassembly, reassembly, investment, and exchange” (Haraway, 1991, p. 164). The issue, here, is that the process of translation is erased, the codes are taken as raw fact, and the corresponding rearranging is unproblematic and benevolent.

The impacts of Pill Talk in this climate could very easily go unquestioned (except perhaps by the people on the ground who grapple with them firsthand). In the world of

the clinic, providers are used to dealing constantly with doubt, having to act with uncertainty in the hopes that things will work out for now, or at least enough that they can follow up later. We must act the same as interveners in care, and indeed the uncertainty around intervention is why ethnographic research can be so valuable to both design and study interventions in health care. It can create a picture of what an intervention does in a practice environment, what it replaces, and the changes it introduces. It can shed a light on what a technology enacts – the tenuous goods and bads of care, the multiple ways in which it affects a care environment beyond the narrow outcomes measured by clinical trials. Often, there will be problems (and successes) that patients and providers have already identified and navigate in their everyday practical work (indeed that was how Pill Talk got started!). Ethnography serves to formally bring these goods and bads forward, articulate them in depth, complicate them, and explore possibilities for how things might otherwise be.

4.5. Conclusion

In chapter 2, I offered a theoretical argument for following a thread of STS scholarship interested in providing accounts of sociomaterial practice. This way of doing research is a change from positivist, mechanistic and critical social constructivist accounts of care that are formed at a distance from care and that take an interest in only a small segment of activity. While researchers focus on collecting quantitative data about patient outcomes or analysing patient-provider conversation, there is a world of sociotechnical practice that goes unexamined, in which providers worry about practical concerns and not the representations of researchers. In Chapter 3, I described how action research and ethnographic methods are a way of expanding the domain of research to get involved in these practical concerns, aiming not to represent or abstract from care but to intervene thoughtfully in it. I described my work with the Pill Talk project and the situation into which the project team and I were entering.

This chapter is a demonstration of how insights based on a theoretical frame of sociomaterial practice, and carried out with the proximity to practice offered by action research and observation can inform intervention in practice in ways that positivist and social constructivist methods can't (or don't try to). I explored adverse drug events, drug

safety, and information as things that are enacted or done in clinical care, that come into being, provisionally and uncertainly, via the local constructive work of the clinician. Providing good care requires a navigation of the practical circumstances of a patient's situation and creative response. I argued that improvement may be best achieved by developing analytical accounts of this work, and finding ways to enable clinicians to make critical, lived and located judgements (Jerak-Zuiderent, 2012).

Positivist modes of drug safety to prioritize and facilitate data collection in care require reflection. What is this approach doing in practice? What does it prioritize and what does it leave behind? What unsafety does it produce? Are there other ways of doing drug safety that might be better? As the drug safety community devotes research, resources, and policy tools to trying to get clinicians to produce data (an effort that has been ongoing for over fifty years in the case of ADE reporting), I argue that other normative orientations beyond producing general knowledge are worth investing in. How, for example, can we better enable the communication of patient drug information between providers? How might we give them more time to spend reviewing medications with patients? How can we add to patients' abilities to self-manage their medications? How can we leverage patient stories (e.g. from online platforms) to better inform care? How can we address overdiagnosis and overmedication? And how can all of this be coordinated at a local level, with sensitivity to local issues, individual patient circumstances, varying resources, provider abilities, and practices?

Certainly these avenues have not been entirely ignored, but they fall outside the dominant plan offered by a feedback control system frame. They are not easy to collect data on, to test with RCTs and quantify effects. They won't easily be fixed by a new technology, protocol, or plan. They also involve forms of coordination in which social research would be invaluable but all too rarely takes part: the design of information infrastructures, documentation practices, workflows; the amplification of frictions and differences in practice; the storytelling of technologies, diagnoses, treatments in practice. In this thesis, I have introduced the turn to practice as a resource to inform intervention so that these opportunities are not missed, to attune research to the practical activity that it has always been a part of. To close in the next chapter, I summarize my work in this thesis, traversing the theoretical, methodological, and empirical which here I have set

apart to give a certain coherence to a way of doing research, but which are always intertwined in action. I try to return to this action and point to directions forward.

Chapter 5.

Conclusion

As Latour and Woolgar (1979/1986) point out with respect to order and disorder in the lab: while order is created out of disorder – new disorders are also created. Masses of data, manuscripts, and notes plague the lab and must themselves be subject to an analysis to bring order in the form of a coherent, concise publication (Latour & Woolgar, 1979/1986). Such a description resonates well with my thesis writing – a long process of ordering a mess of ideas, field notes, memos, new angles, materials, false-start drafts, literatures. And of course, ordering means suppression, a rejection of the way things could have otherwise been. In my clean accounts of positivism, social constructivism, and the turn to practice, I've tacked together wide swathes of theory that contain incredible amounts of dissonance. I've lumped together Auguste Comte, Karl Popper, Frederick Taylor, and Archie Cochrane. And I've made bedfellows of Emile Durkheim, Gyorgy Lukács, Thomas Kuhn, and David Bloor.

In my exploration of the practice of drug safety, I've reduced large bodies of drug safety research and work to general themes. I've told only two of many patient stories that I observed. Some detail never made it into my awareness or my notes, some detail was expunged as I simplified and cleaned up my accounts so that they would be readable and clear. My analysis gives an order to activities that might differ from others, and undoubtedly I found certain things intriguing or remarkable that others would have left out. I've expelled intricacies and complexities, taken multiplicities and wrapped them into singularities.

This is not a confession of incompetence or error. As Mol (2002) writes, “a text cannot be everywhere at once. It cannot do everything at the same time nor tell all” (p. 6). What I claim to offer is an account that gives order and voice to a way of doing research in medicine. In Chapter 2, it is an account of how the literature might be read as a three phase trajectory. It shows how bodies of academic writings might be held together by shared themes and how this trajectory might point to where research in medicine might go and how it might be done. I don't claim for this account to be definitive, rather it is an

assemblage of links that I (following others) have done work to make hang together for the time being – others might do work to disassemble and reassemble it in new and different ways, bringing in new theoretical and empirical resources.

In chapter 2, I began by walking through a trajectory of three styles. First, positivism, a style that is based on a separation between human and nature, and that uses sophisticated methods and technologies to orient its work in establishing just exactly what nature is and how it might be better manipulated to meet our needs. Then, social constructivism, a style oriented chiefly to critique of the scientific, employing the human/nature scheme but showing the ways in which the scientific picture of nature never escapes mediation by the social and cognitive frames of the human and thus remains non-absolute. Finally, sociomaterial practice, a style that comes out of the social but places humans and non-humans on the same plane of analysis, that takes reality as multiple and examines local activity –things, ideas, people in action. Practice research is concerned always with where knowledge comes from and what it does in the world, and is consequently attentive to its own location and its own intervening. I showed how each of these various styles are employed in studying and doing medicine and to what effect.

My aim, here, was to draw together a convincing rationale for moving towards a situated understanding of medicine and its unique problems, knowledges, materials, and practices. Part of this aim is bringing proximity where there was once distance. The simplifications made in both positivist and social constructivist conceptualizations come to bear on the world of care in ways that deserve attending to. We need to move away from the myth of positivism that we are or can be in total control, and equally the myth of heavy-handed critique that technical control is always in opposition to a vital, human social. The advantage of situatedness, I believe, is that it allows us to live with uncertainty without attempting to expel it, to acknowledge contingency but take steps forward, and to consider with more depth the possible effects of our actions. It also, crucially, is a path to opening up different ways of doing and being in the world in that it attends to questions that are on the margins of normal discussions (categorizations, calibrations, inconsistencies, workarounds, etc.), and can thus bring attention to things that aren't normally sites of contestation but whose impacts on day-to-day activity are significant (e.g., information infrastructures).

In chapters 3 and 4, I have tried to demonstrate how these insights might be mobilized in the practice of research and combined with empirical resources. Embedded in an action research project aiming to address the problem of adverse drug events in medical practice, I employed ethnographic methods in emergency departments alongside clinical pharmacists as they dealt with medications. Using accounts from both the academic literature and my ethnographic work, I examined adverse drug events as things that are enacted in sociomaterial practices. I showed that ADEs are not clear cut, and that their diagnosis, treatment, and documentation processes were intertwined. I reconceptualised drug safety as something that is also locally enacted, a form of good care that emerges out of the circumstances of a situation and a provider's uncertain but practical action. It is something that comes out of a managing or doctoring processes, where providers attend to various frictions, uncertainties, problems encountered in their work in attempts to bring good care to their setting.

Understanding ADEs and information as activities that are done and the work of clinical pharmacists as situated drug safety allowed me to break from formal notions of what it means to intervene in care. First, intervening is not a process where I as the researcher stand outside of the care system, identify a problem, and design and implement a solution. Rather, I am myself embedded in the system (or systems), with others, caught up in and shaping the situation. I used the Pill Talk project as an example of how an intervention can be informed by work that is attentive to practice and I note some of the possible benefits and drawbacks of care that it might bring about.

This approach diverges significantly from traditional drug safety discourse and methods, which posit a divide between research and practice, and thus between study and intervention. ADE reporting isn't understood as itself an intervention in care, rather it is seen as a neutral method that informs interventions through drug withdrawals or warnings. It is perhaps for this reason that drug safety efforts have struggled so much in stimulating reporting, despite constant study of the problem. Along with others in the drug safety community, I believe that proactive drug safety initiatives are needed, initiatives that recognize themselves as interventions in care and that are attentive to care as a collaborative activity, not simply a data source. We should tap into potentialities that already exist: empower providers who see a problem frequently in their work to share their

knowledge and develop solutions; empower patients to collaborate in their care; draw on the rich resources now available on the internet where patients go to talk about their experiences with drugs. We might do more ethnographic work, partner with provider and patient groups, bring their stories to bear, and follow objects in action (conduct ethnographies of medications, diseases, drug markets, diagnostic tools, labels, prescribing practices, etc.). And in all of these activities, we might put local practices in dialogue with the philosophical and sociological attention that is so adept at articulating and interrogating the normative considerations relevant to problems. In this way we might bring latent controversies to light and at the same time reveal other ways of living with drugs – uncertain and hazardous as they may always be.

It is also fruitful to make the analogy of our everyday selves as providers, as carers and interveners in the world. There are lots of care trajectories available, lots of ways to improve and live in the world, both individually and collectively (Mol, 2002). We encounter new circumstances in every moment of the day, make links and give situations order, draw on ideas, tools, and other people to help orient our action, and make practical and creative decisions to try to bring about the local good when we can. Attending to our styles of working is a major part of this process, and limiting ourselves to a single style, a limited set of practices for all problems is surely unwise. Control feedback systems may be wonderfully suited for the design of engines and ventilations systems and even drugs, but are they the best model for organizing clinical care? Critiques of medicalization may be helpful to assess the impacts of diagnosing personality differences, but are they the best frame in which to evaluate public vaccination? In these individual and collective decisions, good intentions are not enough. We must act with attention to the translations that we and others make: where our facts come from, what practices have crafted them, what people, logics, artifacts played a role, how we figure in and what effects, good and bad, our interventions may have. There is no doubt that at times we will be wrong and we will fail, but it is only through thoughtfully adjusting, collaborating, and experimenting with some alternatives that we can – for the time being – enact a better world.

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