ONCOLOGISTS' PERCEPTIONS OF THE ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF GENETIC TESTING AND MICROFLUIDIC LAB-ON-CHIP TECHNOLOGY

A Thesis Submitted to the College of Graduate Studies and Research in Partial Fulfillment of the Requirements for the Degree of Master of Arts in the Department of Sociology

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ABSTRACT

The objectives of this study are twofold: firstly, to give an account of the current methods of knowledge production, and secondly to contribute a consultation piece on oncologists' perceptions of non-technical issues regarding the ethical, legal and social implications of microfluidic lab-on-chip technology (MF LOC). Two connected theses statements are put forth. First, understanding the transformations of knowledge production will allow for a more socially and ethically informed mode of governance to emerge. Second, it is important to consider who might use the technology and how it might impact institutions and individuals.

Interviews were conducted with 31 Canadian oncologists during August 2004 to February 2005. Qualitative analysis was used to examine the oncologists' responses. It was found that of the different types of knowledge production that were reviewed (Mode-1, Mode-2, Triple Helix, and Post-normal science) the Triple Helix thesis was most supported. However, an integration of characteristics of Mode-2 with the Triple Helix thesis best accounts for the current description of knowledge production. The principles inherent in Post-Normal Science provide a starting point for developing an approach for building capacity for an independent institution that examines the ethical, legal and social concerns regarding transformative technologies. In relation to the second thesis, the results indicate that MF LOC devices have great potential to transform institutional practices and affect individual lives. And it is important to understand that the oncologists studied constructed their understanding of MF LOC technology within a scientific and biomedical repertoire consequently, future research should assess the perceptions and concerns of other groups of people that are different from the scientific and biomedical repertoire.

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DEDICATION

I would like to dedicate this thesis to the unborn children of the future whom will be entering into a vastly different world shaped by global, technical, and social transformations unprecedented by historical records. May we have the wisdom today to prevent the calamities of tomorrow.

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ACRONYMS

MF LOC – Microfluidic lab-on-chip
PCR – Polymerase chain reaction
DNA – Deoxyribonucleic acid
CIHR – Canadian Institute of Health Research
CFI – Canadian Foundation of Innovation
GM – Genetically Modified
GMO – Genetically Modified Organism
PNS – Post-Normal Science
HIPPA – Health Insurance Portability and Accountability Act
HCP – Hereditary Cancer Program
SCOT – Social Construction of Technology
STS – Science and Technology Studies
SSK – Sociology of Scientific Knowledge
P – Participant

1.0 CHAPTER ONE

1.1 PROLOGUE

Time: 790, 000 BCE the dark night sky is cascaded with stars and a nearly perfect round moon, the air has a crisp bite and it will not be long before the cold season arrives. Beasley (an early hominid) sits shivering in his makeshift hut of twigs and branches from an olive tree. Images start flashing across Beasley's mind…memories of a time not too long ago of when he ran away from a brilliant beam of light that seemed to dance across the trees, a light that gave off an immense sensation of warmth. A thought occurs to Beasley that perhaps there was something in the wood of the trees that made the warmth come out. He grabs a couple sticks of wood from off the ground and starts tapping them on a rock, he does this for a while but nothing happens. He doesn't give up; he starts rubbing the sticks together between his hands and immediately feels warmer from the friction. He sits rubbing the sticks for a long time until finally a small billow of smoke emerges followed by a young flickering flame. He has created 'fire'. Content, Beasley curls up and falls asleep by his small flame of warmth. A little while later he wakes up to find his entire hut engulfed in flames. Feeling both fascinated and distraught he watches as the last bit of his hut turns to ash. He immediately begins rebuilding his home and the next night he digs a hole in the ground big enough to contain the fire…an innovation known as the 'fire pit'.

In a sense we (humanity) are still like Beasley, observing what is in our environment, responding with certain actions and witnessing the effects. The need to control and manipulate our surroundings through technological innovation has become as inherent to human nature as flying is to an eagle. Our history with technology has taken us down paths of both wondrous discovery and enormous

devastation[1]. The creation of materials, weapons, medicine, automobiles, plumbing, energy sources, computers, better housing, etc. has enhanced our way of living and protected us from outside elements, but the path of technology is a two-way street that has also led to pollution, industrial disasters (e.g., Chernobyl), divisions of social class, and more devastating war tactics (Leiss, 2001). In order to anticipate the impacts and reduce risks it is thus becoming more important in society to understand how we generate knowledge of the world around us, and how that knowledge then is managed and transferred into technological applications. This first chapter will reveal the central thesis statements and corresponding questions along with the purpose and significance of the study. A brief discussion of the definition of microfluidic lab-on-chip (MF LOC) device is also provided.

1.2 STATEMENT OF THESIS, QUESTIONS AND PURPOSE

Most individuals are born into the world with the ability to see, touch, smell, taste and feel. But what happens when our senses do not provide us with enough information to probe the world around us, or even the processes within us? Humans develop tools such as telescopes that enable one to peer into other galaxies, or microscopes to observe microscopic phenomenon. Scientists and engineers are currently working on a portable microfluidic lab-on-chip device capable of analyzing an individual's deoxyribonucleic acid (DNA) with the

[1] Technology (definition): "Application of knowledge to the practical aims of human life or to changing and manipulating the human environment" (Encylopedia Britanica, 2005).

intention to monitor changes within cancer cells (Pilarski et al., 2004). The social concerns arising from the possible applications of this technology focus on issues of patient confidentiality and the privacy of genetic information including inappropriate use of genetic information to facilitate genetic discrimination. Since this technology (MF LOC device) is still in the developmental phase, it is important that analysis of various actors who will potentially be affected by the use of this technology be conducted. This research examines how Canadian oncologists view how this device may impact not only their patient's lives but also their own practice. My main argument is that by gaining insight into the underlying mechanisms of how a society adopts certain technologies will allow for greater understanding of the ethical, legal and social implications of emerging technologies.

Advances in biotechnology and genetic testing have transformed the way health and illness are perceived, researched, diagnosed, and treated (Conrad, 1992). In an era dubbed the 'information age,' the accumulation of 'new knowledge' is given greater weight as a driver of economic, environmental, and societal sustainability. But how and where that knowledge is *created* are at the center of mass debates between ideologies of scientific certainty and the social construction of knowledge (Nowotny, et al. 2001; Gibbons, 1999 and De Marchi & Ravetz 1999).

The development of a transformative technology has to overcome barriers both tangible and abstract. The tangible barriers include cost and production, whereas the abstract barriers include social acceptance and regulations. My work

focuses mainly on the social barriers, and I use qualitative analysis to understand the perceptions of Canadian oncologists regarding genetic testing and something often called “lab-on-chip” technology.

This is a unique time to carry out research with this particular nanomedical technology as it is in the embryonic stage of development, and thus an opportunity exists to tap into the initial thoughts and reactions of what oncologists think about this technology and the impacts it may have on society. Two thesis statements are put forward. The first thesis is that understanding the transformations of new scientific knowledge production will allow for a more socially and ethically informed mode of governance to emerge. The question that emerges within this thesis focuses on the type of knowledge production we are currently experiencing. In order to respond to this issue a literature review combined with an analysis of the oncologists’ interview responses is provided.

The second thesis states that it is important to consider who might use the technology and how that might impact certain groups of individuals. Two questions emerged regarding this thesis. The first is what insight might oncologists provide in guiding policy concerning the use of MF LOC devices at both the institutional and individual level? The second question is how does a scientific and biomedical repertoire shape the oncologists’ concerns regarding the acceptance and application of MF LOC Devices? The response to these questions will emerge primarily through a qualitative analysis of the oncologists interviewed, combined with input from various authors compilations of subject matter in the area of biomedicalization. This shall contribute to a holistic

understanding of the social, ethical and legal concerns regarding the development and application of MF LOC devices.

1.3 CONCEPTUALIZATION OF MICROFLUIDIC LAB-ON-CHIP

The MF LOC device is a technology that is currently under development in Canada (and elsewhere) by a range of oncologists, engineers and other researchers. It is a technology capable of carrying out a complete analysis from cell selection, to employing polymerase chain reaction (PCR) techniques, and capillary electrophoresis within a relatively short period of time (e.g., 20 minutes). Essentially, the device can be used to decode DNA and to help indicate the presence of certain genes, and to help tailor individual drug prescriptions. Backhouse et al. (2003: 377) describes the intended process and use of the MF LOC device:

> Microfluidic technology applies photolithographic methods, glass etching and bonding to produce microchannels in glass that have dimensions similar to the capillaries often used in molecular biology. The development of miniaturized devices capable of automated real time analysis of genetic profiles is likely to enable routine genetic analysis of diseases such as cancer, whether for diagnosis or monitoring treatment throughout the course of the disease.

The development of microfluidic platforms for the use in lab-on-chip devices has the potential to reveal detailed health information through automated real-time analysis (Backhouse et al., 2003). Just as large computers have been decreased to the size of dime-sized chips, so too have the tools of biotechnology undergone drastic miniaturization (Staeder, 2002). The development of

microfluidic lab-on-chip devices allows the time-intense laboratory tests to be done on automated real-time miniature lab-on-chips (Staeder, 2002).

The major difference in the MF LOC device from existing genetic analysis technology is that the size of the components is drastically smaller and can fit into the palm of one's hand. The advantages of MF LOC devices include decreased time and increased sensitivity of diagnosis, targeted and tailored treatment and decreased cost of laboratory supplies (e.g., reagents): "The potential ability of automated chip platforms to carry out many of the tasks normally performed by technologists and/or multiple large and expensive pieces of equipment is enormous" (Pilarski et al., 2004: 41). Microfluidic systems that employ nanoscale molecular manipulations will enhance disease classification and help direct proper disease management practices for patients. Since horrendous side effects occur in a small percentage of patients on certain prescription and non-prescription drugs, MF LOC devices could be used to offer individually tailored health care. The ability to effectively pre-screen and monitor patients would be cost effective and help identify high-risk genetic profiles. By making medical interventions more targeted, efficient and faster, health care costs are decreased and value is added to the economy (Pilarski et al., 2004).

1.4 SIGNIFICANCE OF THE STUDY

The introduction of transformative technologies into society inevitably produces winners and losers. An extensive examination of the ethical, legal and social implications of such technologies will contribute to a more "socially

sensitive" and better-informed decision making capacity. This study is significant in that it attempts to examine some of players (oncologists) involved in developing knowledge and technology, as well; this study examines the ethical, social and legal issues that need to be addressed before commercializing MF LOC devices.

Currently, there are only a few genetic diseases that can be tested for including Huntingtons Chorea, Cystic Fibrosis and Haemochromatosis. Since many diseases are polygenic, and as such have multiple gene components, deriving the genetic heritage of the disease is not an easy task (Pilarski et al., 2004). If an individual is found to be genetically predisposed to Haemochromatosis, a condition that may end in organ failure and death; one can dramatically reduce the development of the disease by adjusting to healthy lifestyle changes (Pilarski et al., 2004). Clearly, there are significant advantages to the development of MF LOC devices; however, it will come with great social responsibility and require elaborate cooperation between policy-makers, natural and social scientists, industry, government, and the general public to ensure the appropriate application with minimal risk to individuals or society.

The increased capacity of databases to store vast amounts of information have created a situation whereby sensitive patient health information is now being stored electronically. The implications of archiving genetic test results on an electronic database are tremendous. Questions of who has access to this information emerge at the forefront. If patient confidentiality cannot be ensured,

then patient willingness to partake in the benefits of genetic testing may be limited.

> In an age in which medical information is being collected in databases that are increasingly accessible to any health care provider, this will present a dangerous situation in which very sensitive information is widely available while being very valuable to insurance companies and others. Large databases of personal information are likely to be accumulated in the future (Pilarski et al., 2004: 41).

There are currently no laws in Canada prohibiting companies or insurance agencies from requesting a genetic profile of employees or clients. The potential for genetic discrimination exists and the time to shape policy to ensure social justice is now. This is particularly so given that the development and use of portable, rapid, low-cost, easy-to-use MF LOC devices for genetic analysis creates the potential for a wide-range of non-clinical uses by insurance companies, employers, and even by individual consumers (Pilarski et al, 2004). The likely chance that MF LOC devices will be used for other purposes requires an extensive expert and public consultation process in order to educate and then consult with end users like the medical community, government regulators, and the general public to determine societal priorities and the appropriate level of risk (Pilarski et al., 2004).

2.0 CHAPTER TWO: OBSERVATIONS OF THE KNOWLEDGE PRODUCTION PROCESS

The purpose of this chapter is to lay out the characterization of the various types of knowledge production models that are used in this thesis such as Mode-1, Mode-2, Triple Helix and Post-Normal Science. The convergence of fields such as biotechnology, nanotechnology and information technology are creating new forms of knowledge and novel applications of technology. Knowledge-based economies are characterized by increased interest in applied versus pure research with the resulting transformation to the nature and organization of scientific knowledge production and application. Developing and applying new scientific knowledge in the form of new technologies is a primary source of economic growth in knowledge-based economies. It is also the source of many uncertainties and unintended consequences.

The microfluidic lab-on-chip is one such technology currently being developed in Canada through a national collaboration of researchers, scientists and oncologists. This technology, in the form of a handheld, automated device, is intended to enable doctors to monitor, diagnose and provide individualized care to patients through the analysis of single cell material, including specific genes. This analytical work will be possible more quickly and without the need for extensive laboratory space and equipment as is currently the case.

Given that the current regulatory and legal frameworks remain unchanged, it is possible that the MF LOC device may become institutionalized into corporations and used for the selection of genetically superior employees. Insurance agencies, if allowed, are also likely to use the device to assess their client's genetic profile and to set differential premiums for individuals who are found to be 'predisposed' to certain genetic ailments. A society that identifies humans according to their genetic code would inevitably witness a new form of discrimination based on genetics. It is especially important to examine the knowledge production and networks involved behind developing the tools that are used to access and assess genetic information.

Current models of knowledge production are debated by sociologists such as Gibbons et al. (1994) regarding the concepts of Mode-1 and Mode-2 models of knowledge production and Etzkowitz and Leydesdorff (2000) regarding the Triple Helix model of knowledge production. Additionally, Post-Normal Science is emerging as a concept that attempts to include extended peer communities into the production and guidance of novel technologies, and in science in general. This section addresses different theories of knowledge production using MF LOC devices as an illustration of an emerging technology. It is imperative to understand the dynamics of the new modes of knowledge production in order to assemble an effective, socially responsible form of governance[2] which addresses

[2] The term 'governance' refers to the process of policy making, macro-level decision making and implementing regulations. Governance operates on multiple levels and includes different agents responsible for specific kinds of decisions (Refer to Kezar and Eckel (2004) for extended definition).

the ethical, legal and social implications of emerging technologies such as MF LOC devices.

2.1 MODE-1 AND MODE-2 MODEL OF KNOWLEDGE PRODUCTION

The emergence of an open system of knowledge production is what Nowotny, Scott and Gibbons (2001) describe as *Mode-2 science*. The increasing complexity and uncertainty in society is reflective of a *Mode-2 society* (Nowotny, Scott and Gibbons, 2001). The differentiation between science and society is decreasing and a co-evolution has emerged whereby science and society both contribute to each other's development (Nowotny, Scott and Gibbons, 2001). The co-evolution of science and society allows for a dialectical relationship in that science not only speaks to society but also listens to the concerns of society. The notion of contextualization refers to "reverse communication" where a society is able to impact science. Also the individuals in the process of knowledge production are from different arenas, from target groups in markets to legal regulators (Nowotny, Scott and Gibbons, 2001). The process of contextualization is what guides science from reliable knowledge into a more socially robust knowledge production system or approach (Nowotny, Scott and Gibbons, 2001).

The institutionalization of Mode-2 knowledge production creates a new social contract between science and society (Gibbons, 1999). The pre-existing contract consists of bureaucratic-directed science leaving avenues of public participation up to representative institutions. The new contract would include a

more “socially robust” form of science that is both transparent and participative within society. Gibbons (1999) argues that a shift is occurring between “reliable” knowledge to “socially robust” knowledge. The conditions and procedures that have been at the foundation of science as ‘reliable knowledge’ are not changed by the shift to socially robust knowledge. Also “reliable knowledge” was incorporated and validated within boundary limitations, and as such science was viewed as incomplete. Knowledge was gained primarily through a consensual acceptance through peer groups. A socially robust knowledge regime invites the entire scientific community, including the public, to participate in the discourse. This allows new knowledge to be contested and not safeguarded within the environment of scientific peers. Socially robust practices allow for a more insightful understanding of societal impacts of emerging scientific knowledge and its possible applications.

Reciprocity is important in that the public is informed of scientific progress while the science community understands the needs of the public (Gibbons, 1999). Gibbons uses the term “agora” to refer to the public space as a new arena of scientific discourse whereby the public can “speak back” to science. The agora is where the renegotiation of scientific knowledge plays out. The media plays an especially important role in this arena as it acts as the medium through which knowledge is both transferred to the public and debated by the public

Nowotny, Scott and Gibbons, (2001) claim that as science moves out into the agora, the role of scientific and technical expertise changes as expertise becomes more socially distributed. This pattern disrupts traditional linkages of

expertise and institutions. In order to combat the fragmented voice of scientific expertise the emergence of narratives of expertise culminates to provide a collective voice to scientific knowledge and applications.

Nowotny, Scott and Gibbons (2001) characterize narratives of expertise as transgressive in the sense that experts have to address non-scientific issues and communicate those issues to a wide range of audiences. Narratives of expertise are collective such that not only one type of expertise can suffice in explaining the complexity of a phenomenon within scientific and social circumstances. Narratives are also self-authorizing since the heterogeneity of disciplines creates a built-in safeguard against dominating views from one expert domain. The links that reinforce the socially distributed knowledge allows for checks and balances within and between experts.

In order to achieve a new social contract an element of reflexivity is needed to think critically of the unintentional or misappropriate applications of a new technology. A more open and reflexive scientific community will result in a socially robust knowledge production process. The malleability of this new social contract allows for a renegotiation of scientific knowledge rather than a fixed process. Gibbons (1999) also encourages scientists to leave the "ivory tower" to immerse themselves within the agora to increase the effectiveness of the social contract and to enhance the socially robust nature of scientific knowledge.

In earlier writing, Gibbons et al. (1994) differentiate between Mode-1 and Mode-2 forms of knowledge production in order to understand the shifts of knowledge production. Mode-1 is characterized by a separation of knowledge

production and application (Gibbons et al., 1994). Consequently, the site of knowledge production differs from the site of its application. In Mode-1 there is a strong division between university and society, and in Mode-2 the university is characterized as weakening and being replaced by other institutions that take over the production of knowledge (e.g., think tanks and government or industrial laboratories).

A combination exists of knowledge production and application that emerges from Mode-2. A shift in focus away from basic and towards applied research is a hallmark of Mode-2 and it gives way to a transdisciplinary approach to research. As explained by Nicolescu (2002) the term "transdisciplinary" refers to a study between, across and beyond all disciplines[3]. Nicolescu describes disciplinary research as a focus on one level of reality, whereas transdisciplinarity examines various levels of reality simultaneously. The term multidisciplinary refers to the study of a *particular* research topic in more than one discipline simultaneously; for example the Virtual College of Biotechnology at the University of Saskatchewan was created to study biotechnology across various disciplines such as commerce and economics, natural science, social science, and humanities. Interdisciplinary research entails the use of one discipline's method in another discipline (Nicolescu, 2002). Trandiscisplinary research is guided by a quest for universalism and shares a mutual complementary relationship rather

[3] Basarab Nicolescu (2002) wrote this paper for the International Center for Transdisciplinary Research (CIRET). It is a "non-profit organization, located in Paris and founded in 1987. The aim of our organization is to develop research in a new scientific and cultural approach - the transdisciplinarity - whose aim is to lay bare the nature and characteristics of the flow of information circulating between the various branches of knowledge" Website found at: http://nicol.club.fr/ciret/english/indexen.htm

than an antagonistic relationship with multidisciplinary, interdisciplinary and disciplinary research (Nicolescu, 2002).

In Mode-1, the ethical and social issues would be addressed primarily through academic means, whereas in Mode-2 the ethical and social considerations would include input across disciplines and organizations, again reflective of transdisciplinary orientations. The development of MF LOC devices is an example of the Mode-2 transition of knowledge production since it requires transdisciplinary collaboration. However, the Mode-2 model is weak in it's argument that the role of the university is lessening. Since the production of the MF LOC device is in large part being developed by various professionals mostly from academic backgrounds, the Triple Helix model (Etzkowitz and Leydesdorff, 2000), does a better job accounting for the role of the university as integral to the knowledge production process.

2.2 TRIPLE HELIX MODEL OF KNOWLEDGE PRODUCTION

Etzkowitz and Leydesdorff (2000) remark that Gibbons et al.'s position on the emergence of the new mode of production of scientific knowledge does not fully address linkages in the networks between industry, government and academia. Etzkowitz and Leydesdorff (2000) feel that the new mode of production (Mode-2) should be characterized as an emerging system rather than an outcome. Etzkowitz and Leydesdorff (2000) further argue that Mode-2 is not a new concept, and question why Mode-1 has emerged before Mode-2.

Etzkowitz and Leydesdorff (2000) refer to the Triple Helix model as a set of relations between university, industry and government. Negotiations brought on by technological change, such as information technology, between these institutions create a dynamic that leads to a renegotiation of underlying processes. The Triple Helix thesis emphasizes the university's enhanced role in innovation especially in more knowledge-based societies. For example, in Canada the quest to develop a MF LOC device is largely driven by academic actors.

The Triple Helix model explains the transformation of relations and blending of roles between university, industry and government. It is the elaborate and interdependent network between these organizations that fuels the drive behind the emergence of scientific knowledge-based innovative advances (Leydesdorff and Etzkowitz, 2001). Universities' role in this matrix transforms from the once education-based institution to the establishment of facilitates that create new technological developments and new firms and spin-off companies. The entrepreneurial university emerges to establish economic development as well as academic research within its mandate (Leydesdorff and Etzkowitz, 2001). Universities serve as an incubator along with the cooperation between other university, government, and financial institutions. Technology licensing offices play a large part in facilitating relations between universities and companies (Leydesdorff and Etzkowtiz, 2001).

The Triple Helix thesis is viewed by Etzkowitz and Leydesdorff (2000) as an alternative to the national systems of innovation approach that views industry as the leader in innovation where the state is the leading source of innovation.

Etzkowitz and Leydesdorff (2000) focus on communication networks as the driver of institutional change between university, industry and government actors. According to Etzkowitz and Leydesdorff (2000), systems of innovation should be viewed as the dynamics of change in systems of both production and distribution. In relation to the Triple Helix thesis, Etzkowitz and Leydesdorff (2000) view government involvement within the production puzzle as the main shift from the double to the Triple Helix; thus leading to the development of trilateral networks to help resolve social and economic problems.

The juncture at which transformation is taking place exists at the level which the roles and processes of each can be carried out by the other (Leydesdorff and Etzkowitz, 2001). As already discussed, the university shares industry roles through the creation of incubator facilities and new firms. The government assumes industry roles by funding new developments and providing regulatory oversight. Industry takes on academic roles by offering training and carrying out high-quality research. Although they still operate individually, the closer relations is creating interdependency between the institutions (Leydesdorff and Etzkowitz, 2001).

The MF LOC device fits nicely under the Triple Helix model as it involves input from academics, government and industry. The government's role is to provide funding through organizations such as the Canadian Institutes of Health Research (CIHR) and Canadian Foundation of Innovation (CFI) for research and to develop technology. Academics and other researchers from industry collaborate to develop the technology. This unification of institutions

signifies a shift in the new production of knowledge in so far as different groups emerge within the arena to contribute to the social and technical development of an emerging technology.

Etzkowitz and Leydesdorff (2000) posit that the contribution of science to the economy has driven international competition for science development. Science and knowledge-based growth are increasingly identified as key drivers of an economically robust nation. It was not until recently that the place where research was conducted became a concern. The view that the location of science/knowledge production is not connected to a first adopter's advantage is no longer a strongly held notion. Etzkowitz and Leydesdorff (2000) refer to Silicon Valley as a case in point whereby an expansion in information technology led to a large increase in economic activity in that region.

The main impetus now for legitimating scientific research is not essentially based on military or health objectives, but rather on the contribution that the research would have on economic development. Etzkowitz and Leydesdorff (2000) maintain that the university can remain as the core institution of knowledge development so long as it keeps to the primary mission to "educate". A university's competitive edge is found in the flow of "human capital" whereas corporations are more static with respect to the throughput of workers contributions: "The turnover of students insures the primacy of the university as a source of innovation. The universities unique comparative advantage is that it combines continuity with change" (Etzkowitz and Leydesdorff, 2000: 118).

The establishment of a global economy has created a need for institutions within nations to pool their resources and to collaborate in order to be competitive with the rest of the world; thus, also supporting the links between university, government and academia. In order for countries to be innovative, university-industry-government relations need to change to align to the new economic goal. According to Leydesdorff and Etzkowitz (2001) regardless of whether a country starts with state control of incorporating industry and academia towards a shared developmental goal, the end result is that these institutions are all gravitating towards a common direction. The Triple Helix thesis combines the following three areas which can be found amongst the network relations in various countries:

1. The action in the market place in regards to what individuals are interested in.
2. Internal dynamics between companies and an exposition of what each company is doing.
3. Governance of the interface of relations between university, government and academia (Etzkowitz and Leydesdorff, 2000).

The argument put forth by the Triple Helix model is that the dynamics between university, industry and government are essential for enabling the progress of innovation in a knowledge-based society (Etzkowitz and Leydesdorff, 2000). However, in looking closer at the Triple Helix thesis of innovation an irony emerges in recognizing that there is no independent regulatory system outside these institutions to address the ethical, social and legal considerations

flowing from emerging technologies; in fact, such issues are often deemed to be non-regulatory. In establishing the linkages there also emerges a sense of co-dependence, and thus the success of one institution depends on the success of others. As universities and governments become more concerned with the agenda of the corporate world the ethical, legal and social discussions may be jeopardized.

Although the Triple Helix model is conceptualized by Leydesdorff and Etzkowitz (2001) as “multi-structural” and “multi-functional,” the inclusion of other types of “softer” productions of knowledge are lacking such as cultural values and ethical discourses. The Triple Helix model exists to describe the current state of knowledge production and the process of innovation, and does not account for the production of ethical and social knowledge surrounding the implications of emerging technology applications. Regardless of this shortfall, evidence of the Triple Helix thesis can be found in Canada from collaborations on scientific tools as small as lab-on-chip devices to as large as synchrotrons. The trend of universities partnering with industry and government to incorporate research with commercial purposes supports the Triple Helix thesis. A clear illustration of this can be found in Saskatoon, Canada, in the development of the Canadian Light Source (synchrotron) which is partly funded by government, owned by the University of Saskatchewan, and is open for industrial use. In Saskatoon a strong trilateral knowledge cluster has also emerged in relation to biotechnology. The University of Saskatchewan is at the core. A government agency, Agriculture and Agri-Food Canada, is on campus and Innovation Place is

also on university grounds and proclaims itself as one of North America's best research parks.

The critical downside of these links is that the public's already skeptical views of industry motives may further jeopardize public trust in government and academia if the boundaries increasingly blur between these institutions. If MF LOC devices are commercialized without proper social and ethical consideration for individual rights, this will further diminish the public trust in the governance of emerging technologies in general. Building a strong capacity to assess the ethical, legal and social issues independently from ulterior motives is imperative to monitoring transformative technologies such as MF LOC devices.

2.3 POST-MODERNISM/POST-NORMAL SCIENCE AND KNOWLEDGE PRODUCTION

A post-modernist response to how we know what we know, how knowledge is produced, and what constitutes science differs from traditional practices (Rosenau, 1992). Most post-modernists would reject the Mode-2 and Triple Helix approaches to knowledge production since both approaches still adhere to a rational objectification of knowledge. A skeptical post-modernist disagrees with contemporary versions of science, epistemology and methodology (Rosenau, 1992). Affirmative post-modernists opt for a reformative approach rather than an abolishment of scientific methods.

Post-modernists declare an end to all paradigms and in doing so they reject the Kuhnian (Kuhn, 1970 as cited in Rosenau, 1992) model of science which

relegates knowledge to a stream of successive paradigms (Rosenau, 1992). Rosenau (1992) claims that a major problem with post-modernist epistemology and methodology is that in the end anyone can say what they want and claim equal validity. “Anything” can range from fascination to out right absurdity, and post-modernists have no way to differentiate between the two (Rosenau, 1992).

Many post-modernist thinkers reject representation. Representation is viewed as a tool of modernity to form social organizations and political structures. Rosenau (1992) uses a variety of words to put representation into context: *delegation* (individual representation in parliament), *resemblance* (painting), *replication* (photograph or image), *repetition* (words in writing), *substitution* (lawyer), *duplication* (photocopy represents the original). Affirmative post-modernists agree on the following: “a rejection of modern science, a questioning of the modern idea of progress, a refusal to affiliate with any traditional institutional political movements that have what they consider a ‘totalizing ideology’ and an abandonment of logocentric foundational projects with comprehensive solutions – be they liberal centrist or conservative” (Rosenau, 1992: 144).

Many affirmative post-modernists like the idea of a public sphere that is independent of the private sphere in which citizens can through deliberations come to a consensus. This is very close to Habermas’ (Braaten, 1991) articulation of a public sphere that can partake in political and social discourse. The aim of the public sphere is for individuals to come to a consensus that reflects the common good in the form of an open public forum. At least the affirmative post-

modernists vie for a revitalization of the public sphere to lead to better democracy. The skeptical post-modernists, however, disagree and believe that a consensus is not possible.

Some theorists say that the differentiation between the public and private sphere is blurring. Skeptical post-modernists reject the exchange of discourse within a public sphere and promote subjective private experience as reality. They also reject the public sphere because it "assumes the possibility of effective intersubjective communication" (Rosenau, 1992: 104). Also the public sphere is viewed by skeptical post-modernists as aligned with rationality and reason.

The merging of the public and private spheres is thought to be a reason for the emergence of post-modernism (Rosenau, 1992). The rise of consumerism and a dependence on the private sector for meeting consumer demands may have caused the individual to turn away from the public sphere and be more self reflexive in everyday life concerns (Rosenau, 1992). But skeptical post-modernists argue that the private sphere is also disappearing and leaving nothing but a void thus allowing post-modernism to thrive (Rosenau, 1992).

> Given the skeptic's belief in the demise of a viable public sphere, the end of history, the absence of truth and the death of the author (as a responsible agent) it is not surprising that they might refuse to advocate action, that they are anti-participatory or indifferent with respect to politics (Rosenau, 1992: 139).

It is unclear how the post-modernist would come to agree on a socially responsible form of governance that took into account the social, legal and ethical dimensions of emerging technologies. Affirmative post-modernists do contend

that an open more involved public sphere would contribute to more direct forms of governance; however their discussion on controlling risk is minimal. Skeptical post-modernists do not even come close to evaluating ways of dealing with governance since they believe that individuals should be discouraged from participating in governance. The existing framework for managing innovations within a knowledge economy is not always sufficient for addressing new emerging technologies. The government's responsibility for regulating and its duty for safety of citizens sometimes conflicts with obligations of national economic growth. On the one hand, the government is expected to help encourage a growing and vibrant economy, while at the same time it is expected to ensure an optimal risk free society for citizens.

The dual role of government as both promoter and regulator of science and technology may lead to the public's loss of faith in the government's role as regulator. Although agencies that do the regulating and promoting are separate entities under the government umbrella, public perceptions of these conflicting roles creates an environment of innovation controversy. In the case of genetically modified wheat, Agriculture and Agri-Food Canada (AAFC) partnered with Monsanto Inc. to develop a new modified variety of genetically engineered wheat such as Fusarium resistant wheat. Public organizations such as the National Farmers Union and Network of Concerned Farmers were apprehensive by this partnership and criticized the government of being "in bed" with industry (Stratford Beacon-Herald Newspaper, 2003). The government's defense was that the Canadian Food Inspection Agency and Health Canada are government

organizations that oversee the regulation of food safety. As a result, the disruption of public trust in government has led to the need for more stringent regulatory frameworks and risk management systems. De Marchi and Ravetz (1999) warn that the breakdown of trust in regulatory institutions could inevitably dampen technical innovations and public confidence in government. Regulatory institutions need to become more transparent and include a more rigorous regime in risk management. De Marchi and Ravetz (1999) propose the use of a new regime that includes applying principles from a Post-Normal Science approach.

2.3.2 POST-NORMAL SCIENCE

Initially, risk management was in the domain of the laboratories and mainly at the site of application, this is reminiscent of the Mode-1 type of knowledge production. Due to advances in technologies that produce significant uncertainties, the role in governance of risk and social, ethical and legal domains is expanding. This expansion as noted by De Marchi and Ravetz (1999) requires a Post-Normal Science (PNS) approach that takes technological uncertainty into consideration for decision-making.

Post-Normal Science was initially conceptualized through the increasing pathologies of the industrial system (Ravetz and Funtowicz, 1999). PNS emerged to understand the importance of scientific developments primarily in the information technology (IT) and biomedical sectors, and the potential for damaging consequences to emerge from technical applications. Ravetz and Funtowicz (1999) further characterize PNS as a focus on the quality of processes

between science and society and the lessening of bias towards exclusive technocratic ideologies that anything “scientific” is value-free. There is an emphasis on industrial risks, “A most important task in the articulation of PNS is locating it in its context in contemporary social theory of industrial society” (Ravetz and Funtowicz, 1999: 644). De Marchi and Ravetz (1999) use several examples to illustrate the evolution and further need for industrial risk management.

De Marchi and Ravetz (1999) explain that in order to employ risk managers there needs to be an understanding of the complex nature of the task. The number of individuals involved is extensive: “As a risk issue goes through the cycle from first announcement through to public debate, identification, official acceptance, quantification, then legislation and/or regulation, and finally monitoring, a great variety of actors are involved, in a multiplicity of contexts,” (De Marchi and Ravetz, 1999: 744). No one perspective should prevail.

Trust is an essential element in risk management, especially in addressing the ethical, legal and social implications of emerging technologies and the use of new production processes. De Marchi and Ravetz (1999) built on the cases of the “Seveso” accident (dioxin cloud), the bovine spongiform encephalopathy (BSE) crisis, and the introduction of genetically modified (GM) maize. In their research they methodically show the unraveling of risk issues and the responses by government and other regulatory institutions in an attempt to console and reassure the public of safety. What follows is a brief review of the case studies examined by De Marchi and Ravetz (1999).

Case studies: De Marchi and Ravetz (1999) used Seveso to analyze the response to accidents that occasionally take place. The BSE incident was highlighted to understand an essentially human-made disease that has no measurable incidence; and the issue of genetically modified organisms, was drawn on to illustrate the issue of GM maize as a hypothetical risk.

a) Seveso. The Seveso case was viewed by De Marchi and Ravetz (1999) as an evolutionary construction of a regulatory system. The incident occurred from a factory accident that released a poisonous cloud that contained dioxin. Although the long term epidemiological monitoring of individuals potentially exposed to the dioxin cloud did not lead to any real conclusive evidence of mass harm to human health, the social-political response was far-reaching. De Marchi and Ravetz (1999) symbolically equate Seveso with accidents such as Chernobyl[4] in mobilizing concern about risk governance and loss of public trust. The awareness of the Seveso hazard pre-empted the establishment of a European framework of regulation that sought for the harmonization of prevention and protection measures relating to hazards in Europe.

b) Bovine spongiform encephalopathy. This pathology is believed to have originated from the feeding of sheep remains to cattle. Regulations at the time

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[4] "The Chernobyl accident in 1986 was the result of a flawed reactor design that was operated with inadequately trained personnel and without proper regard for safety. The resulting steam explosion and fire released at least five percent of the radioactive reactor core into the atmosphere and downwind. 28 people died within four months from radiation or thermal burns, 19 have subsequently died, and there have been around nine deaths from thyroid cancer apparently due to the accident: total 56 fatalities as of 2004" (World Nuclear Association).

allowed for the rendering of animal carcasses. Since then an advisory committee was established and it was recommended that brains, spinal cords and other organs were not to be used. The recommendations by the committee were not taken seriously, and in 1995 a human variant of spongiform encephalopathy was found in the form of Creutzfeld- Jakob disease. This created a media frenzy which ended in a ban by the European commission on British beef.

c) Genetically modified (GM) maize. The introduction into Europe of GM maize was met by contestation not on grounds of quantifiable risk but by hypothetical risk and uncertainty backed by an increasingly suspicious public. “In one sense, the risk of this GM maize is ‘post-modern’ in that there is no palpable or even demonstrable injury,” (De Marchi and Ravetz, 1999: 752). The risk of GM maize is also “post-normal” in the sense that food retailers and NGO’s have aligned themselves to develop a voice for mass consumer action which contributes to the “extended peer community.”

De Marchi and Ravetz’s (1999) comparison of the cases show that the “Seveso” incident resembles a shift in the philosophies and management of significant accident hazards. The BSE crisis reveals the need for transparency in the development of risk management. The novel challenges of GMO’s pose unsolved problem in the governance of hypothetical risks. The uncertainty of hazards from biotechnology requires new forms of governance. According to De Marchi and Ravetz (1999), in the absence of reliable scientific evidence, the trustworthiness of government and authorities becomes paramount and requires the participation of the public. “In the terms of post-modernity, in such policy

debates there is no ‘grand narrative’ of scientific objectivity which protects the experts’ assertions from doubt and criticism” (De Marchi and Ravetz, 1999: 755).

The introduction of novel hazards with high levels of uncertainty creates unique challenges for regulators. According to De Marchi and Ravetz (1999), the successes of science-based technology have now created problems which science can not solve without help. The inclusion of other voices outside of the expert domain is needed in order to help with decisions regarding the application of potentially hazardous technologies. The lack of serious reforms in regulation in the light of new advances in technology could lead to a depletion of public trust in government regulations. The solution according to De Marchi and Ravetz (1999) lies in a Post-Normal Science that utilizes the voices of “extended peer communities” through focus groups, citizens juries, consensus conferences or stakeholder forums. “Such an enrichment of the peer community would be central to the implementation of a program for ‘knowledge assessment’ in relation to risks and environment or health hazards” (De Marchi and Ravetz, 1999: 756). The success of MF LOC devices will also hinge upon the incorporation of a proper assessment of the human health and social impacts of other potential uses of MF LOC devices such as for employee selection and insurance evaluation.

2.3.3 POST-NORMAL SCIENCE AND THE PRECAUTIONARY PRINICIPLE

Ravetz (2004) suggests that science is in a new troubled situation in that it must deal with issues of confidence, legitimacy and power. Ravetz (2004) divides

science into two arenas, “the mainstream” which is connected to industry and the “post-normal” which is linked to the precautionary principle[5]. Ravetz (2004) explains that the dimensions of Post-Normal Science include relying on public debates and extended peer communities. Post-Normal Science questions the value system that comes into play in all science, even statistics. Ravetz (2004) claims that Post-Normal Science is necessary in times of uncertainty, or when decision stakes are high. Traditional normal science is not effective under conditions of uncertainty, and Ravetz (2004) views Post-Normal Science as the “extension of democracies appropriate to conditions of our age,” (347). In applying the PNS approach to MF LOC devices, the course of action may be to allow for the development of technology to continue. Before reaching the point of commercialization, however, the precautionary principle should be exercised until an adequate assessment of the social, ethical and legal impacts are complete. Tognetti (1999) describes PNS as a constructive and creative method to understand issues concerning sustainable development without adopting strictly technical solutions. Diversity is key as it provides choices and flexibility; however, science still has an important part in contributing valuable information for decision-makers regarding ecological information.

Ravetz (2004) also gives credit to science as the “great driving force of modern global civilization” (347). He states that industrial society has progressed

[5] The precautionary principle as stated by the 1990 Bergen Declaration of European Ministers: In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation (Levidow, 2001).

on the principle that technologies are safe until proven dangerous. The precautionary principle, which Ravetz advocates, is in many respects the opposite. Ravetz (2004) claims that although great resistance will be met when implementing the precautionary principle, the need for change is inevitable. “When environmental and health policies involving science are debated, in place of facts we have uncertainty and even ignorance. We can no longer separate ‘nature’, ‘science’, and society” (Ravetz, 2004: 348). This is especially evident in the ‘new genetics’ as the use of scientific methods to identify nature are exploited and come to be understood as a means of understanding who we are as humans.

Ravetz (2004) makes the connection that the dismantling of the state’s hold on scientific expertise has repercussions on a state’s authority of governing society. “The ideology of modern science has become the rationale and justification of modern government” (Ravetz, 2004: 348). And as such, scientific expertise has replaced divine authority, birth, and wealth as a legitimate rule for governance (Ravetz, 2004). But now this form is facing its own legitimacy issues. Many scientists want to stay out of the lime light of decision-making, but are certainly aroused if decisions are made that impact their research.

Mainstream science carries the attitude of inevitable progress, and Ravetz (2004) postulated that as mainstream science delves more into molecular genetics the engineering of life itself becomes the norm, but not without risk uncertainties. The race to progress has unloaded the issues of safety and ethics onto regulatory bodies. For example, the cloning of humans has been an ongoing lively debate for the last five years. Discussion to legislate against human cloning and to make it

illegal created a discourse among many scientists claiming that if they were not able to do the research in their country then they would move to a country where it was legal. Clearly, there is a fine line between regulating research and upsetting the knowledge production process.

With respect to advancements in nanotechnology it will be even more pertinent to establish clear understandings of the social, ethical and legal implications so that decision makers can be better equipped to facilitate peaceful progress while deterring unwanted risks and hazards. The Center for Responsible Nanotechnology has established a Global Task Force on implications and policy relating to developments in nanotechnology. The Task Force was officially announced in August 2005. In a fashion reminiscent of Post-Normal Science ideology the Task Force is made up of "experts" from multiple disciplines to establish a holistic account of safe and responsible use of nanotechnology. In an attempt to conceptualize these challenges the Task Force has asked experts to contribute various essays addressing questions of risk: what risks do we really face? How do they relate to each other? And what is most important to know in order to design wise and effective policies for molecular manufacturing?[6]

Ravetz (2003) claims that governments in many parts of the world face current dilemmas in offering security and safety to the public due to the emergence of controversial technological innovations. Ravetz (2003) attributes the crisis to the structural dynamics of the global knowledge economy and the dual roles of government as both promoter and regulator of technological

[6] Website can be found at: http://crnano.org/CTF.htm

enterprises. Ravetz (2003) seeks a reconciliation of technological dilemmas through the recognitions of critical policy and the employment of a Post-Normal Science approach.

2. 4 AN AMALGAMATED MODEL OF KNOWLEDGE PRODUCTION

The single accounts of Mode-1, Mode-2, Triple Helix and PNS do not provide a holistic description of the new modes of knowledge production and praxis for the social and ethical governance of new emerging technologies. I believe that a combination of the Mode-2 and Triple Helix thesis can best describe the current status of knowledge production processes while PNS contributes by suggesting some guiding principles by which the governance of emerging technology may benefit from.

Figure 1. Amalgamated Model of Knowledge Production

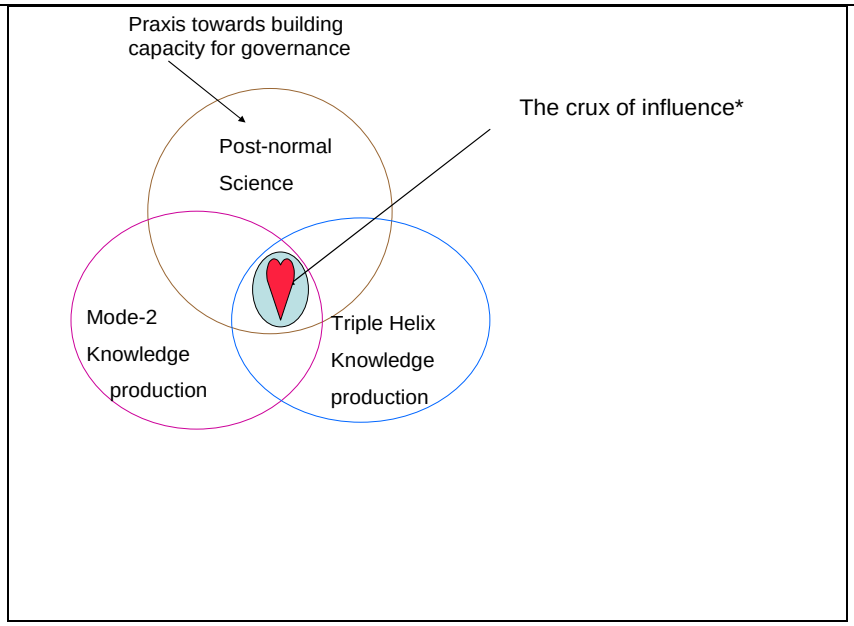

Figure one illustrates how Mode-2, Triple Helix and PNS all operate within separate spheres and yet can contribute to providing a fuller picture of the current knowledge and innovation processes and the importance of governance. Weakness in one model are strengths in another. *The crux of influence refers to the center point where the models come together to contribute theoretical characteristics that both describe the current modes of knowledge production and provide a praxis for socially responsible governance.

Shinn (2002) analyzed Mode-2 and the Triple Helix thesis and found that neither of them took into account that university, industry and government all operate from a national perspective. Where the two theories unite is in the search of “transversality”, essentially the intersection and integration of cognitive, technical, economic and societal boundaries (Shinn, 2002). The Triple Helix model emerges as a sociological analysis of the knowledge-based social order that emphasizes historical continuities and examines the groups from university, government and academia that emerge to take on social/technical problems (Shinn, 2002). Mode-2 theory does not put forth questions, methodologies, or answers but rather unravels its discourse in a fashion similar to a rhetorical political manifesto (Shinn, 2002).

Although Mode-2 theory is weakened by positions that the university’s role is decreasing, it does have a relevant stand point in regards to the heterogeneity of actors involved in knowledge production and the identification of the transition from basic to applied research and development. I also would adopt Gibbons (1999) later thinking on socially robust forms of governance which

includes a reflexive scientific community and the public in the discourse of the knowledge production process. The Triple Helix thesis picks up where Mode-2 theory lacks, and includes universities as vital components of knowledge production. Especially, in the case of MF LOC, one can analyze the trilateral networks that have emerged in the social/technical development of this new technology amongst actors in university, government and industry.

A post-modernist account of knowledge production is elusive with the exception of Ravetz's (2003) Post-Normal Science theory. Post-Normal Science takes into consideration the expansion of democracy by encouraging public participation in the discourses and debates of modern-day issues in science and technology. PNS also extends the peer community to other experts and players to take an active role in the decision-making process. The application of the precautionary principle is another vital component of PNS, which according to Ravetz (2004) is necessary for today's critical examination of emerging technologies before they are applied. Although application of the precautionary principle can be a little critical of technological progress, it is a useful tool to employ before commercially releasing MF LOC devices for the purposes of genetic analysis.

In essence, the combined model would include a socially robust form of governance that would take into account a variety of different factors including:

1. Network analysis of industrial, academic and government institutions
2. Transversality (referring to an integration of the cognitive, technical, economic and social contingencies)

3. Historical continuities (analysis of past success and failures)
4. Heterogeneity (inclusion of various actors in development/decision)
5. Reflexivity (thorough contemplation of actions and implications)
6. Public participation (inclusion of public perceptions and concerns)
7. Precautionary principle (better safe than sorry principle)

Synthesis of the above mentioned components will foster better technical and social governance of emerging technologies. Understanding the linkages between university, government and industry is vital for comprehending the forms of knowledge production. Transversality is important in assessing societal consciousness and the technical and social boundaries within society. It is equally important to take historical trends and mistakes into account when determining present and future actions, and thus the utilization of a reflexive regime is also essential. Public participation is important in building trust between the public and institutions of research and development and governance. If there is doubt and risks are high, an application of the precautionary principle should allow for a socially responsible form of governance that will ensure the safety and well-being of affected individuals.

Combining the strongest elements of each theory of knowledge production will create a theoretical tool that will enable society to progress technologically and socially, while maintaining individual rights and freedoms. It is evident that understanding the transformations of new scientific knowledge production will allow for a more effective socially responsible form of governance of new emerging technologies. The actors involved in developing and forming the

legalities and policies around the MF LOC device will benefit by contemplating these theories of knowledge production, and by thinking critically about the ethical, social and legal issues surrounding the possible applications of microfluidic lab-on-chip devices.

3.0 CHAPTER THREE: SCIENCE AND THE LAW

The previous section provided a background to several theoretical orientations of current characteristics pertaining to the production of knowledge and technology. What was not discussed was the issue of laws and regulations regarding the application of new technologies. The social ramifications of the institutionalization of the MF LOC device into the workplace or within the insurance industries may set a precedent for the largest sanctioned discrimination act if laws are not developed to ensure that individuals are not being discriminated against based on their genetic profile. The emergence of critical fields such as the sociology of science and knowledge provides an avenue to critically analyze the use of technologies in society. The aim of this section is to discuss how the MF LOC device, may impact traditional practices, affect the privacy of individuals and contribute to genetic discrimination. Issues that will be addressed include the electronic storage of patient information and privacy rights. I will also look at lessons to be learned from past technologies and the relationship between science and the law. The thesis guiding this section is that it is important to consider who might use the technology and how that might impact certain groups of individuals

3.1 SOCIOLOGY OF SCIENCE AND KNOWLEDGE

Since the 1970s the sociology of knowledge has started to incorporate the production of science into social analysis (Collins, 2002). This revolution,

according to Collins (2002), reflects the transformation in thought that took place in the west in the 1960s. A major change that emerged within the sociology of knowledge was the concept of not taking a true or false stance pertaining to the phenomenon under social analysis. This paradigm shift allowed for an exploration of how scientific knowledge becomes legitimated.

Collins (2002) reports that the central focus of the sociology of knowledge is that although individuals adopt certain truths about their world, it is really only by chance that they were brought up in a particular society and thus understand things in a particular way. In other words, religious or political truths depend upon the societal context. The development of science itself is seen as largely socially situated. What Collins (2002) fails to examine is the cross-cultural phenomenon of science. Although each culture may differ in their methodology, it seems that understanding the mechanisms of nature is a universal phenomenon. Indigenous, and feminist knowledge also lends itself to uncover truths of the nature of things. A key difference between Collins' (2002) understanding of knowledge as socially constructed and the shared universal phenomenon of seeking to understand the mechanisms of nature lays in the transition of applying science to technology. The ability to manipulate matter with precision down to the atomic level (nanotechnology) is a feat unprecedented in history. Although the development of progressive technology is a cross-cultural phenomenon to some degree, it is not practiced in all cultures. In economic-based (predominantly Western) societies, advances in science have led to progressive leaps in

technology and it has become increasingly important to develop laws to maximize benefits to society while minimizing harms.

Collins (2002) discusses Kuhn's (1970) contributions to the understanding of scientific knowledge and credits Kuhn as the inaugurator of viewing science in the context of paradigm shifts. Scientific knowledge came to be seen as a creation from culture as much from nature. I would argue that the development of the MF LOC technology does represent a Kuhnian paradigm shift as it allows the analysis of genetics to become further institutionalized due to the simplicity, size and decreased cost in comparison to traditional laboratories. Because of the intricate relations between this technology and its potential for (constructed or otherwise) human description and identification, it is imperative to understand the role of the law in regulating this technology for the best interests of individuals and to ensure individual freedom from genetic discrimination.

I do not discount the social construction of genetics, but it is equally important to acknowledge real-world applications of this technology and concomitant social impacts. The remainder of this section provides a critical analysis of lab-on-chip technology, its relation to knowledge production, and the role of the law in technology application. I draw on past examples of how the application of certain technology has clashed with the law, and I make the argument that it is imperative to ensure that laws are created in tandem with new developments in technology. One of the issues at the forefront of genetic analysis technology is the rights of patient confidentiality and the storage of patient information.

3.2 STIGMA, DISCRIMINATION AND PATIENT PRIVACY

Medical privacy is a serious concern for patients. As the capacity for electronic storage of data increases, and the tools to mine data become more refined, the question of secure storage of patient data emerges at the forefront. As the past illustrates with accidents such as Chernobyl, technology can fail and when it does it can be devastating. Although patient records do not seem to be as threatening as nuclear accidents, it can prove to be as problematic. The use of MF LOC devices will enable a scaling up of collecting genetic profiles of individuals that will likely be stored in digital format. If accurate measures are not taken to ensure the safe storage of these data files, a number of problems could emerge. Such as doctors inability to access patients information due to system failures. Also, if accidental deletions of key pieces of patient information occurred, this could result in a tragic situation for patients. For example, if a patient is intolerant to penicillin and this information is lost from their file then it puts the patient at risk if health care workers administer penicillin.

Alpert (2003) warns that the increasingly detailed information about a patient's genetic profile could be risky for the patient if information was obtained by potential (or current) employers or insurance companies. Advances in communication technology allow for easy information transfer to health care providers, hospitals and employers, leaving the patient vulnerable to others knowing their personal information (Alpert, 2003). It has been an ongoing debate as to whether employers or insurance companies should have access to this data.

As of yet there are no laws in Canada prohibiting employers or insurance agencies from using genetic information in their selection process.

The propensity for stigmatization and discrimination exits and will only be amplified if MF LOC devices are commercialized and available for general use. Stigma is defined by Goffman (1963) as a trait that labels the carrier with a "spoiled social identity". Lujan and Moreno (1996) defined genetic discrimination as acts or gestures against an individual or against the members of a family regardless of whether the differences are real or perceived in relation to the "normal" genome.

Carrying out genetic tests on individuals will inevitably increase labeling and thus stigmatizing. Once a stigma becomes recognized (in the case of genetic testing the stigma would be associated with genetic abnormalities) the process of discrimination can occur thus leading to acts against certain individuals or groups of people.

There are four main purposes for carrying out genetic tests: identification of carriers, prenatal diagnosis, pre-symptomatic diagnosis and DNA profiling (Lujan and Moreno, 1996). Lujan and Moreno (1996) further characterize the impacts of genetic testing according to whether they are used in clinical or non-clinical contexts. The non-clinical areas of concern are in the domains of purchasing life insurance and in the work force. Insurance agencies would probably use the genetic information to reduce risks of insuring potentially high-risk clients, and companies may use genetic testing to select out employees who might be predisposed to certain diseases which would lead to absence, loss of

productivity and increased corporate coverage of medical care (Lujan and Moreno, 1996).

In the United States, congress has on numerous occasions dealt with medical privacy issues, but as of yet no agreements have been reached as to the extent of the medical privacy act. At stake as well is patient compliance and a willingness to divulge information to their physicians. In the US, federal laws only protect patient information relating to substance abuse and mental health (Alpert, 2003).

One of the Mandates under the Health Insurance Portability and Accountability Act 1996 (HIPAA), is to improve the efficiency of health care by implementing the electronic transmission of health information (Alpert, 2003). Also included under HIPAA was a five year grace period before the inclusion of legislation or regulation of federal protection for medical records. However, there was not enough time for congress to develop privacy legislation, and it continues to be at a standstill (Alpert, 2003).

The inclusion of genetic analysis is not something that is currently in patient-medical records; however, it may soon become part and parcel of each patients' medical profile (Alpert, 2003). A major concern with describing an individual's genetic code is that even if one possesses a gene for a certain disease, it does not necessarily mean that the person will develop the illness, it only predisposes them. Since it is false to espouse a genetic determinist position, then it is even more important to develop sensitive guidelines around genetic discrimination. The other concern of including a genetic profile in everyone's

medical file is that it essentially labels all at risk to some degree to an ailment. The psychological impact of learning that you are predisposed to certain diseases would be difficult to measure. It should also be a patient's right to not obtain knowledge of their own genetic profile.

Everett (2003) argues that 'genes' as we have come to know them today, have taken on a "social life of their own". Although federal agreement on medical privacy laws has turned up inconclusive, there are a number of states in the US such as Oregon that have constituted a Genetic Privacy Act (Everett, 2003). This Act gives individuals inalienable property right to their own DNA. Everett (2003) contends that both sides of the debate, of who should own property rights to DNA, display a property metaphor that relegates genes as part of the human body to something similar to a commodity. This approach neglects the veracity of the body (Everett, 2003). The evolution of scientific knowledge and its relation to the law are central to understanding how genes become commoditized. Everett (2003) acknowledges that recombinant DNA-based technology, and changes to patent law, are monumental, but just as colossal is generating wealth from the body.

Everett (2003) reports that in a survey of 1500 genetic counselors and physicians there were 785 cases where patients had lost their job or insurance coverage due to a genetic condition or test. In another survey by the American Management Association, about 30% of mid-sized to large companies used genetic information from employees and 7% admitted to using information in the selection process and in promotion decisions (Everett, 2003). Currently, 33 states have developed legislation to help prevent genetic discrimination in regards to

health insurance, and 19 states have legislation against employee discrimination. Although the progression of some state laws is a good start, it does not suffice for the whole of the nation in the US. Also, Canadian laws are lagging behind in addressing the issue of patient privacy and genetic information. Addressing the limitations of current laws and regulations is imperative to avoid genetic stigma and discrimination in society.

3.3 THE SCIENCE-LAW RELATIONSHIP

In the past, science and the law came into conflict whenever scientific search for the truth collided with the laws sense of justice (Jasanoff, 2001). Law and science share an intricate relationship since the beginning of modernity; however, the relationship between science and law changed by the end of the 1900s (Jasanoff, 2001). Different perspectives were divided on the issue of how legal institutions should interact with scientific experts. Just as science has introduced new ways to handle the law, the law has also influenced the extent to which science is carried out. It is now more imperative than ever to develop science and law in relation to one another.

The relations of science and law are so intertwined that they would essentially use each other, to some degree, to build up authority (Jasanoff, 2001). For example, the use of witness accounts was used earlier in science to reflect a type of truth. In a democratic society science became a means of organizing disciplines and individuals. Science gave credence to the division of individuals into categories of normal, pathological, mainstream and deviant. And the law has

evolved to reflect the norms of society such that deviant behaviours become ‘outlawed’ and punished. In relation to science and technology, the use of risk analysis helps to incorporate necessary laws that enhance safety while diminishing harm.

In looking at the law-science relationship, the 1990s emerged as a major turning point that sparked a view that the hybridization of law and science was of great interest to the public (Jasanoff, 2001). For instance the use of biological markers in DNA for the identification of criminals was co-developed with the legal systems input which provided the necessary context for the successful use of DNA identification technology with standardization and regulation.

In the case of microfluidic lab-on-chip devices the incorporation of nanoscale components into the device signifies the integration of nanotechnology, biotechnology and information technology. The use of the device as a genetic testing tool, and for other biological analysis, poses questions that centralize around individuals livelihoods. It is with irony that MF LOC devices are being developed with the mission in mind to advance health care, but the misplaced use of that same technology in another institution constitutes a tool that imparts judgment against one’s livelihood. For example, if an employer uses the device in the selection process for potential employees, this could lead to a genetic divide between the so called “genetically normal” and “genetically defected”. The following scenario illustrates this point:

Imagine during the next job interview you go to, the human resources personnel informs you that you will be required to provide a DNA sample for

genetic testing. You comply and watch as they deposit your DNA swab into the hand-held microfluidic lab-on-chip device which relays information to a desktop computer. Before you even get to the interview a genetic counselor informs you that you will no longer be a potential candidate for the position as you have been found to be genetically predisposed to Alzheimer's or Huntingtons. As members in a society we need to ask ourselves if we are willing to be subjected to the slippery slope of genetic testing for the purposes of employee selection. In the biotechnology realm, farmers may be concerned about corporations owning the right to create terminator seeds and to require the purchasing of new seeds every year, but corporations who have the right to select employees based on genetic profiles is more worrisome. There is a definite need for science, technology and law to collaborate in ensuring that ethical and social implications are taken into consideration before commercialization of a transformative technology such as MF LOC devices.

3.4 SCIENCE, TECHNOLOGY AND RISK

The area of risk analysis poses a fundamental focus on the hazards of industrial production. As technology advances it is important to ensure ongoing safety for workers, consumers and the environment. The industrial relations between law and science can help safeguard against injury. However, conflict emerges when industry does not have sufficient safeguards in place, and the law is left to retrieve the pieces. For example, the commercialization of genetically modified Canola sparked organic farmers to legally challenge biotechnology

companies such as Monsanto and Aventis with law suits to compensate for contamination of organic crops and subsequent loss of market potential (Mehta, 2005). Another example is asbestos workers and the manufacturers' negligence in employee health. After many died and others were severely injured by asbestos exposure in mines or ship yards, a lawsuit was brought against the asbestos manufacturers which resulted in bankruptcy for the industry[7]. If laws and safeguards were in place in advance through proper risk analysis techniques than these types of episodes could be avoided.

The key is to embark on a rigorous and comprehensive risk analysis of the potential applications of a technology before it is too late. This is especially important before introducing new technologies such as GM products. The role of science in risk analysis is to come up with new methodologies and expressions of knowledge in order that instruments and processes can be developed to assess risk and employ preventative techniques. Beck (1999) claims that we are increasingly becoming a risk society and we need to practice reflexivity and caution with future technological endeavors.

In his book, *World Risk Society*, Beck (1999) traces the origins of current global transformations to industrial developments and advances from the first modernity. Beck (1999) claims that we are now in a second modernity; the first of which focused on equal distributions of wealth, and the second modernity focuses on minimizing risk.

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[7] For further information on asbestosis law suites: http://www.kazanlaw.com/practice/asbestoslit.cfm

The risks that are current today are a result of the unforeseen consequences of the successes of the first modernity (Beck, 1999). Beck differentiates the first modernity from the second modernity by placing the first modernity within the context of the beginning of the industrial era. The second modernity is the current state of western society and it is now destabilized by globalization, individualization, gender revolution, underemployment, and global risks. The challenge now is to respond to these issues concurrently (Beck, 1999). MF LOC devices encompass global concerns to the extent that the device as a genetic analysis tool further substantiates the notion of genetic determinism. As individuals and organizations around the world become aligned and adopt the "perception" of genetics as a viable piece of knowledge that identifies who we are as a human, regardless of the truth of the claim, then the potential for genetic discrimination and stigmatization increases.

In this new era of risk assessment and risk-based policy formation, Beck (1999) encourages the involvement of non-western nations into the calculation of the world risk society. This is especially important since the risk impacts are no longer regionally located, the increase in global exports creates a potential for the wide-spread of risks. For example, if genetically modified wheat is developed in Canada, and it is later found to contain a modified protein that induces an allergic response, the devastation is potentially global in nature. Beck (1999) states that we are in the midst of an ecological enlightenment stage and that individuals are increasingly aware of potential industrial and technological impacts on the environment.

The rise of non-governmental organizations such as Greenpeace and ETC Group demonstrates how the notions of risk and uncertainty are held in a technologically advanced society. The ETC Group, formerly known as RAFI, have railed against applications in biotechnology and now are directing their efforts to be critical of nanotechnology. They have published with a report entitled, "*The Big Down: Atomtech-Technologies Converging at the Nano-Scale (2003)*[8]. In the report they outline some of the dangers inherent to nanotechnology development and explore the stakeholders involved including actors from government and academic scientific institutions. A motive of the ETC group is to supply policy makers with recommendations for action, including a moratorium on all nanotechnology development. However, I do not believe that curtailing the development of MF LOC devices is the answer. The use of MF LOC devices can have beneficial applications as in the use of cancer diagnosis and disease monitoring. But as with many things, with the good comes the bad; and it is within our human potential to control for negative consequences while harnessing the benefits that will allow health technology to evolve in an effective manner.

Beck (1999) acknowledges that the boundary between the scientific laboratory and society is disintegrating. Beck claims that the conditions of freedom have shifted, "Freedom of research implies freedom of application" (Beck, 1999: 61). Meaning that today there are few controls that exist for the risks from a scientific progress. "The main question is how to take decisions under conditions of manufactured uncertainty, where not only is the knowledge base

[8] To access the ETC article go to: http://www.etcgroup.org/article.asp?newsid=375

incomplete, but more and better knowledge often means more uncertainty" (Beck, 1999: 6). A range of actors such as government, industry, and non-governmental organizations have emerged to partake in what Beck refers to as a sub-political environment. Within the sub-political environment it becomes hard to discern who is doing the decision-making.

3.4.1 LESSONS FROM THE PAST

Those who develop, regulate and study emerging technologies can learn from the experiences of nuclear power and biotechnology. The accident at Chernobyl not only had a physical consequence, but also impacted on public trust. The public has increasingly become skeptical of the applications of technology. The inclusion of genetically modified organisms in much of today's processed food has brought forth concerns from many consumers. The lack of labeling on such products disrupts a contract of informed choice between consumer and producer, and the withholding of information is viewed by many consumers as irresponsible on the part of industry.

In Canada, Bill C-287 was introduced to make labeling of GM products mandatory; it was defeated in October, 2001. Industry fought back arguing that it would require too many resources that would eventually be reflected in consumer cost. Instead of making labeling mandatory, the outcome was a five year period of voluntary labeling with the possibility of mandatory labeling laws at the end of

the five year period[9]. If action was taken before the commercialization of GM products, then conflict could have been minimized. However, the lack of public consultation resulted in expenses and time spent on rectifying the situation.

The commercialization of products of nanotechnology can be found in cosmetics, clothing and medicine is on thin ground according to Einsiedel and McMullen (2004). What is disturbing is that properties at the nano-scale behave differently and in unpredictable ways than at the macro-scale. And as Einsiedel and McMullen (2004) point out, few studies have been conducted to test for toxicity levels in regards to human health of these products.

Mehta (2004) states that benefits from nanomedicine are possible if past mistakes are not repeated and if public trust can be gained. If nanotechnology enabled products produce hazards to human health or the environment the potential of nanomedicine may be jeopardized (Mehta, 2004). An incident in Germany had investigators scurrying to analyze whether or not a commercialized cleaning product called “nano magic” contained nano-particles that may have contributed to nearly 100 cases of respiratory problems from people who used the aerosol spray. (Associated Press, 2006). If these technologies are not regulated properly, public trust will diminish further.

When and where is it best to introduce new policies into the existing legal framework? As argued by Kerr and Bassie (2004) it is not sufficient to merely partake in scientific forecasting. A broader network of social actors is required. It

[9] The Canadian government in 2004 passed legislation slating a voluntary labeling of GM products. Any product containing less than 5% GM product could be labeled GM free.

is essential that science and technology policy is developed in such a way that alternative futures can be assessed and accommodated (Kerr and Bassie, 2004).

The application of "foresighting" as a methodology for thinking about a technology and its long-term future impacts is described by Kerr and Bassie (2004) as a shift from short-term to long-term thinking that incorporates a non-linear system type approach to identify the best economic and social course.

The use of foresighting can be applied to examine consequences; anticipate problems; examine implications of possible future events; and to identify attractive features of future societies (Kerr and Bassie, 2004). It allows for a wider examination of social and economic outcomes of a particular application of technology in society.

> Instead of standing on the side lines, cheering on a combative and adversarial scientific arm-wrestling match, diverse groups of social actors ought to assemble to examine potential profits and pitfalls of the technologies that miniaturized from as many different angles and perspectives as possible with the aim of consensus building (Kerr and Bassie, 2004: 59).

Perhaps if foresighting and public consultation were used by Mryriad Genetics before commercializing their genetic tests then they could have avoided post-commercialization backlash. The following case study illustrates it is not always clear how individuals and organizations will react to the law especially if there was no public consultation. For instance, Williams-Jones (2002) did a case study of Myriad Genetics and their patenting of BRCA 1 and BRCA 2 genes. The genes are used as diagnostic markers for breast and ovarian cancer. This case study emphasized the need for social, ethical and policy-oriented examination of

genetic technologies. Myriad Genetics acquired the patent rights to BRCA 1 and 2 and as such was given a monopoly position on the commercialization of diagnostic technology using these genes as markers.

To put the history of genetic patents into context, Williams-Jones (2002) explains that the first significant court case of Diamond v. Chakrabarty 447 U.S 303, on June 16, 1980 saw the overturning of prohibitions of patenting biological organisms[10]. Since then in many countries genes have been patented in so far as they are found to be "artificial genes" or are isolated and shown to have a function. By the year 2000 there were more than 25,000 DNA patents on a global basis (Williams-Jones, 2002).

In 1996 Myriad Genetics commercialized a genetic testing device that screened for mutated versions of BRCA 1 and BRCA 2 genes. The device was recalled and pulled from the marketplace after concerns of wide-spread public harm from lack of proper genetic counseling to prevent consumers from misinterpreting test results. The test was then allowed to be used only by a physician and when genetic counseling services could be provided.

In 1996 Canada used genetic testing for the BRCA 1 and BRCA2 genes on a research trial basis. Provincial programs were established such as the Hereditary Cancer Program (HCP) in British Columbia which covered genetic testing, patient counseling and physician and patient education on cancers with a genetic basis. By October 2000 Myriad Genetics was granted Canadian patents on both BRCA 1 and 2 genes which was followed by a "cease and desist" letter

[10] Legal description of court case Diamond v. Chakrabarty 447 U.S. 303: http://caselaw.lp.findlaw.com/scripts/getcase.pl?navby=CASE&court=US&vol=447&page=303

by Myriad Genetics to all health care facilities using the genes as diagnostic markers. Any future testing was to be sent to MDS Laboratory Services in Toronto, a broker agency for Myriad Genetics in Canada.

The cost of a full gene analysis test was about C$3,850 (Williams-Jones, 2002). The HCP in British Columbia stopped providing the genetic testing as they could not afford the fee. However, if a patient agreed to pay the fee, then HCP would provide genetic counseling and facilitation of the test. At the time many other provinces with the Hereditary Cancer Program ignored the patent rights of Myriad and continued to use the genes as diagnostic markers (Williams-Jones, 2002).

In February 2003, the HCP of British Columbia was allowed to provide the testing service without a patient fee as the British Columbia Ministry of Health Services changed their position on honoring Myriads patent (Williams-Jones, 2002). The national contestation against Myriad's patent of BRCA 1 and BRCA 2 led to the Canadian Cancer Society and the National Institutes of Health to encourage the federal government to not allow Myriad's patents to block testing of BRCA 1 and BRCA 2 mutations (Williams-Jones, 2002).

The impact of gene patents on genetic services is something that will need to be addressed soon as the potential for wide-range diagnostic services through the use of MF LOC devices becomes a reality. Depending on whether the Myriad patents are enforced or not will have a large influence on how scientific knowledge becomes integrated into the marketplace and into clinical practices (Williams-Jones, 2002). The examination of case studies such as this one allows

us to anticipate future conflicts between science and the law, and further amplifies the need for co-development of regulations with the production and knowledge and application of technology.

As illustrated in this section, it is integral to understand the new forms of knowledge production in the sciences and their potential for technological application in order for the construction of adequate laws to regulate the ethical and social implications of MF LOC devices. The role of science in risk analysis is to come up with new methodologies and expressions of knowledge in order that instruments and processes could be developed to assess risk and employ preventative techniques. The institutionalization of MF LOC devices will create a demand for regulations to protect patient privacy and confidentiality of genetic profiles to ensure that genetic discrimination does not occur in the workplace or by insurance agencies. The role of the law and the intricate relationship between science and technology will undoubtedly lead to much debate over the application of genetic and biological identification tools. It is important to also include public consultation in this process.

Although I have not discussed in detail the social construction of genetics and whether or not it is viable to use genetics as valid source of knowledge, I have alluded to the notion that the *perception* of what is true is just as powerful. And if mainstream society views genetics as an important feature in defining what it means to be human than the social ramifications of developing these tools needs to be addressed under the premise that the information garnered from MF LOC devices is credible. As such, I again stress that it is essential to understand the

perspectives of the different groups of individuals using the MF LOC devices, such as oncologists, and to develop laws in conjunction with the technology in a way that is congruent with societal ethics and values.

4.0 CHAPTER FOUR: METHODOLOGY

In this section I provide an overview of the core processes of this research. First I will summarize my epistemological, theoretical and methodological orientations, and then I will discuss social constructionism, and include a detailed section of the methods involved in conducting the research. I will also briefly discuss reliability, validity and limitations in regards to the research. I believe, as does Crotty (1998), that within the research process different factors need to be aligned in order to have a coherent and logical understanding of your research investigation. There are four main elements within a research process that flow and feed into each other, they are: epistemology, theoretical perspective, methodology and methods (see Crotty, 1998).

1. One's epistemological perspective is related to the theory of knowledge that dwells within the theoretical perspective and methodology (Crotty, 1998). Closely related is the concept of ontology which refers to the orientation of one's nature or essence of research (Mason, 2002). The 'nature of reality' embedded in my theoretical outlook for this research is stemming from a contructionist perspective of reality, constituting that aspects of reality can be understood through perceptions, discourse, attitudes, beliefs and accounts (see Mason, 2002).

2. One's theoretical perspective is that which underlies the methodology and is the philosophical reasoning which forms the methodology and beholds a platform for substantiating the logic and criteria embedded in the methodology

(Crotty, 1998). The theoretical perspective draws from the epistemological orientations, so in regards to my research the theoretical perspective draws from an orientation towards sociology of science studies and an epistemological perspective of social constructionism.

3. Methodology entails an in-depth look at the strategy, evolution, or design incorporated within the selection of methods used (Crotty, 1998). The methodology is also influenced by one's epistemological and theoretical perspectives. A qualitative approach to the social constructionist epistemology is used and the design of choice for this particular research is thematic analysis.

4. Method refers to the techniques or processes by which one generated and analyzed data in relation to a set of research questions (Crotty, 1998). In this case the main method used was interviewing oncologists across Canada. A detailed section of the methods is discussed later in this chapter.

These four elements build a solid foundation by which the analysis and results can emerge as epistemologically, theoretically and methodologically sound. Theoretical discourse was covered in section 4.1, the remainder of this section will discuss the epistemological framework of social constructionism, which aids to inform the methodological logic.

4.1 EPISTEMOLOGICAL FRAMEWORK: SOCIAL CONSTRUCTION

The emergence of the social analysis of science and technology studies initially started as a criticism of scientific determinism. And just as different disciplines like biology, computer science, and engineering have come together to

develop biotechnology, so too can different sociological methodologies and epistemologies converge to help better understand the ethical, social and legal impacts of transformative technologies. It is important to explore how we generate knowledge and how it affects us. According to Crotty (1998) constructionism posits that no there is no objective truth waiting to be discovered. Only through our interaction with the realities in our world can truth come into being. Meaning is only possible if experienced by a mind and thus is not discovered, but constructed. Scientific knowledge as well is developed through a constructed design of knowledge (see Crotty, 1998).

Burr (1995) describes social constructionism as multi-disciplinary as it has been developed by several disciplines including sociology, philosophy and linguistics. Social constructionism takes a critical stance towards taken for granted knowledge and challenges notions that one can achieve knowledge through an unbiased, objective observation of the world (Burr, 1995). Social constuctionism is in stark opposition to positivism and views reality as bound within historical and cultural specificity. Thus knowledge is an artifact of culture leading to the understanding that no one way of understanding is superior to other ways (Burr, 1995). Burr (1995) contends that knowledge is perpetuated through social processes and people construct their version of knowledge through daily interaction; therein lays the impetus for a social contructionists' interest in investigating social interactions and language.

The study of how we know what we know has been the bedrock of social studies of knowledge, and the foundation for the development of the social study

of science and technology. The Social Construction of Technology (SCOT) perspective views knowledge, including scientific knowledge, as defined as socially constructed and therefore is partly developed from the scientists, institutions (political, educational, industrial, etc), instruments and the accepted norms of discovery. Constructivists (Bijker, 2001) posit that the truth of scientific facts and development of technology should be studied as accomplishments that are constructed, not inherent elements of the technology. It is important that the social context is included when analyzing the development of science and technology (Bijker, 2001).

According to Bijker (2001) the SCOT approach came forth from three movements including the Science and Technology Studies (STS) movement, Sociology of Scientific Knowledge (SSK), and the history of technology. The primary goals of SCOT were to study the social responsibilities of scientists, the risks of nuclear energy and use of nuclear weapons and environmental pollution. SCOT started out as a criticism against technological determinism. Technological determinism espoused that technology was autonomous and shaped society to a great deal (Bijker, 2001). Evenutally, SCOT researchers came to study both the impacts of technology on society and the influence of society on technology. Research in SCOT integrates empirical case studies with questions of the modernization and politicalization of society as well as the organization of innovation. Bijker's (2001) heuristics of SCOT include three major steps:

Step one: Includes relevant social groups that view technology in the same way (interpretive flexibility), and provides a depiction of an artifact through the perspective of relevant social groups.

Step two: The researcher analyzes how interpretive flexibility disintegrates due to artifacts gaining dominance over others. As different meanings are constructed from a technology they integrate, and finally one artifact yields from the process of social construction (closure, stabilization).

Step three: The course of stabilization is examined in an extensive theoretical framework: why does a social construction process follow this course rather than another (technological frame)?

Bijker (2001) argues that the process of social construction is a cycle which begins with the development of an artifact to the technological frame to the relevant social group, and back to a *new* artifact and technological frame and so on. Technology also impacts social institutions so one needs to understand technology's impact on society. SCOT offers a conceptual framework for politicizing this technological culture (showing hidden political agendas, putting issues on the political agenda, opening issues up for political debate). Political decision-making can be facilitated through the cooperation of relevant social groups and consensus conferences, public debates, and citizen juries (Bijker, 2001). In the application of SCOT all relevant social groups have an equal say. In relation to health care, concepts such as medicalization and biomedicalization are used by social contructionists (Conrad, 1992 and Clarke et al., 2003) to unpack and understand the process of medical control in society. This study will draw

heavily on the social constructionist orientation and in particular aspects from Bijker's (2001) understanding of SCOT. Using a social constructionist epistemological framework, I believe, can provide a meaningful qualitative analysis of the current technological phenomenon under study.

4.2 QUALITATIVE RESEARCH

Quantitative research frequently draws on the use of statistical analysis to investigate relationships between certain variables, it is very useful, and is a more straightforward methodology than qualitative research. However, qualitative research allows for an in-depth and meaningful account of social phenomenon that cannot be attained through objective quantitative methods alone. The use of qualitative methods allows one to examine a multitude of dimensions of the social world including experiences of everyday life, along with the actions, perceptions and beliefs of the research participants and the meaning and importance of ways that social processes, institutions, discourses or relationships work (Mason, 2002).

According to Mason (2002) a qualitative researcher will likely borrow from several reading processes to generate meaning from the data. The three most common include a literal, interpretive and reflexive reading. In answering the question 'what constitutes as evidence in the data' one can take a literal stance and evaluate the words, language and literal content within the discourse. An interpretive reading would essentially have the researcher construct an account of what one thinks the data is revealing. And the reflexive reading incorporates the researcher as part of the data generating process, viewing the role of interpretation

as coming from the researcher as going beyond the data while acknowledging one's role in the generation of the data (see Mason, 2002).

Mason (2002) advises that the systematic sorting, organizing and indexing can facilitate the emergence of surprises from the data that may not be as apparent from a less rigorous analysis. One way would be to apply cross-sectional indexing or categorical indexing of data which involves systematically indexing a data set to include different categories based on common principles (Mason, 2002). This will be useful in order to examine the oncologists' responses in such a way that a systematic overview of the data can be achieved to ensure coverage of leading themes.

Mulkay and Gilbert (1982) state that the main question queried on in sociology of science studies is "in view of the empirical evidence about scientists' actions and beliefs, how does science actually operate?" (pg. 311). But rather the more useful question would be "how do scientists construct their version of what is going on in science rather than what is really going on in science" (pg. 314). I will examine the emergence of a scientific and biomedical repertoire in order to answer how the oncologists construct their understanding of the MF LOC device and the concerns around the ethical, legal and social issues of genetic testing. The following section will discuss the technical details of the methods used in carrying out the research.

4.3 METHODS

The research undertaken included interviewing Canadian oncologists about MF LOC technology. It is important to understand how oncologists construct this technology. Since the initial purpose of the development of the MF LOC device was to diagnose and monitor patients with genetic defects and cancer. Interviews were conducted with Canadian oncologists during August 2004 to February 2005.

A qualitative approach is used to analyze the perceptions of oncologists regarding the development and use of microfluidic lab-on-chip devices. I developed a structured 14 question instrument in consultation with Dr. Michael Mehta (see appendix one). A pilot study was not conducted. The questions center on the ethical, legal and social implications of multiple uses of MF LOC devices. A small sample was used in this study, and the technique for collecting informants means that the results of the study are not generalized to all oncologists in Canada. Nevertheless, studies like this are useful for highlighting the range of opinions on topics of social importance.

Thirty-one oncologists were interviewed in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, and Nova Soctia (see appendix three). The time of each interview was approximately 15 minutes. Ethics approval was secured from the University of Saskatchewan as of June 2004. This research is part of a larger project under the direction of Dr. Michael Mehta at the University of Saskatchewan who has been funded through the Canadian Institutes of Health Research. The study of the oncologists' perception is a second stage of Dr.

Mehta's research investigating how MF LOC devices may impact society. The first stage of the research was to examine how the general public perceived this upcoming technology. The final stage of this project will be a series of consensus conferences in which various players such as oncologists, scientists, engineers, academics will congregate to discuss the outcome of this project.

The methods used to obtain a list of oncologists included conducting internet searches of websites listing oncologists in Canada such as www.cancercare.on.ca; and the snowball method of asking for referrals from the oncologists that were interviewed. In most cases oncologists were emailed a description of the research followed by a telephone call to set up an appointment. Microsoft Excel was used to keep track of the oncologists' contact information and the appointment times.

To record interviews a recording device was attached to a Sasktel Vista 350 telephone. I notified the interviewees and asked permission for the recording of the interview session. A preamble to the interview included a verbal consent, and once that was obtained I began by defining the term microfluidc lab-on-chip device as:

> Microfluidic platforms are microsystems that incorporate microelectronic and biological components onto a hand-held device. Such devices are currently under development, and within 5-10 years are expected to revolutionize how health care providers monitor human health. By placing the capabilities of a large diagnostic lab in a platform the size of a wrist watch, point-of care applications including genetic testing, pharmacogentic testing, and assessment of viral load may become commonplace in medical clinics, pharmacies, and elsewhere. To assist in making diagnoses, MFPs will require real-time data acquisition and integration with human genetic and other kinds of databases (Mehta and Poudrier, 2004).

All interviews were transcribed and prepared for textual analysis. The interview version that this type of research adheres to is a mixture of positivism, emotionalism and constructionism (Silverman, 2001). Positivism because the interview questions are standardized and structured such that each interviewee receives the exact same question with no room for the researcher to deviate from the question. Emotionalism because I am after the authentic perceptions and experiences of the oncologists in regards to their thoughts on MF LOC devices. Although the questionnaire is structured, the majority of the questions are open-ended allowing for a narrative discourse to emerge from the oncologists interviewed. Constructionist in that I am interested in understanding how oncologists create meaning.

A literature review was conducted of the various models of knowledge production. This forms the backbone for understanding the importance of knowing who is involved in developing technology and how it may be used in society. A selection of various articles regarding Mode-1, Mode-2, Triple Helix and PNS were used to examine the differences and similarities between the approaches.

Since the methodological framework selected was qualitative, I divided the analysis section into two different aspects. The first part is a thematic analysis that delves into areas of knowledge production, dependence on the professional, data storage, and discrimination and policy implications. The second part

examines how oncologists socially construct their understanding of the MF LOC device through the use of scientific and biomedical repertoires.

4.4 RELIABILITY AND VALIDITY

From a reliability standpoint it is important to ensure that one's methods and analysis have been thorough, careful, honest and accurate, as well that they appropriately address the research questions (Mason, 2002). Ensuring validity requires that one accurately measures or explains that which one claims to be measuring or explaining (Mason, 2002). In order to achieve this one must retrace the directions of method and the process of how one reached an interpretation.

For qualitative analysis the validation procedure is embedded within the analysis. Potter (2003) says that there is no clear distinction between validation and analytic procedures; the deviant cases can help to indicate whether a generalization is robust or insufficient. If a piece of work has coherence, meaning that several studies elicit similar findings than validity can be supported. Another way is through reader's evaluation, since in many cases the researcher supplies the reader with excerpts along with their analysis this process invites the reader to judge for them self the significance of the claim. "Any study which cannot effectively show participants' own orientations to a phenomenon, which cannot deal with deviant cases, which is out of line with previous research, and fails to offer convincing interpretations of reproduced extracts is unlikely to be worth serious consideration" (Potter, 2003: 19). For purposes of this study, whenever a discourse from a participant is referred to, the literal translation will be provided.

4.5 LIMITATIONS

Some of the limitations include the lack of ability on my side to build rapport with the oncologists interviewed. Since I used telephone interviews instead of face-to-face interviews I was not be able to use body language as a way to convey a strong sense of human interaction that usually allows for a more in-depth expression of the interviewees thoughts and experiences. Although the research study is intended for oncologists across Canada, I was not be able to access the perspectives of strictly French speaking oncologists as I do not have French as a second language. Another impediment to the study is that many oncologists had not heard much about the development of MF LOC devices. I anticipate that this probably caused some oncologists to not want to participate in the interview process. Since oncologists' time is in high demand within a structured health care system their ability to participate in an interview was likely impacted by time constraints.

Aside from these limitations I believe that this research will provide useful information about the potential risks and benefits involved with certain applications of MF LOC devices. An analysis of oncologists' perceptions will provide insight into how an emerging technology such as MF LOC devices could potentially be shaped by users, and how this technology may also change the current practices of oncologists and other potential users. The insights gained from this study will contribute to the literature surrounding ethical, legal and social concerns of emerging transformative technologies.

5.0 CHAPTER FIVE: ANALYSIS AND DISCUSSION

In this section I provide an analytical overview of the key themes and repertoires that relate to the specific thesis statements and research questions that were established at the onset of this research. A total of 31 oncologists were interviewed, twenty-four were male and seven were female. Age ranged from 31 to 64 years, and the average age was 46.55 years. The length of years that the oncologists practiced at the time of the interview ranged from 1 to 33 years with 14.74 years as an average. Oncologists were interviewed from different provinces in Canada including Saskatchewan, Alberta, British Columbia, Manitoba, Ontario, and Nova Scotia.

Several readings of the data allowed for two separate analyses to unfold. The first one that will be discussed is the identification of themes that emerged from the responses to the questions. The second analysis involves the construction of repertoires that can be found within the oncologists' discourse.

The thematic analysis will help address the research questions regarding the first thesis statement of this research: understanding modes of scientific knowledge production will allow for a more socially and ethically responsible form of governance to emerge surrounding new technology applications. The main question pertaining to this thesis is what type of knowledge production are we currently experiencing? The thematic analysis will also investigate policy implications. The main question surrounding this issue is what insight might

oncologists provide in guiding policy (laws and regulations) surrounding the use of MF LOC devices?

5.1 THEMATIC ANALYSIS

1. **Thesis:** *Understanding the transformations of new scientific knowledge production will allow for a more socially and ethically informed mode of governance to emerge.*

Question: *What type of knowledge production are we currently experiencing?*

5.1.1 THEME: KNOWLEDGE PRODUCTION

The main question is what type of knowledge production are we currently experiencing? So the impetus is on which type of knowledge production will be most evident in the oncologists' responses; i.e., Mode-1, Mode-2, Triple Helix or Post-Normal Science? Interview question number 9 asked: what role do you think government, industry and universities should have in developing lab-on-chip technology? The responses to question 9 as well as other questions will provide a glimpse into the orientation that oncologists have in regards to knowledge production.

Some of the oncologists commented that industry, government and universities are to have separate roles in the development of lab-on-chip technology. This is more reflective of Mode-1 specifics of knowledge production.

> 9.9 Well I think the government should fund research that's done by academics and I think industry should develop products that are of value in genetic testing. So I think that the industry has a role to play in the

> development of the technology. So I don't think that it should be limited to academics or government I think industry has an important role to play.

In participant 9's response it is evident that according to their response, the production of knowledge is still done primarily in the universities and the role of the university is restricted to researcher. The government's role is not one of co-researcher or co-developer, but simply as financier of the research. The role of industry takes on great significance as it is viewed as the core developer of the research initiative. So these clear distinct roles and separation of knowledge reflect the tendencies of Mode-1 ideals in that there is a separation of knowledge production and application. Essentially the site of knowledge production (the university) differs from development and application (industry) (see Gibbons et al., 1994).

The majority of other responses reflected a collaborative approach ideal to the roles of industry, government and university in the development process. This supported both a Mode-2 type of knowledge production (Gibbons, 1999) and Etzkowitz and Leydesdorff (2000) Triple Helix thesis of knowledge production. Participant 10 indicated that knowledge should be achieved through collaborative efforts by universities and labs, and, somewhat similar to participant 9's response, that government should provide financial support, but not be directly involved in the development of the technology. So here we see a slight shift into a Mode-2 type of knowledge production with more emphasis on collaboration.

> 9.10 I think that universities and labs should be working collaboratively to increase our knowledge and be able to develop tests that maybe useful in

> terms of diagnosing people or giving prognostication. I think that government's major role should be in funding the universities I don't think that the government should be directly involved in the research itself. But they should have better funding access for major universities or research institutes to be able to give to qualified investigators.

Participant 12 strongly reflects an orientation to the Triple Helix thesis by attributing roles to each institution while the university maintains a critical role in the development process in partnership with industry. Even though the public was not mentioned in the question as having a role in the development, participant 12 indirectly includes the public by saying "that society in general should have input into how these technologies are implemented"(9.12).

> 9.12 I think just like any other technological venture that involves something as important as a medical technology should be done in partnership between universities and industry. I think that given the societal issues and financial issues and ethical and moral issues that surround the development of genetic testing that the government and society in general should have input into how these technologies are implemented.

Participant 2 remains vague on their perception of the role of the university; however, makes it clear that industry is the lead innovator by saying 'everyone walks hand in hand with industry'. "Well now a days everyone walks hand in hand with industry I don't think any government is developing anything completely alone is it?" (9.2).

With a somewhat confusing response participant 7 claims that neither government, industry, nor university should take part in the development process. It is not made apparent through P7's response whom the said developer would be; however, P7 subsequently follows up with the perspective that the university, government *or* industry should control the *application* of the technology. The

conjunction “or” is used instead of “and” thus conveying a sense of separation, not collaboration.

> 9.7 Government, industry and university should not have any involvement in development of the technology because if they control the development of the technology we will never progress, ever. But once the technology is developed by the researcher, or investigator then I think the application of that technology should be controlled by the government or industry or by the universities because it is the application that would create a problem not the development. I think that the development should continue unhindered and the researchers should have their own creative avenues open to create the best technology possible.

Another interesting comment made by P7 is that involvement by the government, industry and university in the development of the technology would not lead to progress. This lack of faith in current institutions can be read as a post-modernist orientation; indicating that an alternative method of knowledge production is needed. Unfortunately, P7 does not discuss the alternative institution by which the “researcher or investigator” would develop the technology.

The inclusion of the public is characteristic of the Mode-2 model and the Post-Normal Science approach. Participant 4 stresses the importance of sharing information regarding technology with the public in order to facilitate a discussion.

> 9.4 I think like any other technology you should have the public involved because it gives the general public a better… not control, but at least some understanding about how the information can be used or where it is going because, I would hope so anyway, that they would be more open to ….discussion about this technology rather than it being developed in a closed corner some place and then being introduced quietly.

Questions concerning reliability and validity increasingly reflect the tendency towards a mixture of responses of who should be responsible for

ensuring reliability and validity. Many of the responses include reference to more than one institution as the overseer of confirming questions regarding reliability and validity.

A person does not need be trained in the area of computer programming in order to use the resulting software (such as Microsoft's PowerPoint). It is important to know that when one does use the program that it is reliable and valid software. Lab-on-chip technology, in the form of a handheld, automated device, is intended to enable doctors to monitor, diagnose and provide individualized care to patients through the analysis of single cell material, including specific genes. This analytical work will be possible more quickly and without the need for extensive laboratory space and equipment as is currently the case. The important factor that will impact the utility and wide-spread use of the technology is the extent to which it can be shown to be valid (meaning that it is measuring that which it is supposed to) and reliable (meaning that it will consistently give proper results). The oncologists interviewed were adamant throughout several questions that the MF LOC device would need to prove high levels of validity and reliability. Where the oncologists did differ in opinion was on who should be ensuring the reliability and validity of the product.

There is also an emphasis on having reliability and validity tested within a scientific-based institution, likely meaning a laboratory setting and having the information from the tests widely shared. As participant 5 indicates:

> 10.5 Reliability and validity has to be done in experimental settings so I think whenever a test is done it has to tested in different trial format before

> it's put in common place like in use and it has to be published in peer reviewed journals.

The reference to "peer reviewed journals" is reflective of Mode-1 type of knowledge production that emphasizes the use of experts while excluding other sources of potentially valid information. The emphasis on oncologists being able to view the data themselves is strong. The doctors do not seem willing to accept MF LOC devices as a diagnostic tool unless they can see through published works or otherwise that the technology is reliable and valid to their standards. As mentioned by participant 3, there is little room for accepting the diagnostic tool without "scientific data" to back it up. "Depending upon if I have the data I mean I need the scientific data so I have not reviewed the data so I cannot answer this question again" (13.3).

The type of institution that is involved in ensuring that the lab-on-chip technology is both valid and reliable plays an important part, and the discourse did not reveal any one institution as being the number one burden-of-proof center for analyzing validity and reliability. A mixture of responses included the government, laboratories, first developers, clinicians and shared between government, university, and clinicians.

> 10.1 I think the authorities that license the laboratories are responsible for that kind of a process and the laborites themselves are responsible for meeting certain standards.

> 10.4 I guess the easy answer is the government.

Participants 1 and 4 advocate a single institution approach to validating technology while the following participants 6, 7 and 10 believe that multi-

institutional collaboration is necessary. The tendency towards multi-institutional collaboration supports the Triple Helix thesis of knowledge production.

> 10.6 It should be shared responsibility. Certainly the scientific community meaning the researchers and clinicians should be responsible for the first step in terms of reliability and validity and then like there should be guidelines similar to the guidelines available now from organizations or sort of either oncology organization in general there should be some sort of guidelines rather than leaving things to personal preference.
>
> 10.7 I think that everyone who is involved and the previous question the government, the industry, the university, the researchers, the users, the oncologists everyone has to be extremely careful in ensuring that the technology is reliable and it should go through a thorough testing procedure at the various levels before it is accepted as a common tool.
>
> 10.10 Ultimately the first person who is responsible is the person designing the test, and so if the university is designing it, or in conjunction with a laboratory it is their responsibility first and foremost to ensure that they have done all the quality assurance mechanisms and controls that they require. Once the test is licensed for use that's a federal government's authority and so I think that the federal government has a responsibility through health Canada for oversight to review the literature that would be provided to them regarding it. I don't think the government should be responsible for directly doing the testing but I think they have an obligation to ensure that the data that's given to them is considered to be adequate in the scope and breadth to be able to say that the test is reliable and has an adequate positive and negative rate, false positive and false negative.

Although there is a slight dominance of orientation towards the Triple Helix thesis of knowledge production, there is still a mixture of Mode-1 and 2 as well as a slight orientation to the PNS approach. Understanding the oncologists' perceptions regarding knowledge production has provided insight into which institutions are believed to be producing the knowledge and which should be responsible for ensuring validity and reliability of the products of knowledge.

2. Thesis: *It is important to consider who might use the technology and how it might impact institutional practices and individuals.*

Question
1. *What insight might oncologists provide in guiding policy surrounding the use of MF LOC devices?*

5.1.2 THEME: DEPENDENCE ON THE "EXPERT"

Oncologists, for the most part, do not want genetic testing devices to be available without counsel since the average person would lack the educational background necessary to understand the test results, and would put themselves at emotional risk. The greatest concern that the oncologists had with the commercialization of MF LOC is that patients would resort to self-testing and become over-anxious of the test results. Many of the oncologists believe that a disconnect would occur between using the MF LOC device as a self-administered diagnostic tool and having adequate education (knowledge) of how to interpret the results.

> 6.10 I think that the impact (on health care) would almost crush the public health care system in terms of patient visits because I think that patients if they could self test everyone would do self testing wouldn't have any knowledge about what the implications would be in terms what a positive test would be nor would they necessarily understand false positives and false negatives and that would lead to a large amount of panic and a large amount of patient visits to their family practitioner and that will overload the system because it can't cope it will also probably lead to incredible

> amount of referrals for opinions from oncologists about how to prevent the cancers that might be genetically predisposed to and the cancer system can't coup with volume either. I think that it would have a pretty devastating impact on the system overall.

Participant 10 fears that commercialization and self-testing would disrupt the health care system and overload it with people who "wouldn't have any knowledge about what the implications would be in terms of a positive test" and thus would result in panic. Participant 7 is similarly concerned with panic and chaos and also emphasizes the need for care after the results are obtained, the role of the oncologist in P7's passage is one of caretaker rather than interpreter within a health care system.

> 6.7 I think that would be real chaos and anarchy because I think that if you are looking at a general population who may or may not have sufficient knowledge about various implications of various tests and so I would suspect that this should not become an at home pregnancy test type of technology because the diseases that particularly that I deal with as an oncologist need significant medical expertise to provide sort of care after the test result comes through.

Participant 8 refers to the layperson as someone "who may not be able to interpret the results correctly" and that the laymen need "guidance of a physician or someone who knows how to interpret the results". The oncologists generally are indicating that they do have a continual and important role in the diagnosis of the disease process. The idea of having that component of their job taken over by a "machine" essentially would likely contribute to a discourse defending the importance of the continual role of physician as diagnostic consultant.

> 6.8 Meaning if individuals have access then anyone who could afford probably will want the test done although maybe that will be a benefit to I suppose to the company who developed it, but it may not always be a help

> to the people who get the test done because quite often the patients or the laymen may not be able to interpret the results correctly and then secondly that particular test may not be relevant to the given person so that it can cause unnecessary anxiety on part of the patient. And if this are done then it should be done on guidance of a physician who tell at least if this test is relevant in your case and also the interpretation of the results should be done with the guidance of the physician or somebody who knows how to interpret the results so for the layperson like with testing for blood sugar results and taking insulin according to results, it is more complicated than that. I would be concerned if it is freely available because it can be misused it can be overused and it can cause unnecessary anxiety on part of the people who use it so it has to be done cautiously and I think and with help and guidance for patients.

An opposite stance emerged (less frequently) within the responses that deviated from describing laymen as an uneducated consumer and depicted the "patient" as having the ability to interpret results. Although the task still remains contingent on education, at least a couple of the doctors interviewed believe that individuals are capable of self-administering and interpreting tests.

> 6.9 I think it is all right as long as the patients/individuals know, are educated and the implications of what a positive and negative test means. In a way it's not a lot different from some of the home testing that is done like home pregnancy testing. So I am all for being educated and if they are educated using the education to learn about themselves and the implications of that.

Particpant 9 stresses the importance of education as indicated in the above quote where the word "education" was used four times. When P9 was asked "how useful do you think lab-on-chip technology could be for individuals in remote locations, like Northern Canada, and developing countries?" the theme of education was consistent for remote areas like Northern Canada, but when the response focused on developing countries P9 acknowledges that there are other

more immediate concerns that need to be addressed before individuals would benefit from MF LOC technology.

> 12.9 I don't think Northern Canada is any different than anywhere else I think it's um the challenge with be the education of individuals and making not only the technology but the education that's required for patients to understand what are the implications of testing and the results. I think in the developing countries it is less of an issue they have other issues to be concerned about with nutrition and public health and safety and things like that so it's less of an issue there in the developing countries.

It is clear, that according to the majority of the oncologists' responses that having a professional who is properly informed of the procedures is necessary to carry out the interpretation of genetic test results in order to divert from patient panic and stress on the health care system.

5.1.3 THEME: DISCRIMINATION AND POLICY IMPLICATIONS

Discrimination exists in society in many forms such as age, race, ethnicity, gender, socioeconomic status, etc. The application of laws is meant to limit the occurrence of discrimination in society, such as in the work place or obtaining services. Two questions in particular were meant to elicit whether or not the oncologists were concerned about genetic discrimination. The first question read: "There are currently no laws in Canada preventing companies from discriminating based on genetic test results. Would you be worried about discrimination if employers had access to results?"

There is a general acknowledgment from the oncologists that there are not sufficient laws prohibiting companies to discriminate based on genetic profiles.

> 3.7 currently there are no laws discriminating or controlling the companies from discriminating patients based on their health status whether they have a diagnosis of cancer or not or any other diagnosis for that matter so I don't know whether specifically genetic test results will have any specific implication on that. I think it should be much more wider that companies should not be allowed to discriminate based on the health status of the individual. So, people can be prevented and I think employers should have a limited access to the health status which is still not controlled within Canada right now.

There is some ambivalence as indicated between the response of P7 and P16 as to currently how much legal coverage one has over their health information. P7 starts out by stating that "there are no laws discriminating or controlling the companies from discriminating patients based on their health status" and P16 states "there are laws to protect against…or that protect the privacy of your health information". Since the question was regarding corporate discrimination, I assume that P16 is referring to privacy of health information regarding employment opportunities.

> 3.16 I don't think employers should be given access to the health results one way or another I mean it is a separate question if there isn't laws to protect against those kind of things and probably that needs dealing with but there are laws to protect against….or that protect the privacy of your health information so I would hope that if things are done it's still under the protection of your health information.

Some of the oncologists understood that there is that option to run genetic tests already; however, the big difference with the commercialization of MF LOC technology is that it would become more normalized and routine since the procedure to do genetic testing would be cheaper, quicker and easier. So although there are laws protecting medical files of patient health information the option to

subject potential employees to corporate administered testing would get around requiring the release of patient medical file information.

From an employers' perspective the prospect of obtaining information regarding genetics may be viewed as another rung on the ladder for finding the best suited employee. Skill, intelligence, physique, and personality are currently popular areas of examination in job selection processes. So would not genetic testing simply be an additional way to "select" the best potential candidate? The biggest difference is that almost everyone can to some capacity improve or change their skills, intelligence, physique and personality these are not static. Genetics is more static, in that one cannot easily improve or change their genetic profile. Eating more broccoli may help deter the onset of some cancer but it will not eliminate the predisposition to cancer if one has inherited a cancer-linked gene. So the notion of selecting based on genetics should at least be treated in similar context as laws that prohibit racial discrimination.

> 3.19 There is that possibility now with standard genetic testing. It is just more cumbersome right now. So I guess it's a concern now so it's a concern with any device that would make discrimination based on your genetics your genotype easier so that employers could purchase these machines and do it themselves. Where as right now patients are protected by rules of confidentiality about their medical data. So I think that's where the concern would come from would be that employers would start testing patients themselves more easily and perhaps cheaply with this technology.

A couple comments supported the corporate use of employee genetic testing. Such as from participant 17 who remarked, "Oh for sure. If I was an employer I would discriminate and so would the insurance companies and so

would even the federal government." This comment seems rather inflammatory, and borderline cynical.

The proliferation of discrimination was also a strong concern when associated with insurance companies, but in comparison to the concerns expressed in regards to employee selection there was more acceptance among the oncologists when using genetic testing as a discriminatory tool for insurance companies. The question was asked: "Insurance companies are always looking for ways to reduce risk and will increase premiums for high-risk clients. What role do you think lab-on-chip devices may play in setting premiums for clients? Is it fair for insurance companies to use these technologies?" Some participants were aligned with the position that it would be unfair to allow insurance companies to use genetic health information in order to assess client risk. As participant 6 explains, it is not fair and it creates an unequal power balance in favor of the insurance companies.

> 4.6 No I don't think that it is fair. The whole idea of insurance is that you don't know, but if you know then the insurance company would be the only benefiting partner from the relationship. The person/patient will not be benefiting it will be unfair to the patient.

The flip side to this of course is that potential clients may go on their own for genetic testing and those who are given a clean slate of health (as indicative of their genetic profile) may be less willing to invest in health insurance. Participant 13 sums up this sentiment quite well: "No, because the people who need the insurance won't get it and people who are low risk probably don't need to buy insurance" (4.13). Participant 5 is also concerned that insurance companies will

exploit the use of genetic testing but sees the government as having the task to develop appropriate regulatory protocols to limit the exploitation of genetic testing.

> 4.5 No I don't think the insurance companies should be given access to this data and the governments need to have firm regulations in place before this should be done. Obviously you can't stop the technology but the government should have very firm rules in place otherwise I am positive that this is going to be exploited by insurance companies.

A response reminiscent of Post-Normal Science rhetoric lays out a viable solution that does not single out government as the sole creator of legislation but also includes "patient right advocates, the company's scientists, and physicians" (4.27).

> 4.27 I think that there is going to need to be some careful discussions and legislation with a number of people including patient right advocates, the company's scientists, physicians and they are going to have to come up with some reasonable guidelines so that people's rights are protected and that they can get insurance but at the same time that business aren't bankrupt somewhere there is a middle ground were those things can be worked out but I don't think its an easy question to answer. I think that it is going to need some serious discussion and the time to do it is probably now because even though I don't think these things are ready for prime time just yet, it is very well likely be ready in the next decade and people need to have thought about this complicated issue sooner rather than later.

As mentioned earlier, the oncologists studied were more apt to accept the use of genetic testing by insurance companies than for use in employee selection. In some respects the acceptance emerges as the participant puts themself in the place of the insurance company. "If I were in the insurance company seat I would say I am forced to do it there is no way I cannot do it. But as a physician I'd rather not have that discrimination done" (4.2). Participant 10 says it is "fair game for

(insurance) companies to consider employing this technology and to not agree to insure patients", he/she then back-peddles by saying that they do not think it is ethically or morally right, but simply a case of how the insurance business is set up.

> 4.10 Insurance companies are in the business of making money and so I think that given the way that the system is set up right now I think that it is fair game for companies to consider employing this technology and to not agree to insure patients if they find test results that this person has a high risk of health problems that will require cashing in on their insurance. I don't necessarily think that it is ethically or morally right but you know I think that it is more a question on how the insurance business is set up than it is necessarily about what they use to determine risk.

I surmise that the reason for this may be as a result of the hierarchal nature between finding a job and purchasing life insurance. Possessing a job in today's society is viewed as a "need" at least in the majority of cases. Possessing life insurance is, I would argue, more closely related to a "desire". In questioning the ethics of applying genetic testing to employee selection and insurance rate assessment thus requires two different sets of criteria. The purchasing of insurance is done out of the desire to buy security for one's self and possibly one's family. In order to purchase life insurance one needs to have money, the primary source of obtaining money is through employment. Thus, when genetic discrimination is applied in the work force then it is in the ethical domain of dealing with people's *livelihoods,* and when genetically discriminating against individuals regarding insurance premiums it is in the ethical domain of dealing with people's *sense of security.*

5.1.4 THEME: DATA STORAGE

In responding to whether or not current methods of storing data are sufficient for protecting patient confidentiality there was no dominant response. Some oncologists admitted that they were not aware of how well protected the current methods were, “I cannot answer this question, to my knowledge it seems to be okay but I don’t know about it” (5.3) and “I am not aware I don’t know how they store (the data) but I hope they do according to like any other health care setting like in trials there is a coding they should probably be doing it, but I don’t know as I am not directly involved” (5.5).

Some participants felt that there are sufficient measures taken currently to protect patient confidentiality, however as is the case with P10, the concern lays with the future potential of generating greater information about the clients and limiting whom has access to the patient files.

> 5.10 Current methods with the testing that we currently do I think they are. But depending on where the technological advances go and the kinds of information that we may get in the future that we currently don’t have access too because we don’t have the ability to test for, that’s when we are probably going to need to have safe guards placed on to who can have access to that information.

In some cases the onus of sufficient storage is de-focused from a “technical security” perspective to that of human responsibility. Essentially, the electronic technology available for data storage is viewed as sufficient for holding the data, but easily breached, as P12 indicates “I think that the technology is sufficient, but I don’t know that it is necessarily being implemented in a sufficient way.”

> 5.12 I believe that the technology that exists is sufficient but I think that the technology that is used to store information now that the electronic age its much easier to have breaches of confidentiality occur so I think that the technology is sufficient but I don't know that it is necessarily being implemented in a sufficient way.

Participant 14 declares it is a human issue saying that "It depends on who is doing the storing" (5.14). Whereas participant 17 sees it as a technical issue and as explicated in the following quote, P17 has more confidence in the traditional methods of storing patient information in paper format within files.

> 5.17 I used to think so but I am less certain of that. I don't know how good the ….because it will all become stored in presumably in some kind of an electronic data base because that's actually how we are all moving in medical records…some type of computerized stuff if it where a paper chart it is probably safer because it would be harder break into 30 thousand paper charts but I think it is possible to break into 30 thousand computer charts. But ah so I probably think it is over 99 percent safe but I don't think that it will ever be a 100 percent because we can't even keep income tax results that way.

The difference of shifting the storage of patient information from paper to electronic format is one of space containment and level of abstraction. By space containment I mean that the act of electronically storing data transcends a physical space by existing in an almost inconceivably minute amount of space. The information is presumably etched within a hard drive be it a local hard drive or a server, and can be easily copied once accessed. It also transcends physical institutional barriers, where once the paper files were kept physically locked within a file cabinet and, when the clinic is closed, physically locked within the building. Now the information exists in an electronic data matrix protected by encryption and/or codes. This transforms the storage of information from a

tangible artifact (paper data) to an abstract artifact (electronic data). Thus, the keeper of the information is becoming less physical and more abstract. As the threat of information access extends outside the physical barrier, the need to protect patient information becomes greater. The electronic storage of data can provide a more efficient and organized system; however, measures need to be taken to ensure that patient privacy and confidentiality is maintained.

5.2 INTERPRETIVE REPERTOIRES

Thesis 2, Question 2. *How do oncologists use language to construct their understanding of MF LOC devices? (within the context of scientific and biomedical repertoire)*

The second part of the analysis will use interpretive repertoires to understand how the oncologists conceptualize and come to validate the MF LOC device. The main question here is how do oncologists use language to construct the meaning of this MF LOC device? The use of a scientific and biomedical repertoire emerged as the main impetus by which the oncologists grounded their perceptions and attitudes.

5.2.1 SCIENTIFIC REPERTOIRE

Since I am dealing with a group of individuals who, although, come from different backgrounds and reside in different parts of Canada, all share the extensive experience of acquiring a medical degree and specializing in oncology. This extensive training would expose the oncologists to similar discourses and

ways of thinking from a scientific-medical perspective. This is quite evident in the use of language and reference points that rhetorically emerged through a scientific repertoire in many of the participants' responses. In general the oncologists construct their perception of the MF LOC device based upon how it measures up scientifically regarding issues of validity and reliability.

When asked how confident would you be in trusting a lab-on-chip device to detect and diagnose patients, participant 20 uses the word "valid" three times while explaining how "trust" is generated.

> 13.20 That sort of depends. It depends on how valid it was how well it was tested. I mean do I trust tests? I trust tests that have been well validated and I wouldn't trust ones that haven't been well validated.

Participant 12 also has a similar stance and admits that at this point in time he/she has no confidence in the MF LOC device; however, his/her perception would change if the device were put through rigorous studies.

> 13.12 Right now I have no confidence in it, but if it were to be demonstrated in rigorous studies that it worked just as well as currently available methods then I could certainly be convinced. I have no reason to think that it couldn't happen.

There is also a sense of comparison in P12's response which is another form of measurement regarding how well the new technology measures up to the prior technology. Statements such as "I would have to see the evidence first" (13.13) clearly speaks to the power of "scientific" proof. If MF LOC devices do fail to sufficiently pass tests of validity and reliability to the standards held by the potential users, then the chance for this technology to be disregarded is high. Thus understanding that the oncologists discourse and ultimately the way they think

and conceptualize phenomenon is grounded within a “scientific repertoire” can help clarify how they come to assess the use of MF LOC technology.

In trying to illustrate the emergence of a “scientific repertoire” I feel that it is important to acknowledge that concepts such as validity, reliability and evidence seem intuitively appropriate for assessing the usefulness of MF LOC devices, but in saying this I recognize my own bias towards “scientific rationality”. The problem emerges when agreeing on what type of validity or measure of reliability is correct? Is there a “proper way” to validate the technology? Participant 19 says, “Things would have to be tested and validated in the proper way” (13.19). Participant 27 also alludes to the need to do things properly through a process of “standardization” and remains optimistic for future potential of MF LOC devices, while refraining from accepting it as currently reliable.

> 11.27 I think it is very interesting from a research stand point. I think from a practical stand point working in the real world on a routine bases I think it has a bit of a ways to go primarily because I think that there are no standards about how to collect samples, how to process them, what you are looking at, how to analyze the results that you are looking at. So I think that there is a whole host of technical issues that need to be standardized and made more routine and reproducible from lab to lab and place to place before this is ready for prime time. But I think that those are all doable and I would suspect that there is going to be some real stuff out in the next five to tens years that is reliable. But my own personal opinion is I wouldn’t rely on it right now.

The whole idea of collecting, analyzing and interpreting data is a positivist notion which underlies a belief in discovering truths through observation. P27 adheres strongly to a scientific repertoire by referring to these positivist concepts. In ascribing to a scientific repertoire, the oncologists appear to view themselves as

a beholder of information, essentially an expert, and as such they take on an instrumental role of informing the patient of the condition of one's body and informing the patient of remedial options.

The notion of "expert opinion" is strong within the scientific repertoire. In some cases the oncologists view the patient as incapable of handling the information that the MF LOC device may provide. As participants 4 and 23 indicate the use of MF LOC devices for self-testing would require a professional to interpret the results.

> 6.4 I don't think that that would be a good idea. Too much knowledge can be a bad thing sometimes. You know I think that it should be just like any other testing it should be done by a professional who is trained in the interpretation of these tests. You don't necessarily want to cause people to become anxious or depressed about what they find out.
>
> 6.23 I think if people can self test then that would create a lot of unnecessary anxiety. I think that any sort of testing of anything, its not just chip technology but you know any diagnostic test should be done in a setting where someone has appropriate training to interpret that results of those tests. So to make them really available to anybody again being a lot of people out there who don't really know how to interpret the results you know may get things that are meaningful or may get things that aren't necessarily meaningful and there is going probably, at least in the short term, increase the number of health care in Canada that are required to even to clarify that information.

The justification that P4 gives is that the patient may become unnecessarily depressed by the results if they take it upon themselves. So, presumably according to P4 the oncologist would be able to present the information in such a manner that the patient does not become upset or depressed. I suppose this is possible if one takes into account that the oncologist can also

offer remedial options. A comment from P1 also opposes self-testing and feels that the patients need “guidance”.

> 6.1 I don’t think individuals should be self testing because I think they need a lot of guidance. I think the ramifications of acquiring information about yourself has to be very well understood simply because these kinds of tests, genetic testing, are unlike any test that most lay people are used to. In other words, if you have a blood sample taken from your arm and they give a result it says what’s going on in your body today right now. Whereas with genetic testing it usually gives you a prediction of what might happen not what will happen so it could put you at a greater risk of a certain disease ah but there is no guarantee that you will in fact get that disease and so without the proper understanding of the ramifications, for not only you, but your siblings and cousins and all your relatives has to be understood. So I think that this is very powerful technology that has to be managed in an appropriate way to protect people.

Participant 1 discusses the difference of a genetic test from current tests on the market today. Tests today give information regarding the current state of the body such as blood sugar levels, while genetic tests are predictive and may only give information predisposing the individual to a possible future condition. The second last sentence in P1’s response expresses the difference, “Whereas with genetic testing it usually gives you a prediction of what might happen not what will happen so it could put you at a greater risk of a certain disease ah but there is no guarantee that you will in fact get that disease and so without the proper understanding of the ramifications, for not only you, but your siblings and cousins and all your relatives has to be understood”. So there is this idea that the information accessed by the individual not only affects their own life but since there is a genetic component it may also provide information about other family members genetic potentials. P1’s last sentence: “So I think that this is very powerful technology that has to be managed in an appropriate way to protect

people” uses the word “protect” and warns that there is potentially a danger in knowing about your genetic information. This perpetuates the notion that an expert is needed in order to help make choices about genetic testing and interpreting the results. It seems prudent to point out that it is just as important to consult groups of people outside the domain of “experts” to achieve a broader understanding of how genetic testing may impact society and individuals so that instances of stigmatization, such as in the case of the Ashkenazi Jews, can be avoided.

5.2.2 BIOMEDICAL REPERTOIRE

Describing an individual’s health through genetic traits is a recent phenomenon that not only perpetuates but also contributes to a genetic determinist ideology. Within the oncologists’ responses these different forms of medical social control become evident, especially when discussing when it is necessary for a patient to go for genetic counseling and be tested for genetic traits.

The emergence of a biomedical repertoire signifies and supports the notion of a paradigm shift from a process of medicalization to a process of biomedicalization. Medicalization is defined as a process whereby non-medical conditions are defined and treated as a medical illness (Conrad, 1992). "Medicalization consists of defining a problem in medical terms using medical language to describe a problem, adopting a medical framework to understand a problem or using a medical intervention to treat it" (Conrad, 1992:211). The process of medicalization has transformed “deviant” behaviour and “natural life”

processes into medical conditions. Examples of deviant behaviour include: madness, alcoholism, homosexuality, opiate addiction, obesity, anorexia, child abuse, compulsive gambling, and infertility. Natural life processes include: sexuality, child birth, child development, PMS, menopause, aging and death" (Conrad, 1992:).

In the context of medicalization, Conrad (1992) distinguished between different types of medical social controls: medical ideology (an elaborate medical model developed from social, ideological beliefs); collaboration (the collaboration of doctors as information providers); medical technology (drugs, surgery and genetic or other types of screening.) This enables instances of "medical excusing" to occur from disability to the insanity defense (Conrad, 1992:216). Advances in genetic testing will escalate the exploitation of medical "excusing" if everyday individuals become labeled with certain propensities to develop debilitating conditions such as Huntingtons disease.

An additional form of medical social control is medical surveillance (Conrad, 1992). According to Foucault (1973 as cited in Conrad, 1992), medical surveillance suggests that certain conditions are analyzed through a medical gaze, which then allows physicians to lay claim to all symptoms and activities concerning the condition. Consequences of medicalization range from an assumption of medical moral neutrality to domination by experts and the indvidualization of social problems. "It decontextualizes social problems, puts them under medical control" (Conrad, 1992:223). The oncologists' responses exemplify much of the characteristics of a medicalization discourse; however, it

more strongly adheres to the processes explained through the concept of biomedicalization.

Where medicalization sought to control biomedical phenomenon, biomedicalization sought to transform it (Clarke et al., 2003). Biomedicalization is the incorporation of molecular biology, biotechnologies, genomization, transplant medicine and new medical technologies which - in conjunction with computers and information technology - to institutionally transform medical practices (Clarke et al., 2003).

The technoscientific innovations in biomedicine have inaugurated an era of biomedicalization. Biomedicalization is an intensive extension of medicalization. "Biomedicalization is our term for the increasingly complex, multisited, multidirectional processes of medicalization that today are being extended and reconstituted through the emergent social forms and practices of a highly and increasingly technoscientific biomedicine" (Clarke et al., 2003:162). Clarke et al. (2003) described the current surge of advanced biomedical technologies as a transformation from the phenomenon of medicalization to biomedicalization.

The shift to biomedicalization occured around 1985, although there is no single occurrence or phenomenon that pre-empted the shift. Increasingly technoscientific innovations culminated to bring about revolutions in biomedicine (Clarke et al., 2003). The commodification of health, and a focus on individual responsibility for health care is a focus of biomedicalization. The conceptualization of health risks and continual self monitoring has led to an

environment of the "worried well", "rendering us ready subjects for health related discourses, commodities, services, procedures and technologies (Clarke et al., 2003:163). This leaves little room for individuals to not be "at risk".

Key elements in biomedicalization include clinical innovations such as new diagnostic tools (such as microfluidic lab-on-chip devicies), treatments from genomics, proteomics (study of proteins), and genetic engineering. The biomedicalization era recognizes not only disease and illness as its medical jurisdiction but also the health of the individual (Clarke et al., 2003). Another core premise of biomedicalization is that science, technology and social change are co-produced within biomedicine.

Advances in computer technology and data banking are also embedded in the backbone of biomedicalization. The application of computer technologies within multiple biomedical domains and their organizational infrastructure are thereby mutually constructed, creating new social forms for orchestrating and performing the full range of biomedical related work (Clarke et al, 2003). The convergence of information technology, molecular biology and the mapping of the human genome make way an increasing incidence of biomedicalization in technoscientific cultures. The development of the MF LOC device is yet another avenue in which the process of biomedicalization is taking place.

In analyzing the responses from the oncologists it is clear that the introduction of MF LOC devices into clinical practices and society at large will contribute to the commoditization of health and a larger emphasis on individual action for health care. Clarke et al. (2003) argue that individuals are evaluated

based on varying degrees of risk as either low, moderate or high. Each level is defined by certain reduction protocols the individual is expected to buy into and take responsibility for themselves. Health becomes less medicalized as the onus of responsibility falls less on the physician and more on the individual. Participant 29 discuses the empowerment of the individual "giving patients power, people power and control over their own health is a modern development in medicine and there is a concerted effort on part of the medical community to try to empower patients and this is quite a substantial patient empowerment tool".

> 6.29 The other aspect of that is if patients have access to this technology a lot of patients would be testing themselves and I'm sure there would be some results that were positive, true positives, that would be a significant benefit. But I would imagine there would be a lot of both false negatives as well as false positives and that might drive up consultation and excessive investigations and that might also have a significant impact on healthcare. But that being said you know giving patients power, people power and control over their own health is a modern development in medicine and there is a concerted effort on part of the medical community to try to empower patients and this is quite a substantial patient empowerment tool. We would have to very carefully consider that and consider what the costs would be and the implications would be in terms of our medical system versus patient interest.

Participant 24 expresses that it is "up to the patient" as to whether they should be tested for diseases if no treatments are available.

> 7.24 That's up to the patient. If they want to know if they have got a hereditary disease it is up to the patient. Ya I think it is up to them, if they want it they should be allowed to have it.

A common justification for the testing of genetic diseases is that it helps with making life decisions regarding family planning. This increases the emphasis of individual responsibility for health care not only for one's self but for the future

potential of offspring. Participant 12 illustrates this by saying it is valuable for "people who have genetic pre-dispositions to serious illnesses in their family for the purposes of family planning." Other participants also expresses this sentiment such as P13. There is a sense that an individual's behaviour would be affected not only in family planning, but also in their own lives…a sort of do-it-before-you-die sentiment as expressed in the following phrase by P13: "doing things before it is too late".

> 7.12 I think sometimes there is a need to do that. I think that there is a argument to be made that such tests can be of value in for people who have genetic pre-dispositions to serious illnesses in their family for the purposes of family planning for example or for the purpose of planning their own lives you know if someone is going to die at the age of fifty of Huntington's disease then they may wish to know that ahead of time even if there is no affective treatment. So Yes.

> 7.13 I guess in some situations ya like Huntington's you want to know to make where it is distinctly hereditary to make decisions about having children and maybe life decisions of doing things before it is too late. So ya I guess a qualified yes.

Having knowledge about an individual's genetic make-up can also lead to stigmatization. This stigmatization is not only relegated to society at large but also within one's own family as illustrated in the point that Participant 2 raises:

> 3.2 I think that is something that we have to start thinking about now and see that it doesn't happen. Not only employers it might be if a father has two children one of whom has a genetic abnormality and the other does not will they start thinking I should spend more money on education and the life of the normal kid. It's not only the company it is the whole social status will that change it in the home in the school in the playground. Those things have to be thought of.

The commoditization and individualization of genetic testing receives a lot of power and prestige from the potential, not only to help diagnose a patient, but to predict a future potential of developing a disease. As participant 1 indicates "which will probably be able to predict whether people will respond to treatment or not and give us some idea of prognosis" there is also a potential to predict if an individual will respond well to certain treatments.

> 12.1 Well I think it will apply to anybody in any place who needs treatment ah so I think if you take a look at the DNA arrays that are being developed through this micro-chip technology which will probably be able to predict whether people will respond to treatment or not and give us some idea of prognosis that will probably prevent a lot of resistance to various systemic agents on which we use for treating cancer or it might even allow us to do interventions early on in life of people, no matter where they live, so that they create lifestyles that are probably going to diminish their chance of getting type-two diabetes or some other genetically related disease.

Participant 1 also hits on the concept of commoditization through the process of buying into preventative treatments if a disease potential is detected before it has developed, and says that early interventions would allow the individual to "create lifestyles that are probably going to diminish their chance of getting type-two diabetes or some other genetically related disease." Essentially, as genetic testing becomes more "normalized" it will lead to transformations at the institutional and individual level.

Participant 26 argues that as testing becomes more prevalent even for non-treatable genetic diseases, the epidemiological benefits may paint a picture of how much more common a disease is then was once believed. This in itself may provide enough support to invest further research to search for a cure:

> 7.26 That's a difficult one. Testing for disease when there is no treatment for it has some benefits in the long run because it gives you an idea from an epidemiological point of view as to the extent of the disease, how wide spread it is and of course what is not available today may be available tomorrow and if one finds that a disease is much more common than one thinks that will act as an impetus to find a cure in the long run so it has some benefits but it is sort of a clouded benefit.

The idea of tracking a disease and controlling symptoms through technological devices is quite characteristic of biomedicalization. Participant 29 notes that testing early would allow one to be "able to track the progress of disease and be able to intervene when symptoms are controllable by the technologies and from what we have at the time."

> 7.29 Yes I do. You need an explanation of why? I think information is important to have even though a treatment at that point in time is not available it doesn't mean that it wouldn't become available in the near future and being able to track the progress of disease and be able to intervene when symptoms are controllable by the technologies and from what we have at the time. So yes even if we can't effectively treat the disease we might be able to treat symptoms and at least give the patients an explanation of why certain things would be happening to them. So yes I do think it is important to test for things even if we don't have treatment for them.

There is a some concern within the responses that the oncologists do not believe that it will be possible for a machine to ultimately diagnose a patient since a multitude of factors converge to help with the diagnostic process and no machine will be able to give an all encompassing diagnosis. This is exemplified in participants' 7 and 10 response:

> 13.7 The device would probably give you sufficient indication as to what is wrong but it may not necessarily give you a diagnosis of a disease complex. Specific information for example the level of hemoglobin or the

> level of blood urea or all that information might be quite precise or might be reliable but to diagnose a patient which is a whole syndrome of complicated combination of things I'm not too sure whether the device would do that.
>
> 13.10 I wouldn't be confident at all in having it being the full method of diagnosing. I would be comfortable if the technology were sophisticated enough with appropriate testing for it to serve as a complimentary test to traditional methods of diagnosis, but if it is to be considered to be the only thing I would not accept a patient referral solely on the basis of lab-on chip technology.

This indicates that there still exists a significant role on the part of the oncologists to fully diagnose and treat patients. The general acceptance of the MF LOC device is that of a "complimentary" tool to aid with the "traditional methods of diagnosis" (P10). However, the question remains: to what degree will a genetic testing tool contribute to the process of labeling individuals as "genetically abnormal"? The coding of the human genome has also allowed scientists to biomedicalize DNA by translating it into meaningful bits of information and according to Kay (1999: 224), the "human genome is now generally viewed as an information system, as a book of life written in DNA language or DNA code to be read and edited. Genetic make-up is increasingly becoming the benchmark of health and wellness. Hall (2003) argues that the "gene" is more or so embedded in a socially constructed form of body and health. "The new genetic knowledge is embedded within and extends the biomedical interpretation of health and the body, and continues the narrowing penetration of the medical gaze into the body" (Hall, 2003;151). It was mind boggling how many times the oncologists used the

word “abnormal” when discussing genetics; participants 23, 24 and 5 exemplify this.

> 11.23 I guess I am answering from probably the point of view of chip technology I think that people are embracing sort of genetic testing in areas such as you know I guess from a cancer point of view then you know with some of the known abnormalities particularly breast cancer because that’s probably the area where it is most developed.
>
> 8.24 So the if the patient wants it we will do it if we think that there is, if I think that it is going to change management then I will send the patient for example with BRCA where there is an increased risk of ovarian cancer and I want to see if other members of the family have the abnormality then I will do that because it will influence prognosis if I know that they are at risk of getting breast or ovarian cancer then I would want to know that.
>
> 2.5 Well it has started being used for a lot of DNA micro tests looking at genetic abnormalities and specifically for oncological diseases and hematological diseases to identify the mutations are translocations or abnormalities where we are kind of initiating our focus of those diseases and met those with those conditions and I guess that that will be very helpful in deciding what are the changes causing these ….how they relate to other diseases and whether there are any particular patterns so I think that it will be very helpful.

The extensive use of the term “abnormal” signifies an association with a scientific deterministic philosophy. Engaging in genetic determinism ignores the environmental and social context in which a subject is situated. "This dominant 'genocentric' discourse is producing an embedded knowledge of direct and deterministic relationship between genes and an ever widening spectrum of physiological and psychological conditions" (Lippman, 1999 as cited in Hall, 2003:151). Another metaphor that is found within the genetics discourse is that of a “gene map”. The concept of a gene map is used to help scientists make sense of their actions in decoding the human genome. "The gene map is the central

analytical tool of the new genetic knowledge. It operates both as an information tool in the gathering of data and as a framework for the subsequent interpretation of genetic information and the linking to conditions of health and illness" (Hall, 2003:152).

Haraway uses the term “reification” to describe gene mapping as an avenue to change an abstract idea into a concept that then leads to the process of materialization (Haraway, 1997, as cited in Hall, 2003:158). Hall (2003) warns that biomedicalization of medical practices and reconceptualizing the body within the framework of “genetic health” and the use of diagnostic devices has major costs for the future. Consequences such as over-stressing the health care system if many patients are tested positive for so called “defective” genetic traits. As indicated in the oncologists’ discourse the health care costs would be surmountable especially if individuals had access to MF LOC device as a public commodity.

> 6.10 I think that the impact (on healthcare) would almost crush the public health care system in terms of patient visits because I think that patients if they could self test everyone would do self testing wouldn’t have any knowledge about what the implications would be in terms what a positive test would be nor would they necessarily understand false positives and false negatives and that would lead to a large amount of panic and a large amount of patient visits to their family practitioner and that will overload the system because it can’t coup it will also probably lead to incredible amount of referrals for opinions from oncologists about how to prevent the cancers that might be genetically pre disposed to and the cancer system can’t coup with volume either. I think that it would have a pretty devastating impact on the system overall.

There were a couple responses from the oncologists that recognized the limitation of technology and the output of results. As with participant 23 they did

not reject the technology as legitimate; however, they acknowledge that it is "not a precise science".

> 3.23 Oh I think so because I think it is hard to know what all the results of a lot of the information. I mean with the technology that is there you have the ability to look a genetic testing and its not a precise science. I mean if you have a genetic abnormality then that is clear but I mean you can have risk, you may well carry unknown genetic abnormalities based on family history you can be a carrier. So I don't think that genetic testing necessarily provides you know all of the answers and again I think that discrimination based on those answers is probably not appropriate.

Although the evidence overwhelmingly leans towards a biomedical repertoire this does not mean that the majority of oncologists were in favor of using or introducing the MF LOC device into their practice or society at large. In fact as we will see in the next few quotes the dystopian oriented repertoires were just as strong as the utopian repertoires.

Of those who held a dystopian view of MF LOC technology a reigning theme of skepticism filtered through the responses. "It would benefit if it works. I am obviously skeptical that there is anything out there right now that is even close to being feasible" (14.11). Aligning the technology to science fiction or fantasy occurred through several responses such as with participant 11:

> 9.11 I think that the university has a big role in it because it is still what I call a science fantasy it is still the figment of somebody's imagination with very few exceptions.

Participant 20 was not impressed by the concept of a MF LOC device and blatantly expressed his view:

> 2.20 That sounded like a load of crap to me a very exaggerated claims, very complex journalized load of shit to me. It didn't sound like it was grounded in the particular realities of a specific technological

> development. You have to remember that in terms of application in cancer medicine at the moment I think the way we practice on average in cancer medicine today lags at least twenty years behind state of the art. Those are the realities in terms of diagnostics in the way things are practiced and also in therapeutics. I am a therapeutic radiologist and if you look at my access to pet scanning which is a low technology, I have none and if you look at my ability to apply modern conformal radial therapy I have none. That it is a technology that is ten years old the first one a technology that has been widely available for twenty. So the medicine that we practice today is a best the medicine of 1990. (2.20)

Participant 20 was quite defensive and felt that the explanation of MF LOC technology was “very exaggerated claims”. His response is emotionally charged and does not readily accept the belief that MF LOC devices will used in clinical practices in the near future. P20 emphasized a twenty year gap between research development and application for cancer medicine.

Some of the oncologists who held a utopian view of the potential of MF LOC technology were extremely excited as well as cautious. Participants 25 and 26 are nothing short of exuberant about the MF LOC technology.

> 12.25 Wonderful. Absolutely marvelous so long as they don’t break down often. I am sure that if they are doing that then they can be linked to wireless and can project results and all these other good things at a distance so that people that who might know what was happening could interpret them and make meaningful interventions so I think that would be the gift of it all even if you were just doing CBC’s and liver functions studies you know really easy stuff.
>
> 1.26 Oh definitely we see it everyday you know there are so many different advances we benefit from now that didn’t exist even fifteen years ago and it certainly has led to improvements in health care not only in quality but also being able to manage larger quantity of patients in a shorter period of time.

In many cases as illustrated with participant 25's response the oncologist supported the MF LOC technology, but also made it clear that they are aware of the potential of technology failure, as P25 says, "Absolutely marvelous so long as they don't break down often." Participant 26's response represents the utopian view and credits technology as bettering health care, "there are so many advances we benefit from now that didn't exist even fifteen year s ago". Many of the utopian responses were also contingent on time as the oncologists acknowledged that MF LOC devices may not contribute immediately but rather some time in the future. Participant 31 sums it up nicely by saying "In 2005 not at all, but in 2015 hopefully" (12.31).

Regardless of the timing, the majority of oncologists acknowledged the potential for MF LOC devices to impact and transform medical practices. The support of a biomedical repertoire indicates that the introduction of MF LOC devices will bring with it transformations of medical practices and possibly transformations in other facets of life too.

6.0 CHAPTER SIX: CONCLUSION

In this concluding chapter I will revisit the various modes of knowledge production and recap the findings from the analysis of themes and repertoires. The purpose of this study was to illustrate the need for a more socially and ethically informed governance of transformative technology. To successfully achieve such an institution this thesis argued that it is important to understand where and how knowledge is produced. I also provided an example, by way of interviewing oncologists, to illustrate how various experts/actors can be consulted in order to understand from a broader perspective the potential benefits and concerns that introducing a new technology may have on institutions and individuals.

The thesis that understanding the current forms of scientific knowledge production will allow for a more socially and ethically responsible form of governance to emerge is substantiated through the thematic analysis of the oncologists' responses regarding knowledge production. The question that followed from this thesis was what type of knowledge production are we currently experiencing? I will return now to a brief review of the different models regarding knowledge production.

The characteristics of Mode-2 model of knowledge production as explained by Nowotny, Scott and Gibbons (2001) refers to an open system of knowledge production. This open system requires a new social contract between

society and science. This contract includes a co-evolution of science and society that is contingent upon a dialectical relationship whereby open communications and influence are intermittent between science and society.

Society's impact on science thus leads to a more socially robust form of knowledge production. The public no longer participates solely through representative institutions, but engages and participates more directly by voicing concerns, joining debates, and making consumer conscious decisions.

There is a shift from "reliable knowledge" to "socially robust" knowledge. The fundamental aspects of "reliable" knowledge are intact; however, what has changed is the scope by which knowledge becomes validated. It no longer solely rests on the consensus of "peer groups", but must also pass the inspection of a range of experts and actors. The "socially robust" regime includes the entire scientific community along with the public to participate in the discourse. Scientists are thus encouraged to go out into the "agora" and converse with the public primarily through media avenues on issues regarding scientific knowledge. The public can then "speak back", thus providing an opportunity to renegotiate the scientific endeavors. Science is also no longer a fixed process as the experts are increasingly required to discuss non-scientific issues to a diverse audience.

The role of the university under the description of Mode-2 thesis has also decreased and has been replaced by other institutions that produce knowledge. This is where Etzkowitz and Leydesdorff's (2000) model of the Triple Helix largely differs from Mode-2 model of knowledge production. The Triple Helix model highlights the links between university, academia and industry as ever

increasing, largely in part due to advances in information technology. The university's role in innovation is not diminishing, but rather enhancing and evolving. The government's role has increased which substantiates the evolution of a knowledge production through a trilateral network. The potential economic impact is what drives the movement of scientific knowledge production. So how much a scientific endeavor impacts the economy will determine the amount of resources and attention a project is warranted. The Triple Helix thesis maintains that so long as the university sustains the essential mandate to "educate" it secures its role in the knowledge production process. According to the Triple Helix thesis the relations between the university, industry and government are all vital for supporting the success of a knowledge based society.

As a way to manage the risks associated with developments in scientific knowledge Ravetz (2004) contends that the employment of PNS principles is important. The PNS approach is similar to Mode-2 characteristics in that there is an increased emphasis on public participation and inclusion of an extended expert domain to contribute to the decision-making process regarding the development and application of new technologies. What Ravetz (2004) adds is the application of the precautionary principle in times of uncertainty and when the stakes are high. The participation of public and extended expert communities can be met through focus groups, citizen juries, consensus conferences or stakeholder forums. Ideally, the development of an independent institution to facilitate these processes would help.

No model captures the holistic nature of the current processes by which knowledge is produced. As evident through the oncologists' responses it would seem that the Triple Helix thesis is most supported. However, remnants from the Mode-2 and Mode-1 models also emerged. There was little evidence of the PNS orientation; however, the PNS approach has more to do with an idyllic way to manage risks brought on through developments from scientific knowledge. Post-Normal Science ideology is a call for what should be, rather than a description of what is. Essentially, an amalgamated model of the current perspectives of knowledge production is still best suited.

In building capacity to devise an institution or committee to oversee certain ethical, legal or social implications of emerging technologies it is essential to understand and to seek input of various actors and experts involved in the knowledge production process. The remainder of this conclusion will focus on the second objective of this thesis which was to illuminate the importance of considering who might use the technology and how it might impact institutional practices and certain groups of people. This exemplifies one way of encouraging the scientists and other experts to discuss non-scientific issues. The first question was what insight might oncologists provide in guiding policy surrounding the use of MF LOC devices?

Many of the oncologists cautioned that the commercialization of MF LOC devices for self-testing would lead to devastating consequences on part of the individual and on the health care system. The diagnosis process involves more than finding a genetic link. According to several oncologists, the patients are

diagnosed based on multiple factors including symptomatic behavior. The health care system is at risk of becoming bombarded by anxious individuals who will want to know what their self-administered test results mean even if they are symptom free, thus leading towards Clark et al.'s (2003) concept of the "worried well".

The opportunity for a new type of genetic discrimination to emerge in society has some oncologists feeling uneasy. The interesting finding that emerged out of the oncologists' discourse on discrimination was that even when discussing genetic discrimination in the work force the general response from the oncologist was that it is not fair to include genetic information in the employee selection process, and laws need to be in place to prevent genetic discrimination. However, when it came to the use of genetic information regarding insurance premiums there was a significant increase in the amount of responses that did not outright oppose discriminating based on genetic profiles.

I speculated that the reason for the difference in attitude regarding genetic discrimination between employment selection and insurance premiums lies in the value distribution between livelihood and sense of security. Applying genetic discrimination against one's livelihood is far more detrimental than applying it against one's sense of security. A livelihood represents a "need", purchasing health insurance is a "desire".

In determining whether or not current methods of storing patients' health information were sufficient the doctors' responses were mixed. A key message was that the electronic storage of data was sufficient, but it is not being

implemented properly. Meaning that the opportunity for accessing patient information and breeching confidentiality is still perceived as high. The electronic storage of data transcends physical barriers and thus outside threats from expert computer hackers become a reality. Ensuring that the best possible software is installed to prevent systems hackers is an obvious answer, as well as limiting the number of people who know codes that enable access to patient files.

Insights that the oncologists provide regarding individual and institutional impacts of commercialization, heightened potential for genetic discrimination and the need for more secure data storage systems can help to inform policy and decision makers of the potential transformations that MF LOC devices will have on society, thus contributing to a more ethical, legal and socially informed governance of MF LOC devices.

The second question to the second thesis statement attempted to unlock the use of language and repertoires to understand how the use of scientific and biomedical repertoires serve to shape the oncologists' perceptions and concerns regarding acceptance and application of MF LOC devices. Knowing that the oncologists work within a perspective of scientific and biomedical repertoires has provided insight into how oncologists fashion their beliefs and thus how they came to construct their understanding and concerns regarding MF LOC technology.

As indicated earlier, the educational experiences of studying and working within the area of medical oncology gives rise to a shared scientific repertoire. The oncologists make sense and base their acceptance of MF LOC technology on

measures of validity and reliability. These two concepts adhere to positivist notions and are characteristic of a scientific ideology. Trust is accomplished through evidence of validity and reliability. The concept of time and comparison of performance emerge as critical factors within the scientific repertoire. Many of the oncologists are skeptical of the technology today, but believe they would change their mind in years to come as "time" would allow for sufficient measures of reliability and validity. The comparison component stresses the importance of demonstrating similar or improved techniques from the traditional forms of testing. The requirement of "scientific proof" is vital and thus the oncologists' assessment of the usefulness of the MF LOC technology is grounded within a scientific repertoire.

Another common element that supports the use of a scientific repertoire was the underlying notion that the oncologists perceived themselves as an "expert" and therefore the beholder of knowledge. Not only does the oncologist possess the knowledge to interpret the test results, but they also can better manage the patients' distress when dealing with the information by providing the patient with information to help prevent or lessen the symptoms of the disease. Providing this information will likely decrease the patients' feelings of hopelessness. Providing the patient with something to do to help control the disease can lead to patient empowerment.

The oncologists' discourse also reflects a biomedical repertoire in that there is an increasing awareness of the convergence of technology and information systems that work to transform the practices in medical institutions

and the experiences of the patient. The shift from medicalization to biomedicalization is truly a shift from control to transformation (Clarke et al., 2003). Biomedicalization is an integration of natural science and computer technology with the purpose to transform medical practices (Clarke et al., 2003). The development and application of MF LOC technology is a good illustrations of what the concept of biomedicalization seeks to understand.

The evidence of a biomedical repertoire within the oncologists' responses is congruent with the characteristics of the biomedicalization paradigm. Many oncologists emphasized the importance of seeking professional help when choosing to carry out genetic testing. Although most oncologists do not agree with commercializing MF LOC devices for self-testing, they do recognize the shift of responsibility onto the patient to take control of their own health. As genetic testing becomes the norm the prevalence of commoditizing health will also increase and more people will be directed to take control of their health by employing preventative therapies. Information garnered through genetic testing not only affects the actions that an individual may take on their own health, but also may impact decisions regarding family planning. The notions of tracking and controlling diseases also supported the emergence of a biomedical repertoire. As some oncologists made reference to the importance of testing for incurable diseases so that epidemiological studies could flourish with the hope of finding a cure.

There is not a full submission of relegating the MF LOC device into the biomedicalization paradigm. The oncologists maintain that the MF LOC device is

a “complimentary” tool meant to help with “traditional methods of diagnosis”. In comparing the utopian and dystopian repertoires it is evident that the MF LOC device will not be readily accepted by all; but the majority does contend that the potential is there for the device to significantly enhance and transform practices at the institutional and individual level.

Understanding where and how knowledge is produced will help inform the decision makers of whom to consult with in order to facilitate a broader understanding of the ethical, legal and social implications of introducing a new technology. Future research in this area should include an account of the perceptions of other groups of people who may be affected by MF LOC technology. It would be ideal to assess the perceptions and concerns of other groups of people whom do not construct their meanings through a scientific or biomedical repertoire.

The quest to continually enhance our existence through technological advances will not stop. It is imperative that insightful guidance co-develops to shape transformative technology trajectories. Not unlike Beasely, the fire-creating early hominid, we need to continually assess our situation and strategically align best practices in order to minimize harm and promote benefit. The development of smaller, quicker and cheaper genetic testing devices will undoubtedly affect our current conceptualizations of humanity and health. Further understanding of the social impacts is needed to better guide the introduction of MF LOC devices into society.

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APPENDIX ONE: QUESTIONNARE

1. In general, do you believe that technological advances contribute positively to health care?

2. What impacts do you see lab-on-chip technology having on oncologists, lab technicians, and patients?

3. There are currently no laws in Canada preventing companies from discriminating based on genetic test results. Would you be worried about discrimination if employers had access to results?

4. Insurance companies are always looking for ways to reduce risk and will increase premiums for high-risk clients. What role do you think lab-on-chip devices may play in setting premiums for clients? Is it fair for insurance companies to use these technologies?

5. Do you believe current methods of storing data are sufficient for protecting patient confidentiality?

6. What do you think would be the impact on health care if lab-on-chip devices were commercialized and individuals had access to self testing for cancers and other diseases?

7. Do you think diseases should be tested for when there are no effective treatments available?

8. Under what circumstances do you advise your patients to seek genetic counseling?

9. What role do you think government, industry and universities should have in developing lab-on-chip technology?

10. Who should be responsible for ensuring reliability and validity of this technology?

11. In your view, how fully do you think the research community has embraced this technology?

12. How useful do you think lab-on-chip technology could be for individuals in remote locations, like Northern Canada, and developing countries?

13. How confident would you be in trusting a lab-on-chip device to detect and diagnose patients?

14. Would this technology benefit or hinder your practice as an oncologist?

Profile

The interview is now complete. Finally, I would like to ask a few questions for demographic purposes.

Gender (ask only if necessary): Male_____ Female_____

What is your age in years_____. If unwilling to provide, how about the following range?

- 26-35
- 36-45
- 46-55
- 56-65
- 66-75
- 76+

About how long have you been practicing as an oncologist in years?_____If unwilling to provide, how about the following range?

- 1-5
- 6-10
- 11-19
- 20 or more

What Province do you live in?

Closing

Thank-you for taking the time to participate in this interview. We appreciate your time and value your opinions. If you are interested in following our project, please do so by accessing our website at: www.music.net.ca. If you have any questions or concerns, please contact the lead researcher, Dr. Michael Mehta, of the University of Saskatchewan at (306) 966-6917, or the Office of Research Services at the University of Saskatchewan at (306) 966-8576.

Thank-you
Good-bye.

APPENDIX TWO: INTERVIEW CONSENT FORM

I am inviting you to take part in a research project, being led by Dr. Michael Mehta, of the University of Saskatchewan. The proposed research has been approved on ethical grounds by the University of Saskatchewan Behavioral Research and Ethics Board.

This project is entitled *Novel Platforms for Genetic Analysis*. This particular project is part of a larger project with scientific and medical researchers at the University of Alberta and University of Calgary. The overall objective of this project is to "assess how Canadians understand issues related to health information, genetic testing, and privacy" and to assess how medical practitioners (oncologists) in Canada perceive the use of microfluidic platform technologies for clinical applications.

You are being asked to participate in the interview portion of the study. The interview will last approximately fifteen minutes. The interview recordings will be transcribed word for word, and the recordings and transcripts will be securely stored by Dr. Mehta at the University of Saskatchewan (in a locked filing cabinet in Room 1015 Arts) for a minimum of five years following the end of the study period. You may choose to withdraw your participation at any time, and your withdrawal will not reflect unfavourably upon you in any way.

Should you agree to participate, your responses will be kept confidential. Names and other identifying information will be removed from all publicly released data, and your identity will not be disclosed unless otherwise requested. If any direct quotations are used from your transcript, they will be attributed to a pseudonym. Results from this study may be published in academic journals and may be presented at various conferences.

If you have any questions or concerns regarding the study, you may discuss these with the researcher or contact Dr. Michael Mehta of the Department of Sociology at the University of Saskatchewan at 306-966-6917. Questions regarding your rights as a participant may be directed to the Office of Research Services at 306-966-2084.

APPENDIX THREE: DESCRIPTION OF ONCOLOGISTS CITED

Particpant no.	Sex	Age	Years in practice	Province
1	M	64	33	Saskatchwan
2	F	41	7	Saskatchwan
3	M	31	1	Saskatchwan
4	M	38	4	Saskatchwan
5	M	40	5	Saskatchwan
6	M	49	20	Saskatchwan
7	M	53	16	Saskatchwan
8	M	59	22	Saskatchwan
9	M	56	25	Saskatchwan
10	M	35	5	Alberta
11	M	56-65	27	Alberta
12	M	33	2	Alberta
13	M	44	11	Alberta
14	F	46-55	15	Alberta
16	F	36	7	Alberta
17	M	57	29	Alberta
19	M	43	10	Ontario
20	M	56	25	Ontario
23	M	39	10	Ontario
24	M	53	21	Manitoba
26	M	60-65	26	British Columbia
29	M	32	3	Ontario
31	F	37	8	Nova Scotia