

Overcoming the Obstacles: A Collaborative Approach to Informed Consent in Prenatal Genetic Screening

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“The social distance built into current ways of looking at the human body — the view of an objective scientist looking at another bodily object that is clearly separate and distinct — will be expanded to include a new type of social connectedness, where two human beings will be able to share their commonly felt experiences at their social membrane. In the new clinic, immunization from the emotional experiences of one’s fellow man will no longer be seen as either a vital necessity or a particularly virtuous aspect of scientific objectivity.”¹

The Human Genome Project has brought with it incredible and rapid advances in the field of genetics, but such praise must be approached with caution. Undoubtedly, genetics is receiving increasing attention as the ability to detect genetic predispositions has increased and continues to do so. The amount of information that is available, or rather that seems to be available, to physicians is proliferating, along with the proliferation of technology. And the public is beginning to expect and require that such information be provided to them in the decision-making process in the health care arena. At the same time, people have come to expect that, with the advances in both genetics and medical science, the children they bear should be as close to “normal” as scientifically possible to predict. This has resulted in wrongful birth and wrongful life lawsuits, which fall under claims of medical malpractice, a subset of negligence law.² A wrongful life claim is advanced where the disabled child attempts to show that, had the proper procedure been provided, or had the “abnormality” been detected, the pregnancy would not have been initiated or terminated. A wrongful birth claim, on the other hand, exists where the claim is that the health care provider deprived the parent, or parents of a child, of accurate information which would have led them to refrain from having the child. Both claims stem from a failure to receive adequate information or “informed consent” during pregnancy. With the proliferation of potential information engendered by the mapping of the human genome, what now constitutes “adequate information?”

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¹Neil Sharpe, “Reinventing the Wheel?: Informed Consent and Genetic Testing for Breast Cancer, Cystic Fibrosis, and Huntington Disease” (1996-1997) 22 *Queen’s L.J.* 389 at 440.

²See for example *Zhang v. Kan*, 2003 BCSC 5, [2003] B.C.J. No. 164; *Raina v. Shaw*, 2006 BCSC 832, [2006] B.C.J. No. 1219; *Cruz v. Robins*, [2006] O.J. No. 3086. 150 A.C.W.S. (3d) 236 (Ont. Sup. Ct. J.).

The informed decision-making process may be complicated further by the vast knowledge that the progress of genetics seems to provide. The area of genetics is complex and offers the potential for so much more information than may actually be required or available to make an informed decision about medical care. With new technologies, new questions must be addressed, and old standards may have to be re-evaluated. In an era of constantly developing genetic techniques and prenatal genetic screening and diagnostic testing, are the present standards of informed consent adequate? Does prenatal screening differ from other medical procedures? This paper will attempt to address these questions. In the first part, I will provide an overview of prenatal genetic screening and diagnosis in Canada. The second part will examine the obstacles to fully informed consent for prenatal screening and diagnosis and consider whether the present test for informed consent can still be applicable in light of these obstacles. The third section will examine the obstacles to achieving patient autonomy in decision-making, as an objective of informed consent, in pregnancy and genetics. If the goal of informed consent is patient autonomy in decision-making, then how can this goal be achieved in the area of prenatal screening and diagnosis? The informational, social, and psychological obstacles to adequate informed consent for prenatal genetic screening will be considered. The final part of this paper will consider how a patient's reproductive and decisional autonomy can be best fulfilled having regard to the challenges to informed consent presented by prenatal genetic screening and diagnosis. The present standard for informed consent, coupled with the principle of non-directiveness, is inadequate given the dynamic nature of genetics, the uniqueness of pregnancy, and the practicalities of a medical practice. A collaborative approach to informed consent in the area of prenatal genetic screening, in which the physician and patient collaboratively decide the best course of action, would contribute to a more completely informed and autonomous patient as decision-maker.

I. Overview of Prenatal Genetic Screening and Diagnosis in Canada

Prenatal screening and diagnosis takes place after a woman has become pregnant. It involves many screening and testing techniques, some more invasive than others, to detect whether or not the fetus is "healthy." Non-invasive techniques normally include screening for maternal age and family history of disease or disability. A prenatal ultrasound is routinely carried out, especially on women over the age of 35 who are considered to have a "high risk" of having a baby with Downs Syndrome or who have other children with disabilities, or a family history of disability or "abnormality." Maternal Serum Screening [MSS] is becoming a more common screening technique as well.³

³The Roeher Institute, *The Construction of Disability and Risk in Genetic Counseling Discourse* (January 2002) 22, online: Centres of excellence for Women's Health <<http://www.cewh-cesf.ca/PDF/nnewh/construction-disability.pdf>>.

If a genetic predisposition to a disease or disability is detected at the initial screening stage, then more invasive tests or 'diagnostic testing' is required, including amniocentesis and Chorionic Villus Sampling [CVS]. Amniocentesis is performed after 14 weeks of gestation, though results are only available one to three weeks after the test. At this stage, termination of pregnancy entails a greater risk to the woman both physically and psychologically, and is not available in all parts of Canada.⁴ The risks of the procedure are low and the results are highly reliable. CVS is performed between ten and eleven weeks of gestation. This test is highly accurate and yields earlier results, however, there is a risk of spontaneous pregnancy loss.⁵ Other testing techniques include cordocentesis and foetal tissue sampling. Testing can be used to confirm a clinical diagnosis, to detect a genetic predisposition to a disease so that preventative measures can be taken or to help a patient prepare for the future, or to give parents the option of terminating a pregnancy or beginning treatment as early as possible.⁶

The Canadian College of Medical Geneticists [CCMG] and the Society of Obstetricians and Gynaecologists of Canada [SOGC] recommend that invasive prenatal testing should not be routinely offered to all women.⁷ Some commentators argue that prenatal screening and diagnosis have become routine in obstetrical care.⁸ Presently, two Canadian provinces, Manitoba and Ontario, have government support and widespread proliferation of MSS. In Ontario, it is recommended that all pregnant women be offered MSS testing and genetic counseling. In fact, 88 percent of family physicians, obstetricians and midwives providing antenatal care or attending births, who responded to the survey in question, reported that they offered the test to all pregnant women on a routine basis.⁹ In Manitoba, only 60 percent of respondents offered the test to all pregnant women, though in British Columbia, the situation appears to be similar to that in Ontario.¹⁰

While some genetic tests are covered through provincial health insurance (and thus, available to the general public), many tests are still in the clinical research

⁴Roxanne Mykitiuk, Stephanie Turnham & Mireille Lacroix, "Prenatal Diagnosis and Pre-implantation Genetic Diagnosis: Legal and Ethical Issues" in Neil F. Sharpe & Ron Carter, eds., *Genetic Testing: Care, Consent and Liability* (New York: John Wiley and Sons) [forthcoming].

⁵*Ibid.*

⁶Michael M. Burgess, Claude M. Laberge, & Bartha Maria Knoppers, "Bioethics for Clinicians: 14. Ethics and Genetics in Medicine" (1998) 158:10 CMAJ 1309; see also John A. Robertson, "Procreative Liberty in the Era of Genomics" (2003) 29 Am. J. L. & Med. 439.

⁷Society of Obstetricians and Gynaecologists of Canada & Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists, *Genetic Indications for Prenatal Diagnosis* (SOGC Clinical Practice Guidelines, No. 105, July 2001) at 2. This document reviews the circumstances under which such testing should be undertaken.

⁸Sonia Mateau Suter, "The Routinization of Prenatal Testing" (2002) 28 Am J. L. & Med. 233.

⁹*Supra* note 3 at 28.

¹⁰*Ibid.* at 29. However, the Alberta Public Health Association reports that in Alberta, only 24% of physicians are routinely offering maternal screening to their patients. See Alberta Public Health Association, *Support For A Provincially Funded And Centrally Organized Maternal Serum Screening Program*, online: Alberta Public Health Association <<http://www.apha.ab.ca/Resolutions/2004res01.html>>.

trial stage and access is limited. In Ontario, genetic services are currently funded under the Ontario Health Insurance Plan [OHIP].¹¹ For example, all services provided at Toronto's Mount Sinai hospital are funded, which includes genetic counseling, nuchal translucency and first trimester biochemical screening for Down Syndrome, MSS, amniocentesis, CVS, detailed ultrasound, and referrals to specialists when indicated.¹² Access to these tests would presumably be limited based on clinical indications.

There is currently no legislation to regulate either prenatal diagnosis [PND] or prenatal screening. The *Assisted Human Reproduction Act* [AHRA],¹³ has only limited application. The applicable provisions relate to restrictions on selection and embryonic manipulation. For example, sex selection is prohibited, but there is no prohibition against termination of pregnancy after discovery of a genetic predisposition to a disability. In addition, the AHRA does not distinguish between clinical reproductive uses and research uses of reproductive materials. As such, the provisions of the AHRA are of limited use post-conception and thus, to prenatal genetic screening.

Because genetic testing carries the risk of social harm due to discrimination, explicit informed consent to a genetic test is required. There is no standard of care for clinical genetic practice, and the test and counseling programs that are offered vary among provinces.¹⁴ Generally, geneticists suggest that obstetricians offer diagnostic prenatal tests when the risk of a serious genetic condition outweighs the risk of spontaneous miscarriage caused by amniocentesis or CVS. Policy guidelines and recommendations, often established for specific diseases with genetic components, have as their most common theme the requirement for pre and post-test genetic counseling. Consent and confidentiality require a thorough discussion and realistic planning prior to conducting the tests. These themes are common to the guidelines and policies established for genetic counseling.

The SOGC and the CCMG jointly issued Clinical Practice Guidelines for Prenatal Diagnosis in August of 1998.¹⁵ These guidelines apply to the offer of invasive PND techniques, such as CVS and amniocentesis, as well as non-invasive techniques, such as MSS, ultrasound diagnosis and screening. The SOGC and CCMG recommend that health care providers know current indications for testing

¹¹ See Schedule of Benefits for Physician Services under the *Health Insurance Act*, effective October 1, 2005; *Health Insurance Act*, R.S.O. 1990, c. H.6.

¹² Mount Sinai Hospital, *Frequently Asked Questions: Prenatal Diagnosis and Medical Genetics*, online: Mount Sinai Hospital <<http://www.mtsinai.on.ca/pdmg/FAQ/default.htm>>.

¹³ *Assisted Human Reproduction Act*, S.C. 2004, c. 2.

¹⁴ *Ibid.*

¹⁵ Society of Obstetricians and Gynaecologists of Canada & Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists, *Practice Guidelines for Health Care Providers Involved in Prenatal Screening and Diagnosis* (Policy Statement No. 75, August 1998); see also *supra* note 7; Society of Obstetricians and Gynaecologists of Canada & Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists, *Canadian Guidelines for Prenatal Diagnosis: Genetic Indications for Prenatal Diagnosis* (SOGC Clinical Practice Guidelines, No. 105, June 2001).

and types of prenatal diagnostic and screening procedures. Prenatal genetic testing, where appropriate, should be offered after non-directive counseling about the advantages and disadvantages and implications of the procedures, though it should be entirely the woman's choice as to whether or not to undergo testing. If an abnormality is detected, a woman's decision about the continuation or termination of pregnancy should be fully supported by the physician.

In April 2000, the Ontario Ministry of Health and Long-Term Care created the Provincial Advisory Committee on New Predictive Genetic Technologies.¹⁶ The Committee recommended that a Permanent Advisory Committee on Genetics be formed to evaluate new genetic tests on a continuous basis, facilitate their implementation and provide advice on educational, legal, and ethical issues relating to genetics. Such a committee has yet to be formed. In addition, the Guidelines Advisory Committee [GAC] is empowered by the Ministry of Health and Long-Term Care and the Ontario Medical Association, to formulate guidelines which are endorsed after an extensive review. The ICSI Guidelines for Routine Prenatal Care is the only relevant guideline.¹⁷ This guideline recommends that each pregnant patient or patient planning a pregnancy receive a comprehensive risk assessment including risks for relevant genetic disorders.¹⁸ It also contains a prenatal genetic risk assessment form in order to aid the physician in evaluating whether risk factors are present and further, more invasive, testing should be ordered. In British Columbia, guidelines and protocols are developed under the direction of the Guidelines and Protocols Advisory Committee [GPAC], jointly sponsored by the British Columbia Medical Association and the Ministry of Health. There is no specific guideline or policy produced by the GPAC regarding prenatal diagnosis or genetic counseling.

As a result of this lack of regulation, the common law provides the main source of guidance for physicians as to the contents of adequately informing patients about the availability and results of prenatal genetic tests, though the SOGC and CCMG guidelines provide some direction. Even where guidelines exist in the form of standards set by professional bodies, they may be considered, but are not absolute evidence of an adequate standard of care.¹⁹

¹⁶ Ontario, Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future* (November 30, 2001).

¹⁷ Institute for Clinical Systems Improvement, *Health Care Guideline: Routine Prenatal Care*, 8th ed. (July 2004).

¹⁸ *Ibid.* at 3.

¹⁹ *Ter Neuzen v. Korn*, [1995] 3 S.C.R. 674 at para. 41, 127 D.L.R. (4th) 577, [*Ter Neuzen*]. This standard remains today: see for example, *Emmonds v. Makarewicz*, 2000 BCCA 573, [2000] B.C.J. No. 2136 at para. 17 (QL); *Edwards (Guardian ad litem of) v. Moran*, 2003 BCCA 687, [2003] B.C.J. No. 2809 at para. 13 (QL).

II. Obstacles to Fully Informed Consent in Genetics and Pregnancy

Medical interventions can only be undertaken with the full and informed consent of the patient, in order to protect patient autonomy.²⁰ Some have suggested that the term “informed choice” or “informed decision-making” is a more appropriate manner of discussing the information required to be given to patients before medical intervention, as it does not carry the implication that the patient is passively consenting to the physician’s recommendations.²¹ For ease of reference, I will refer to the more commonly used term “informed consent.” Informed consent in the context of pregnancy will be fulfilled by a physician where the patient is informed of all material information concerning the existing or proposed pregnancy, including procedures which will test for possible fetal abnormality. Failure to do so constitutes negligence. For example, in *R.H. v. Hunter*,²² the parents of two children born with Duchene muscular dystrophy were successful in their claim that their physicians were negligent in failing to provide or to refer them to genetic counseling. In *Arndt v. Smith*,²³ the parents of a child with Downs Syndrome claimed the doctor was negligent for failing to inform them of the availability of prenatal genetic testing. As a result, informing patients of the availability of prenatal testing is the minimum legal and moral obligation required by physicians.

Both wrongful life and wrongful birth lawsuits fall under claims of medical malpractice, a subset of negligence law. These claims require a finding that the physician failed to adequately inform the patient of the risks or other material aspects of the treatment, and that a reasonable person in the position of the patient would have made a different decision with respect to treatment if he or she had been properly informed.²⁴ The parent must show that the physician or health care provider acted negligently and that negligence caused the harm, that is, the birth of the disabled child as the injury for which damages should be awarded. In order to prove negligence, the claimant must show that a duty of care was owed to the patient and that it was breached; that the breach of this duty of care caused the harm complained of; and that this resulted in compensable damages which could put the claimant in the position he or she would have been in had the damage not occurred, or as close as money can reasonably do so.

The duty of care that a physician owes to a patient is well established and automatically stems from the doctor-patient relationship.²⁵ Physicians have a legal

²⁰ Bernard M. Dickens, “Informed Consent” in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Markham: Butterworths Canada, 2002) at 155.

²¹ *Supra* note 4; See also Rebecca J. Cook, Bernard M. Dickens & Mahmoud F. Fathalla, *Reproductive Health and Human Rights: integrating medicine, ethics and law* (Oxford: Clarendon Press, 2003) at 109.

²² (1996), 32 C.C.L.T. (2d) 44, [1996] O.J. No. 4477 (Ont Ct. J. (Gen. Div.)).

²³ [1997] 2 S.C.R. 539, 148 D.L.R. (4th) 48.

²⁴ Erin Nelson & Gerald Robertson, “Liability for Wrongful Birth and Wrongful Life” (2001) 2:2 ISUMA: Canadian Journal of Policy Research 102.

²⁵ *Supra* note 4.

obligation to disclose all material risks arising from the treatment of a patient in order for that patient to make an informed decision regarding the treatment in question. Failure to inform a patient of all material risks could result in a negligence claim and, in fact, the Supreme Court of Canada has held that a “physicians’ failure to advise constitutes a failure to take an action required by law. A finding of breach is a finding that the physician should have done something which he or she negligently failed to do.”²⁶ A wrongful life claim is advanced where the disabled child attempts to show that, had the proper procedure been provided, or had the “abnormality” been detected, the pregnancy would have been terminated. To date, no Canadian court has recognized a wrongful life claim, though the courts may be more willing to consider these on a case-by-case basis.²⁷ A wrongful birth claim, on the other hand, exists where the claim is that the health care provider deprived the parent or parents of a child of accurate information which would have led them to refrain from having the child. Both of these claims raise as primary concerns, questions about the adequacy or “materiality” of the information provided. In the case of genetic information obtained through prenatal screening, it is difficult to determine both what is material and what to disclose to each particular patient.

(i) Obstacles to Full Disclosure

Pursuant to *Reibl v. Hughes*, the standard of disclosure for physicians is one of full disclosure of all “material, special or unusual risk.”²⁸ I will refer to this as the materiality requirement. The materiality requirement is tempered by requiring a consideration of what a reasonable person would want to know in the same circumstances as the patient, including any “special considerations affecting the particular patient.”²⁹ As a result, this “modified objective test” requires the physician to initially consider what a reasonable person in the position of the patient would want to know, and then inquire further to establish whether there are any other circumstances surrounding the patient’s life, family, or beliefs that may require providing additional information relevant to this particular patient. Yet the inquiry should not become so specific as to become a subjective standard, as this approach was rejected in *Reibl v. Hughes*.³⁰

²⁶ *Supra* note 23.

²⁷ See *Paxton v. Ramji*, [2006] O.J. No. 1179 at para. 165, 146 A.C.W.S. (3d) 913 (QL) (“I accept that a claim properly characterized as a “wrongful life” claim fails in Ontario as the cause of action is not and should not be recognized for the very reasons first enunciated: How can we say abnormal existence is worse than none at all and if we could, however could the compensation be measured?”). But see also *Bovindton v. Hergott*, [2006] O.J. No. 3594, 151 A.C.W.S. (3d) 418 (Ont. Sup. Ct. J.) (QL) in which the Ontario Superior Court of Justice dismissed a motion by the physician for summary dismissal of the plaintiff’s claim for wrongful life for failure to disclose a cause of action. Justice G.I. Pardu stated at para. 18: “While this claim is novel and complex, the legal issues have not been fully settled, and in my view this matter should proceed to trial.”

²⁸ *Reibl v. Hughes*, [1980], 2 S.C.R. 880, 114 D.L.R. (3d) 1. Followed in *Arndt v. Smith*, *supra* note 23.

²⁹ *Ibid.*

³⁰ *Ibid.* at para. 62.

In the case of a wrongful birth action, it must be proven that the physician's legal obligation to inform patients of the availability of prenatal testing³¹ was breached or that there was a failure to give information arising from a prenatal test. At first, this seems like a relatively straightforward requirement. Yet in the case of genetic information, it is not so simple. First, due to a growing public demand for genetic services and an inadequate supply of qualified geneticists and genetic counselors, many of the predictive genetic tests carried out in the process of prenatal genetic screening and testing,³² will be performed by primary care physicians or obstetrician-gynecologists, such that these procedures have entered the domain of routine prenatal care.³³ The standard that a physician will be held to under these circumstances is that of a specialist in genetics, since he or she is essentially providing the services of a specialist.³⁴ As such, the obstetrician-gynecologist who provides genetic testing or screening services may be held to the higher specialized standard of care for medical genetics.³⁵ There is the danger that the non-specialist physician providing genetic testing information to patients lacks sufficient knowledge about both the technology in question and the results of the tests.³⁶ Timothy Caulfield notes:

Malpractice suits in this area are inevitable because physicians are unprepared for the onslaught of genetic information. Medical schools do not emphasize the teaching of genetics, and many practicing physicians have an inadequate grasp of genetics. General practitioners, in particular may find themselves facing liability for failure to provide genetic information.³⁷

Likewise, the interpretation of genetic tests is fraught with difficulty. The tests may be inaccurate because the technology used lacks sensitivity or specificity for the condition.³⁸ Human error in reading results may also create false positives or negatives, whether the error results from bias, inexperience, or incompetence. Even a genuine positive test result should be considered with caution because the presence of the disease or abnormal genetic trait does not necessarily mean that the individual will ever develop the disease.³⁹ Prenatal genetic screening and diagnostic

³¹ *Arndt v. Smith*, *supra* note 23; see also *R.H. v. Hunter*, *supra* note 22.

³² *Supra* note 1 at 432.

³³ *Supra* note 8 at 245.

³⁴ *Ter Neuzen*, *supra* note 19 at para. 33.

³⁵ Neil F. Sharpe, "Genetic Screening and Testing in Canada: A Model Duty of Care" (1996) 4 *Health L.J.* 119 at 124.

³⁶ Timothy A. Caulfield, "The Allocation of Genetic Services: Economics, Expectations, Ethics and the Law" (1995) 3 *Health L.J.* 213 at 226.

³⁷ *Ibid.* at 226 (quoting Lori B. Andrews, "Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks" (1992) 29 *Houston L. Rev.* 149 at 162). For examples of such malpractice suits, see *supra* note 2.

³⁸ Julia Walsh, "Reproductive Rights and the Human Genome Project" (1994-1995) 4 *S. Cal. Rev. L. & Women's Stud.* 145; see also Matthew J. McQueen, "Some Ethical and Design Challenges of Screening Programs and Screening Tests" (2002) 315:1-2 *Clinica Chimica Acta* 41-48.

³⁹ *Ibid.*

testing offers some valuable information but not the complete predictive picture many patients believe, as even a couple who receives good news from a prenatal genetic test still risks a 3-5 percent chance of birth defects.⁴⁰ The rapid increase in technology means that a growing amount of information is available for disclosure. As a result, physicians may themselves have difficulty in determining what is material information, due not only to their lack of knowledge about the information, but also the quality of the information they receive.

(ii) Obstacles to Understanding

The materiality requirement is further complicated by patient difficulty in understanding the information they receive either prior to or after prenatal genetic screening or testing. Prior to testing, many women are not aware of the full extent of genetic information that can be revealed, or even that ultrasound can detect fetal abnormalities.⁴¹ In addition, they may not be aware that further more invasive diagnostic testing may be required if an abnormality is detected through screening. It is clearly difficult to comprehend the variety of different testing and screening procedures, the amount of abnormalities that may be detected, the sophisticated nature of genetics, and the reliance on probabilities rather than certainties.⁴² Discussions about many disorders will require that the patient become almost “entirely dependent on their counselors [or physicians acting as counselors] for information about disabilities and may have difficulty imagining the various possibilities and options.”⁴³ Further, the presence of a genetic marker may not necessarily be a health concern, as not all individuals with a genetic predisposition to a given disease will develop that disease.⁴⁴ Some traits may be associated with lifestyle or quality of life impairing conditions which have not traditionally been considered diseases. Yet people rely on this medical information as the most potent knowledge one could have about the fetus.

This raises concerns about the detrimental impact of information overload on a patient’s ability to understand the process and to make an informed choice. In addition to disclosing the usual genetic counseling information, such as information about the possible disease, the patient’s risk, the testing options, the limitations and accuracy of the test and possible testing outcomes, physicians must also discuss the social and psychological implications.⁴⁵ Whether discussing genetic information

⁴⁰ *Supra* note 8 at 264.

⁴¹ *Supra* note 4.

⁴² *Ibid.*

⁴³ Canada, Royal Commission on New Reproductive Technologies. *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services Canada, 1993).

⁴⁴ Roxanne Mykitiuk & Steven Penney, “Screening for ‘Deficits’: The Legal and Ethical Implications of Genetic Screening and Testing to Reduce Health Care Budgets” (1995) 3 *Health L. J.* 235 at 255; see also Jennifer H. Yen, “Is My Baby ‘Defective’? Fetal Genetic Testing as Part of a Public Health Care Plan” (2003) 36 *Suffolk U. L. Rev.* 391.

⁴⁵ *Supra* note 8 at 239.

prior to testing, or communicating test results to a couple, psychological responses vary on a case-by-case basis but may include depression, anxiety, shock, shame, and guilt.⁴⁶ Whether the physician can appropriately respond to the patient's psychological condition can either aid in alleviating these symptoms or contribute to them. If the psychological state is not correctly understood, this could "have a negative impact on comprehension and retention of genetic information."⁴⁷ Where the physician feels that the information will be psychologically detrimental to the patient, effectively becoming "counter-therapeutic, dysfunctional or distorting for the specific patient," that information may be legally withheld under the therapeutic privilege.⁴⁸ In *Hopp v. Lepp*, the Supreme Court of Canada recognized that therapeutic privilege can be invoked when a patient will likely respond emotionally to the information.⁴⁹ In prenatal screening and testing, an emotional response is almost a certainty, however, the severity of that response must be evaluated by the physician before information can be withheld. But, a physician may only withhold such information without legal ramification if it is perceived that the psychological state of a patient about to receive the results of a prenatal test is "of an exceptional order if not actually pathological."⁵⁰ It is not inconceivable that this high threshold may be met in the case of prenatal genetic screening, though each case must be examined on its own facts.

The physician not only has a duty to understand the psychological state and respond accordingly, but also has a duty to ensure that the information is properly grasped. In *Ciarlariello v. Schacter*,⁵¹ the Supreme Court of Canada held that "it is appropriate that the burden should be placed on the doctor to show that the patient comprehended the explanation and instructions given."⁵² Moreover, physicians must ensure that the patient understands, especially when the patient has difficulty with language or the technical terms physicians use.⁵³ This is an onerous obligation since, as shown above, genetic information is so complex in nature.

Genetic counseling was designed to manage the delivery of complex information surrounding issues including abortion and lifestyle changes. It is supposed to involve detailed disclosure and supportive discussion designed to help patients understand these issues and duties to family members. Genetic counseling is an

⁴⁶ *Supra* note 35 at 126.

⁴⁷ *Ibid.* at 128.

⁴⁸ *Supra* note 20 at 151.

⁴⁹ *Hopp v. Lepp* [1980] 2 S.C.R. 192, 112 D.L.R. (3d) 67 at 77 [*Hopp* cited to D.L.R.].

⁵⁰ *Supra* note 20 at 152.

⁵¹ *Ciarlariello v. Schacter*, [1993] 2 S.C.R. 119, 100 D.L.R. (4th) 609. Some have questioned this standard as unrealistic. See Ellen I. Picard & Gerald B. Robertson, *Legal Liability of doctors and hospitals in Canada*, 3d ed. (Toronto: Carswell Legal Publications, 1996) at 137; see also *Byciuk v. Hollingsworth*, 2004 ABQB 370, [2004] A.J. No. 620 where the Alberta Court of Queen's Bench held that it is sufficient if the physician takes reasonable steps to ascertain whether the patient understood the message being conveyed.

⁵² *Ibid.* at para. 55.

⁵³ *Ibid.* at para. 54.

essential part of the prenatal genetic screening process, and plays a central role in fulfilling the informational and comprehension requirements of informed consent, and therefore, ideally accompanies prenatal screening and diagnosis. This counseling is supposed to be offered to pregnant women or to women considering pregnancy who are considered at risk for having an “affected” or “abnormal” fetus. The principle of non-directiveness requires that the informed consent process involve a discussion of a patient’s values without recommending particular decisions.⁵⁴ In this way, genetic counseling contributes to a doctor’s responsibility and the requirement for informed decision-making and the ethical duty to support patients involved in genetic testing that is consistent with their values, beliefs, circumstances, and life plans. These responsibilities necessarily include following up with patients to ensure they have been able to integrate test results and their implications into their lives.⁵⁵ Whether this actually occurs in practice is debatable and these responsibilities, combined with the volume of information required to be imparted and the inherent difficulty in a patient’s understanding of this information, can be a lengthy and involved process.

(iii) Time as an Obstacle

Impacting on every part of the materiality requirement are time constraints. Genetic counseling is generally offered at various stages during and before pregnancy but generally tends to be during the stages of pregnancy when abortion may be an option.⁵⁶ Time constraints can, therefore, impact on the information presented to the patient. The health care provider must have time to prepare and present the information to the patient, a task that may be quite difficult in a busy clinic setting. The patient may not have, at the time, an awareness of the need to spend a significant amount of time discussing the issues involved in prenatal genetic screening. In addition, time pressures become increasingly important when a woman wishes to consider abortion, because the longer such a decision is delayed, the more risks, trauma, and psychological impact it involves for the woman.⁵⁷ These time constraints may impose an even more onerous obligation on the physician to meet the requisite standards of informed consent, which may not be achievable in practice.

(iv) Causation as an Obstacle

Furthermore, the causation requirement is often very difficult to prove. That is, that the patient would have terminated the pregnancy or made a different decision regarding treatment had she been properly informed of all material risks.⁵⁸ The patient must show that, given her particular situation, it would have been reasonable

⁵⁴ *Supra* note 8 at 236.

⁵⁵ *Burgess, et al., supra* note 6 at 1312.

⁵⁶ *Supra* note 3 at 21.

⁵⁷ Royal Commission on New Reproductive Technologies, *supra* note 43, quoted in Roxanne Mykitiuk, Stephanie Turnham & Mireille Lacroix, *supra* note 4.

⁵⁸ *Supra* note 28.

for her to terminate her pregnancy had she received all pertinent information regarding the risks of carrying her fetus to term. Because of the causation requirement, a woman's ability to recover damages for a doctor's negligence in failing to inform is based, in part, on her views about abortion. As a result, if a woman is opposed to abortion and communicates this fact to her physician, this can potentially affect the amount and quality of information she receives since she lacks the ability to show that any omission in information caused damage.

The patient, however, shares some responsibility for ensuring that she receives all the necessary information. In a British Columbia case,⁵⁹ a child was born with spina bifida and the mother claimed that her physician was negligent in failing to refer her for an ultrasound. The physician successfully claimed contributory negligence on the part of the child's mother for failing to follow medical advice. The physician had not ordered an ultrasound because the mother had not returned to the physician's office for a second prenatal visit until later in pregnancy than such tests would normally be offered. In the case of prenatal genetic screening, the patient may not be aware that such tests exist, and the need to see the physician for such tests, absent the physician informing her.

It is also unclear whether physicians are under a duty to provide information about procedures that appear unavailable to the patient.⁶⁰ Where the patient may want to prepare for the birth of a disabled child, prenatal screening and diagnostic services may nevertheless be provided where a woman has indicated that she will not have an abortion.⁶¹ Accordingly, there is a pre-test informational requirement, but whether the tests are available or advisable may also depend on whether the physician believes that the woman may abort in the presence of genetic irregularities since no liability will attach absent this possibility.

(v) *Summary*

While the materiality requirement of the informed consent standard appears straightforward, it is quite complicated for prenatal genetic screening. The informational component of genetic testing is complex, and not easily understood by either patients or doctors. Though doctors should have a responsibility to remain informed in every area of advice they provide, the ever-increasing capacities of genetic information may outpace the practical abilities of physicians to stay informed in such an advanced manner that the information can be imparted comprehensively to patients. In addition, the probabilistic nature of genetics makes patient understanding all the more difficult. As time constraints on both physicians and patients are factored into the genetic counseling session, the physician may not

⁵⁹ *Patmore (Guardian ad litem of) v. Weatherston*, [1999] B.C.J. No. 650, 86 A.C.W.S. (3d) 981 (B.C.S.C.).

⁶⁰ *Supra* note 4. Reasons of unavailability could include prohibitive cost, lack of hospital resources, or absence of medical indicators.

⁶¹ *Supra* note 8.

be able to adequately ensure patient comprehension, especially in a non-directive manner, and where there are language barriers or patients do not appreciate the magnitude of the information they are receiving. In reality, physicians are required to choose which information they feel is material, given the defined parameters in which the information must be communicated. As Timothy Caulfield notes, quoting Clarke Fraser, “it is difficult enough to ensure that physicians even make the initial mention of the test, much less engage in a time-consuming counseling session.”⁶² Though a reduced standard of care is not appropriate for prenatal genetic screening and testing, the present threshold is simply not practical and does not take into account the complexities of genetic information.

III. Obstacles to Patient Autonomy in PND

If the objective of providing adequate information to the patient is to increase the patient’s ability to make an informed decision, the sufficiency of the present “full disclosure” materiality requirement must be examined in light of its ability to fulfill this goal. Is patient autonomy in decision-making possible where materiality is variable? What information is material to ensuring patient autonomy in decision making? Bernard Dickens explains that the legal role of information is “to serve the patient’s autonomy, permitting the patient to exercise choices among feasible options that accord with his or her own wishes.”⁶³ In order to determine whether the materiality requirement of informed consent is adequate, the notion of “choice” must be examined. Even where a patient can be fully informed and receive appropriate genetic counseling, does a choice really exist not to undergo prenatal screening or not to know the results of such tests?

(i) *Obstacles to Choice*

Whether a woman actually has a choice to refuse prenatal genetic screening is an essential inquiry in determining whether the goal of patient autonomy in the informed consent process can be achieved. There are a number of factors that may effect whether a woman has a choice whether or not to participate in prenatal screening and diagnostic testing, including societal influences, medical discourse, and changing conceptions of need.

First, society plays a major role in constructing the illusion of choice in prenatal screening. As screening techniques have become routine, the possibility of choosing not to know the results is reduced.⁶⁴ If it is standard practice for physicians to perform such tests, the woman who refuses to either undergo the tests or know the results of such tests is deviant. Yet, because obstetricians suggest

⁶²F. Clarke Fraser, “Some Complexities in the Application of Guidelines for Genetic Testing,” (1995) 3 Health L.J. 301; quoted in Timothy A. Caulfield, “The Practice of Human Genetics: Emerging Areas of Consensus?” (1995) 3 Health L.J. 307 at 309.

⁶³*Supra* note 20 at 130.

⁶⁴*Supra* note 8 at 255.

prenatal testing as a part of routine care, without any formal discussion or truly informed consent, many women, without ever realizing they have done so, embark upon a course that may end in a discussion of pregnancy termination due to suspected fetal abnormality.⁶⁵ As a result, the obstacle to understanding stemming from the materiality requirement may constitute a further obstacle to choice.

Yet whether that “choice” is or is not informed, there is a sense that the tests are “needed” in order to reduce high levels of perinatal mortality and morbidity associated with assumed increases in genetic disorders. The choices and needs of women can be influenced by the social and political status of women, as well as the increasing pressure of the medical profession on women to take advantage of the “benefits” of prenatal testing.⁶⁶ Social norms have developed which cause women and couples to view the accumulation of information as responsible behaviour necessary for reasonable decision-making.⁶⁷ The sources of information themselves have become elevated to a higher status as prenatal genetic screening has become more routine; medical data obtained from these tests can be seen as the only valid information about the pregnancy.⁶⁸ While the woman is not divorced from the decision-making process, the societal norms may influence her ability to make completely free and informed decisions.

Contributing to this reduction in free decision-making are societal notions about disability. Women who knowingly choose to give birth to a baby with a disability may be accused of weakening or burdening society,⁶⁹ or may be blamed for the difficult life their child must lead as a result of the disability. In fact, one investigation showed that women who did not make use of prenatal testing, or who did not abort after a positive fetal test, were considered by both physicians and community members to be less responsible, more to blame, less deserving of sympathy, and less deserving of social aid subsequent to giving birth to a disabled child than were women to whom prenatal genetic screening was not offered.⁷⁰ Laura Purdy asks, “[i]sn’t it immoral knowingly to act so as to increase the demands on these [limited] resources, resources that could otherwise be used for projects such as feeding the starving or averting environmental disaster? Isn’t attempting to avoid the birth of those who are likely to require extra resources, other things being equal, on a par with other attempts to share resources more equally?”⁷¹ This supports the assertion that prenatal genetic screening and testing has the potential to transform

⁶⁵ Annette Patterson & Martha Satz, “Genetic Counseling and the Disabled: Feminism Examines the Stance of Those Who Stand at the Gate” (2002) 17:3 *Hypatia* 118.

⁶⁶ Yvonne Peters & Karen L. Lawson, *The Ethical and Human Rights Implications of Prenatal Technologies: The Need for Federal Leadership and Regulation* (Winnipeg: Prairie Women’s Health Centre of Excellence, March 2002).

⁶⁷ *Supra* note 8 at 246.

⁶⁸ *Ibid.* at 263.

⁶⁹ *Supra* note 66.

⁷⁰ *Ibid.*

⁷¹ Laura M. Purdy, *Reproducing Persons: Issues in Feminist Bioethics* (New York: Cornell University Press, 1996).

the birth of a disabled child from an unfortunate event into a regrettable event that the mother could have, and perhaps should have, prevented. As Abby Lippman notes, “[s]ociety does not truly accept children with disabilities or provide assistance for their nurturance. Thus, a woman may see no realistic alternative to diagnosing and aborting a fetus likely to be affected.”⁷² As a result of these social influences, which may further impact on whatever other influences exist in an individual’s life, a woman is not autonomous in her decision-making process, whether or not the materiality requirement is fulfilled.

(ii) *Obstacles to Free Decision-Making*

The factors considered by a pregnant woman in making decisions about herself, her pregnancy, and her fetus are not the same as the considerations which may influence the decisions of a non-pregnant person. Whereas an individual considers her own interests, the pregnant woman may also consider the interests of her fetus and the effect that any medical treatment may have on the potential life inside of her. The legal regulation of abortion has been the primary catalyst for examining the interests of the fetus. The status of the fetus is well established in Canadian law: the fetus has no legal rights until it is born alive, as decided by the Supreme Court of Canada in *Tremblay v. Daigle*.⁷³ In that case, the Supreme Court of Canada found that a fetus was not a legal entity until it was born as a live baby, and thereby denied the father’s argument that he had a right to veto a woman’s decision with respect to aborting the fetus she was carrying because he had helped create it. In *R. v. Sullivan*,⁷⁴ the Supreme Court of Canada further extended this notion into the criminal law. In that case, two midwives were accused and charged after a baby they attempted to deliver died while in the birth canal. The issue was whether the fetus in the birth canal was a “person” within meaning of section 203 of Criminal Code. The Court held that it was clear from the wording of section 206 of the Criminal Code that a fetus was not a “human being” for purposes of the Code. Furthermore, “person” was synonymous with “human being” and therefore, according to section 206, a child being born was not “person” within the meaning of section 203 and the accused could not be convicted of criminal negligence causing death to another person.⁷⁵ Correspondingly, the Supreme Court of Canada agreed that a woman cannot be held responsible for her actions while pregnant until a viable fetus is born in their decision in *Winnipeg Child and Family Services v. D.F.G.*⁷⁶ A pregnant woman, addicted to glue sniffing, could not be detained pending the birth of her child for the protection of the fetus. It was held that, as a general proposition applicable to all aspects of the law, the law of Canada did not recognize the unborn child as a legal person possessing rights. Madam Justice

⁷² Abby Lippman, “Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities” (1991) 17 Am. J. L. & Med. 15 at 33.

⁷³ *Tremblay v. Daigle*, [1989] 2 S.C.R. 530, 62 D.L.R. (4th) 634.

⁷⁴ *R. v. Sullivan*, [1991] 1 S.C.R. 489, [1991] S.C.J. No. 20.

⁷⁵ *Ibid.*

⁷⁶ *Winnipeg Child and Family Services v. D.F.G.*, [1997] 3 S.C.R. 925, 152 D.L.R. (4th) 193 [*Winnipeg* cited to S.C.R.].

McLachlin, as she then was, stated that “once a child is born, alive and viable, the law may recognize that its existence began before birth for certain limited purposes. But the only right recognized is that of the born person.”⁷⁷ As such, any right or interest the fetus may have remains incomplete until the child’s birth. Thus, there was no legal person in whose interests the Winnipeg Child and Family Services could act or in whose interests a court order could be made to detain the mother. As a result of these decisions, Canadian law does not recognize a fetus as a legal entity, though the fetus has a significant role to play for the pregnant woman examining her prenatal genetic screening options.

Accordingly, the legal status of the fetus may differ from the status that the woman carrying that fetus attaches to it. The notion of “autonomy” focuses on the individual. Erin Nelson points out that pregnant women are the “embodied challenge to liberal philosophy in that they are at once self and other; the woman as discrete individual is temporarily displaced by her pregnant self. The pregnant woman is at once self and somehow more than self.”⁷⁸ While the law treats the interests of the pregnant woman as separate from the interests of her fetus, the woman may not feel that this is the case. Robin West provides further insight into the experiences of women and notions of liberal choice:

The descriptive account of the phenomenology of choice that underlies the liberal’s conceptual defense of the moral primacy of consent may be wildly at odds with the way women phenomenologically experience the act of consent. If it is — if women “consent” to transactions not to increase our own welfare, but to increase the welfare of others — if women are “different” in this psychological way — then the liberal’s ethic of consent, with its presumption of an essentially selfish human actor and an essentially selfish consensual act, even when even-handedly applied to both genders, will have disastrous implications for women. For if women consent to changes so as to increase the happiness of others rather than to increase our own happiness, then the ethic of consent may indeed increase the amount of happiness in the world, but women will not be the beneficiaries.⁷⁹

The manner in which a pregnant woman makes decisions as distinct from that of other women, or men, is a relevant consideration in the examination of autonomous decision-making and, by extension, informed consent. If a woman is also considering the interests of the “other” inside of her, however she may conceive of those interests, she is not entirely autonomous as a non-pregnant person may be. The informed consent standard is based on “a model of a self-interested actor, making

⁷⁷ *Ibid.* at para. 11.

⁷⁸ Erin Nelson, “Reconceiving Pregnancy: Expressive Choice and Legal Reasoning” (2003-2004) 49 McGill L.J. 593 at 612.

⁷⁹ Robin L. West, “The Difference in Women’s Hedonic Lives: A Phenomenological Critique of Feminist Legal Theory” (1987) 3 Wis. Women’s L. J. 81 at 92; quoted in Erin Nelson, *ibid.* at 613.

self-interested choices, for self-interested ends. This could not be more different from the situation in pregnancy; surely, pregnancy must be the opposite of selfishness.”⁸⁰ Informing the decision-making process for a pregnant woman must, therefore, include an understanding of common interests and relationships not defined by individualism. Even though the fetus does not have legal interests, a pregnant woman is not entirely “free” in her decision-making as she may be restricted by her perception of the interests of her fetus.

(iii) Societal Interests as an Obstacle

There is a conflict between individual rights to an autonomous decision about whether to abort a potentially disabled fetus and the societal effects that policies that promote such practices may have. Many in the disability community argue that “the ‘choice’ to continue with a particular pregnancy, following a prenatal diagnosis when it discloses a disability, constitutes a false choice because of the social and economic context of the decision, as well as the medical milieu.”⁸¹ The notion of ‘risk’ itself is inherently negative. “Risk” is defined as “the possibility of suffering harm or loss, danger.”⁸² It has also been argued that risk is itself socially constructed rather than biologically determined.⁸³ Women informed that they are at risk may find it hard to refuse prenatal genetic screening and testing, when it is couched in language of “risk reducing measures.” Present in this language is an underlying assumption that having a child with a disability is a bad thing. Genetic counseling is, thus, inherently in conflict with the goals of autonomy as it begins with a negative assertion about the potential disabled child and is thereby based on a value judgment.

The medical language in which prenatal genetic screening is situated is also inherently judgmental. The medical model of disability, as defined by the World Health Organization, “views disability as a feature of the person, directly caused by disease, trauma or other health condition, which requires medical care provided in the form of individual treatment by professionals. Disability, on this model, calls for medical or other treatment or intervention, to ‘correct’ the problem with the individual.”⁸⁴ As a result, the medical model has as its goal the eradication of disease or abnormality. The goal of genetic counseling as being non-directive is, therefore, in conflict with a medical ethic that embraces elimination of disease.⁸⁵ The “social model of disability” makes a distinction between the impairment and the disability. That is, the former refers to biological characteristics of the body and the mind, the latter to society’s failure to address the needs of people with

⁸⁰ Erin Nelson, *ibid.* at 614.

⁸¹ Judith Mosoff, “Reproductive Technology and Disability: Searching for the ‘Rights’ and Wrongs in Explanation” (1993) 16 Dal. L.J. 98.

⁸² *Ibid.*

⁸³ *Supra* note 72 at 29.

⁸⁴ World Health Organization, *Towards a Common Language for Functioning, Disability, and Health: ICF* (Geneva: World Health Organization, 2002) at 8.

⁸⁵ *Supra* note 65.

‘perceived’ impairment. While there are various permutations of the social model, most support the traditional view that it is the societal structures which disable people with impairments and not the impairments themselves. As a result, it is society that must be altered in order to promote the well-being of people with disabilities.⁸⁶ By using language such as “defect”, “abnormality” and “congenital malformation” when discussing prenatal genetic screening and testing, disability is framed in the context of individual pathology rather than in a social context.⁸⁷ In addition, medical definitions of disability or abnormality are not universally accepted by all in society in the same manner. For example, poor women and women of colour tend to view genetic risk differently than medical professionals and are inclined to be more accepting of disabled children than women from the dominant culture.⁸⁸ Moreover, these same women often view prenatal genetic screening techniques within a context of eugenic discrimination and medical exploitation.⁸⁹ Disability can therefore be viewed as a socially constructed phenomenon, which depends largely on what medicine is able to test and what is considered deviant at the time of the determination.

The physician is required by the Canadian Medical Association [CMA] Code of Ethics to “consider the well-being of society in matters affecting health.”⁹⁰ Where a physician is mandated to merely present genetic information and test results without context and attention to societal implications, this fundamental responsibility of the physician cannot be entirely fulfilled. Accepting that the non-directive genetic counseling role assumed by physicians and obstetricians cannot realistically be fulfilled, we must look to other ways of achieving balance between women’s autonomy in decision-making and the physician’s ability to facilitate this process having regard to societal interests and the rights of people with disabilities. The next section will consider how this can be achieved.

IV. Overcoming the Obstacles Through Collaboration

The present standard for informed consent in the realm of prenatal genetic screening and diagnosis is at once idealistic and impractical. While the goal of patient autonomy in decision making is admirable, the present materiality and causation requirements are not achieving this ideal in the context of genetic information. Timothy Caulfield, in considering whether the difficulties in achieving full disclosure in practice should be “allowed to compromise the obligation of

⁸⁶ See David Pfeiffer, “The Conceptualization of Disability” in Sharon N. Barnartt & Barbara M. Altman, eds., *Research in Social Science and Disability 2: Exploring Theories and Expanding Methodologies* (Elsevier Science Ltd. 2001) at 29 (for a review of the literature on models of disability).

⁸⁷ *Supra* note 66.

⁸⁸ *Ibid.*

⁸⁹ *Ibid.*

⁹⁰ Canadian Medical Association, CMA Policy, *CMA Code of Ethics: Update 2004*, online: CMA <<http://policybase.cma.ca/PolicyPDF/PD04-06.pdf>>.

full disclosure” says that “[t]o allow these type of pragmatic concerns, which clearly need to be considered in due course, to erode the conception of these norms may leave practitioners with no clear guideposts.”⁹¹ I am not suggesting that the standard be compromised in assessing the pragmatic concerns of doctors, nor to leave physicians without any guidance. In assessing the standards set for physicians, there should be an awareness of practicalities and, if the lofty objectives of informed consent are not yet serving their purpose as a result of these obstacles, then the policy or standard should be amended accordingly. Not only would this serve the goal of patient autonomy but would also serve societal interests that may effect decision-making.

So how can a pregnant woman achieve autonomy in decision-making facing all these obstacles? Inherent in the informed consent standard and the principle of non-directiveness is the assumption that autonomy means that decisions must be made independently of the physician. Through a collaborative approach to decision-making, which recognizes that when facing enormous decisions about her fetus, a pregnant woman may want and, in fact need, the advice and guidance of her physician, autonomous decisions are redefined. A collaborative approach can facilitate overcoming the obstacles to full disclosure, understanding, and time, by focusing on the decision-making process of the pregnant woman, working with her in reaching a decision that is right for her and her fetus, and balancing the interests of society as well as those of the individual woman.

First, the obstacles to full disclosure are intimately connected to the principle of non-directiveness. As mentioned, information about the procedures and results is difficult to both digest and to communicate. The doctor, as gatekeeper of this information, can provide advice that is both helpful and facilitative. Yet physicians are prohibited from counter-balancing this obstacle with recommendations as a result of the principle of non-directiveness. Disability rights advocates are often concerned that physicians will lead toward aborting abnormal fetuses and thereby, promote arguably eugenic practices which may lead to a further reduction in status and services for people with disabilities.⁹² Within the status quo, this is a fair concern. However, there is a positive role that physicians could have in facilitating understanding of, and preparation for, the life of a disabled person with proper education and exposure.

In order to assist in the decision-making process, the physician must have received the appropriate training. The goal must be education about the potential impact of “positive” genetic tests, life with a disability, and the context in which a pregnant woman makes decisions. As it appears that physicians are not equipped to provide patients with information about genetic testing services, as a result of their lack of knowledge or counseling skills, programs are necessary to train both

⁹¹ *Supra* note 36 at 310.

⁹² See for example Kerry Taylor & Roxanne Mykitiuk, “Genetics, Normalcy and Disability” (2001) 2:3 *Isuma: Canadian Journal of Policy Research* 65.

medical students and practicing physicians.⁹³ When a woman and her partner must make a decision about whether she is prepared to raise a child with a prenatally detectable disease or disability, “they need to know as much as counselors can tell them about the overall experience of children and families living with the diagnosed condition.”⁹⁴ Neil Sharpe discusses the distinct therapeutic model of care necessary in the genetic counseling context. He maintains that the physician must develop a “human vision” as opposed to a purely “medical vision.”⁹⁵ The doctor can thereby assist in the decision-making process, provide reassurance regardless of test results and provide advice and guidance about past experiences. With a balanced and well-informed approach to the genetic counseling process, the fears of the disability community may be allayed, and the woman may be both empowered and aided in her decision.

Second, collaboration with the patient in the decision-making process can also provide psychological support in the process of understanding the information communicated about genetic tests. A doctor who refuses to tell the patient what the doctor would do in the patient’s situation or allows the patient to make a short-sighted decision, without attempting to dissuade her from this route, may merely be contributing to a feeling of isolation and thereby increase anxiety.⁹⁶ A concept of autonomy which allows physicians to offer their opinions while allowing the patient the freedom to reject those opinions, while contrary to the principle of non-directiveness, may facilitate a patient’s ability to understand the information provided to her. It may also reduce a patient’s “sense of abandonment and decision making inadequacy” while “improving the quality of medical decisions that are made.”⁹⁷ In fact, a 2001 survey conducted in the United States showed that 44 percent of primary care physicians stated that, because patients seek their guidance, non-directiveness is an impossible and undesirable goal in genetic testing.⁹⁸ Moreover, 78 percent of at-risk women would want their providers’ recommendations about testing.⁹⁹ The same study showed that most women wanted a recommendation from a knowledgeable and trusted provider, but still wanted the freedom to make their own decisions; such recommendations were not viewed as directive, since patients did not feel obligated to follow them.¹⁰⁰ Where physicians do not fear liability as a result of collaborating with the patient in the decision-making process,

⁹³ Timothy A. Caulfield, “The Informed Gatekeeper? A Commentary on Genetic Tests, Marketing Pressure and the Role of Primary Care Physicians” (2001) 9:3 Health Law Review 14 at 16.

⁹⁴ Adrienne Asch, “Disability Equality and Prenatal Testing: Contradictory or Compatible?” (2002-2003) 30 Fla. St. U.L. Rev. 315 at 335.

⁹⁵ *Supra* note 1 at 440.

⁹⁶ Roger B. Dworkin, “Getting What We Should from Doctors: Rethinking patient Autonomy and the Doctor-Patient Relationship” (2003) 13 Health Matrix 235 at 275.

⁹⁷ *Ibid.* at 276.

⁹⁸ Gail Geller *et al.*, “Clinical Practice and Policy: The Meaning of Autonomy in Genetic Testing: Lessons from Qualitative Research About the Role of Partnership in Decision-Making” (2001) 29: Part 2 Supp. J.L. Med & Ethics 3.

⁹⁹ *Ibid.*

¹⁰⁰ *Ibid.*

autonomy of the woman, as it exists for the pregnant woman, can be promoted in a meaningful manner.

Time constraints may also be addressed through collaborative informed consent. Collaboration can permit the physician to determine what information is required for disclosure, which will assist with the problem of knowledge overload for the patient and thereby facilitate understanding. The patient may be able to make decisions in a faster manner when presented with relevant information as determined by the physician, rather than being presented with all information merely for the sake of reducing the risk of physician liability for non-disclosure.

However, the physician must be trusted in this process. The principle of non-directiveness, combined with the materiality requirement, assumes malicious or potential detrimental motivations on the part of the physician. With proper education, as well as a set of procedures and guidelines, the physician can be both the patient's ally and a societal protector. Additionally, the CMA Code of Ethics presently provides responsibilities that should assuage concerns about the personal motivations of physicians interfering with appropriate genetic counseling. For instance, article 12 provides that the physician must inform patients when personal values would influence a recommendation or performance of any medical procedure that the patient needs or wants. Article 21 requires that the physician provide patients with the information they need to make informed decisions about their medical care and necessitates answering questions to the best ability of the physician.¹⁰¹ Other articles provide for the respect of a patient to accept or reject recommended medical care,¹⁰² and to respect requests for a second opinion.¹⁰³ These requirements, combined with the physician's fiduciary relationship to the patient,¹⁰⁴ are evidence that a collaborative approach to decision-making can be entrusted to physicians if it is also required that they are adequately educated about prenatal screening and other genetic tests. By establishing the bounds of professionalism for physicians, patient autonomy can be further promoted.

Third, the distinct needs of a pregnant woman can be incorporated into the informed consent process, thereby increasing her ability to choose from amongst options. The physician who is able to collaborate with the patient in decision-making can listen to the concerns of the woman, incorporate her perceived needs into the information given, and provide further insight into the interests of the fetus. The physician can help separate the needs of the fetus from those of the woman and allow her to decide whether these are conflicting and how to reconcile the two by providing recommendations. This collaborative process can also allow the woman

¹⁰¹ *Supra* note 90 at art. 12, 21.

¹⁰² *Ibid.* art. 24.

¹⁰³ *Ibid.* art. 26.

¹⁰⁴ See *Norberg v. Wynrib*, [1992] 2 S.C.R. 226, 92 D.L.R. (4th) 449; *McInerney v. MacDonald*, [1992] 2 S.C.R. 138, 93 D.L.R. (4th) 415.

to explore her intuitions that do not have a scientific basis,¹⁰⁵ share them with her physician and receive feedback. Through a collaborative approach to informed decision-making, the woman is involved with the physician in the entire process — from deciding which information should be disclosed and ensuring comprehension of that information, to choosing whether to undergo genetic testing, receive results, or forgo the experience entirely. The patient's autonomy is not sacrificed and the decision is no less informed when information is tailored to suit the patient.

The most central part of a collaborative approach to informed consent is adequate and appropriate physician education. Since it is clear that the principle of non-directiveness does not function in practice, physicians and medical students must be taught not only to understand genetic tests and communicate the results effectively, but also to provide a balanced approach to assessing the results and the value of having those tests. A true understanding of life with a disability requires interacting with both people with disabilities and their families. With such education, the physician must be trusted to provide guidance and information to patients in a manner that will address the pregnant woman's concerns. Perhaps with further education, the societal norms which have contributed to the routinization of prenatal screening and diagnosis may be altered as the medical community learns to provide a "human vision."¹⁰⁶ The lofty ideals of the full disclosure materiality requirement in informed consent are admirable and the law should continue to strive to achieve patient autonomy in decision-making. However, the law should respond to a changing society and find a pragmatic manner of ensuring that its objectives are fulfilled. In an era of constant genetic and technological innovation, such as exists for prenatal screening and diagnosis, legal rules and regulation have an increased responsibility to respond to human needs and potential societal consequences.

¹⁰⁵ *Supra* note 8 at 265.

¹⁰⁶ *Supra* note 1 at 440.

Appendix: Professional Guidelines

Canadian Medical Association, CMA Policy, *CMA Code of Ethics: Update 2004*, online: CMA <http://policybase.cma.ca/PolicyPDF/PD04-06.pdf>.

Institute for Clinical Systems Improvement, *Health Care Guideline: Routine Prenatal Care*, 8th ed. (July 2004).

Ontario, Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future* (November 30, 2001).

Society of Obstetricians and Gynaecologists of Canada & Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists, *Amended Canadian Guideline for Prenatal Diagnosis (2005) Chante to 2005 — Techniques for Prenatal Diagnosis* (SOGC Clinical Practice Guidelines, No. 168, July 2005).

Society of Obstetricians and Gynaecologists of Canada & Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists, *Practice Guidelines for Health Care Providers Involved in Prenatal Screening and Diagnosis* (Policy Statement No. 75, August 1998).

Society of Obstetricians and Gynaecologists of Canada & Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists, *Canadian Guidelines for Prenatal Diagnosis: Genetic Indications for Prenatal Diagnosis* (SOGC Clinical Practice Guidelines, No. 105, June 2001).

