J Genet Counsel (2017) 26:93–104
DOI 10.1007/s10897-016-9983-4

ORIGINAL RESEARCH

Risk for Patient Harm in Canadian Genetic Counseling Practice: It's Time to Consider Regulation

Andrea L. Shugar[1,2] · **Nada Quercia**[1,2] · **Christopher Trevors**[3] · **Marina M. Rabideau**[4] · **Sohnee Ahmed**[5]

Received: 10 March 2016 / Accepted: 24 May 2016 / Published online: 7 June 2016

Abstract With the increasing awareness of genetic contributions to disease in Canada, the availability of and demand for genetic testing has soared. Genetic counseling is becoming a recognized and rapidly growing (yet unregulated) health profession in Canada. We hypothesized that the potential risk for harm to the public posed by genetic counseling practice in the province of Ontario is sufficient to consider regulation. The Ontario Ministry of Health and Long-Term Care (MOHTLC) sets criteria (both primary and secondary) to identify health professional bodies that meet the threshold for regulation in the province. We developed a survey based on the MOHTLC criteria to determine if genetic counselors meet the primary criteria to be considered for health professions regulation in Ontario. We surveyed 120 Ontario genetic counselors about their clinical practice and perceptions of risk for harm to the public. Results indicate that Ontario genetic counselors are highly independent in their clinical practice and are involved in patient care activities, clinical judgement and decision-making that have the potential to harm patients. In particular, cancer genetic counselors were identified as a cohort that practices with relatively high autonomy and low supervision. In summary, our study indicates that genetic counseling practice in Ontario meets the primary criteria to be considered for regulation.

Keywords Genetic counseling · Genomics · Genomic medicine · Health professions · Regulation · Genetics · Genetic testing · Genetic counselor · Cancer genetics · Healthcare · Medical genetics · Licensure

Electronic supplementary material The online version of this article (doi:10.1007/s10897-016-9983-4) contains supplementary material, which is available to authorized users.

✉ Andrea L. Shugar
andrea.shugar@sickkids.ca

[1] Department of Genetic Counseling, Hospital for Sick Children, 555 University Avenue, Toronto, ON M5G 1X8, Canada

[2] Department of Molecular Genetics, University of Toronto, Toronto, ON, Canada

[3] LifeLabs, Toronto, ON, Canada

[4] Genetics and Genomics, Invitae Inc, San Francisco, CA, USA

[5] Genetic Counseling, GeneDx, Gaithersburg, MD, USA

Introduction

Ontario Genetic Counselors and Health Professions Regulation

Genetic counseling is defined as the process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease … and counseling to promote informed choices and adaptation to the risk or condition (Hooker et al. 2014; Ormond 2013; Resta et al. 2006). There are currently an estimated 167 individuals who practice genetic counseling in Ontario (personal communication). They provide service to a population of 13.8 million people (Canada 2015). Historically, genetic counselors worked as team members in medical genetics clinics with medical geneticists providing clinical oversight. There is a clearly defined Canadian entry-to-practice route (CAGC 2012b, c) which includes completion of a Master of Science Degree in Genetic Counseling at an accredited training program, certification exam and maintenance of certification. Although many Canadian hiring institutions favor board-certified or board eligible genetic counselors, there is no requirement at a provincial level to become certified or

demonstrate maintenance of certification (Somerville and Allingham-Hawkins 2010).

In Canada, health professions that are considered to pose a significant risk for public harm can become regulated via a legislative process. Becoming regulated serves to increase that profession's accountability to the public by offering a formal complaint and disciplinary process. It also protects that profession's title (criminalizes its unauthorized use) and may allow that profession to perform specific controlled acts (such as communicating a diagnosis or ordering a test). Akin to American licensure, which occurs at the state level, health care regulation laws are passed at the provincial level in Canada. There are currently 26 regulated health professions in Ontario (O. MOHLTC 2016). To date, no province in Canada has formed a regulatory body for genetic counselors. Some genetic counselors do, however, have medical delegation (a direct order from a responsible physician to perform a controlled medical act for a specific patient) and/or medical directives (a "blanket order" in writing from the responsible physician to perform a controlled act for a clearly defined patient-population) at the institutional level (C. o. P. a. S. o. Ontario 1999). An informal survey by the authors revealed that as of 2015, there is great variability within and between the 8 Ontario genetics centers with respect to medical directives for genetic counselors. This variability ranges between having no directives at all to having medical directives for clearly defined patient populations.

In 1991, the Ontario Government introduced the Regulated Health Professions Act (G. o. Ontario 1991). The purpose of the Act, which is akin to the concept of licensure of healthcare professionals in the U.S., is to address issues of public protection by: restricting which health professionals may perform hazardous acts; prohibiting unregulated practitioners from providing treatment or advice when harm to the patient/client may result; restricting the use of professional titles/designations and providing a mechanism for public accountability (Frelick and McFadden 2009; Rosen and Sunshine 2010). An amendment to this act in 2006 expanded the definition of harm to include mental as well as physical harm (Rosen and Sunshine 2010 (Rosen and Sunshine 2010). A Provincial Health Professions Regulatory Advisory Council (HPRAC) has set out both primary and secondary criteria to assess whether a given health profession meets a risk of harm threshold to be considered for regulation (Table 1) (HPRAC 2011). The primary criterion (which focuses on the potential risk for harm to patients) must be met in order to fulfill the requirements for regulation (Table 1).

A recent expansion of the definition of risk of harm to include mental harm further compels Ontario genetic counselors to investigate the need for regulation, given that a major component of the genetic counselor's role is to provide short-term, client-centered counseling and psychological support and assist families with difficult, sometimes life-altering decisions (Austin et al. 2014; Cameron and Muller 2009; Hooker et al. 2014; Horowitz et al. 2001; Martin et al. 2010; Ormond 2013; Powell et al. 2010; Resta 2006; Swanson et al. 2014; Weil 2002).

A similar concept of harm has emerged from several American state legislative reviews (also called sunrise reviews) which evaluate the appropriateness of licensure for genetic counselors. One such review has defined specific examples and categories of potential harm relevant to genetic counseling practice. These include but are not limited to incorrect test interpretation, inadequate training and title misuse (Table 2) (State of Colorado 2013).

Changing Trends in Canadian Healthcare and Genomic Medicine

The recent shift towards genomic medicine and direct-to-consumer marketing of genomic testing has led to an enormous increase in the number of conditions included in testing, the number of positive and uncertain results, the time required by clinicians to interpret those results and the demand for genetic counseling services (Featherstone et al. 2007; Gordon et al. 2012; Green et al. 2011; Guttmacher et al. 2010; McGowan et al. 2013; Mills and Haga 2014; Ormond 2013; Zierhut and Austin 2011).

With the advent of new genetic technologies, genetic counselors are expanding their roles to provide interpretation and counseling regarding the significance of complex genomic data and possible related health risks (Christian et al. 2012; Clarke and Thirlaway 2011a, b; Machini et al. 2014; Mills and Haga 2014; O'Daniel 2010; Radford et al. 2014; Vig and Wang 2012; Zetzsche et al. 2014). Genetic counselors are being called upon to interpret variants of uncertain significance, to counsel about health risk management strategies, pharmaco-genomic implications and training non-genetics health care providers to provide genetics risk assessment and counseling. Although there is limited data available specific to the Canadian genetic counselling workforce, the literature predicts a future shortage of qualified genetic counselors due to expanded roles and increased demand for genetic testing and counselling (Andermann and Narod 2002; Botkin et al. 2015; Eisenstein 2015; Hawkins and Hayden 2011; Ontario 2008; Vanstone et al. 2012).

The pressure on primary care providers and non-genetics specialists to expand their role in genetic risk assessment and counseling is increasing, despite insufficient training and education (Andermann and Blancquaert 2010; Bensend et al. 2014; Carroll et al. 2009; Egalite et al. 2014; Houwink et al. 2012; Korf et al. 2014; Mendes et al. 2011; Shields et al. 2008; Vanstone et al. 2012; Zhou et al. 2014). It is not surprising then, that increasing numbers of genetic counselors have been hired to work in a variety of non-genetic clinical settings with non-geneticist physicians (Andermann and Narod 2002; Ingles et al. 2011; Matloff and Barnett 2011; Mendes et al.

Table 1 MOHLTC (HPRAC) criteria for evaluating new health professions for regulation (HPRAC 2011)

I Primary Criterion: The health care profession meets a risk-of-harm threshold if:	
1	The profession is involved in duties, procedures, interventions and/or activities with the significant
2	potential for physical or mental harm to patients/clients
3	The profession is engaged in making decisions or judgment that can have a significant impact on patients'/clients' physical or mental health
4	There is a significant potential of risk of harm occurring within the professional duties and activities
II Secondary Criteria: Characteristics of the profession supporting the appropriateness of regulation:	
The profession is able to exercise judgment autonomously in the provision of care	
There are clearly defined educational routes to the profession	
There is a distinct body of knowledge that informs the profession's scope of practice	
The profession can financially sustain the cost of regulation	
There are no better alternate regulatory mechanisms	
Professional leadership and membership are supportive of regulation	
Regulation would likely lead to positive health system impacts	

2011; Powell et al. 2010; Somers et al. 2014; Swanson et al. 2014; Vanstone et al. 2012). A recent Canadian Association of Genetic Counseling professional status survey revealed that 15 % of respondents work with non-geneticist physicians or with no physicians (CAGC 2012a). In these settings, genetic counselors are deferred to as the genetic expert despite not being a part of a regulated profession with adequate malpractice insurance. The genetic counselor may assume a primary role in choosing the most appropriate testing option, interpreting and communicating genetic test results, communicating complex information to the patient and providing psychosocial counseling and support (McCabe et al. 2001; O. M. o. H. a. L. T. C. MOHLTC 2002). Now that genetic counselors are assuming more independent, comprehensive and widespread roles in the delivery of health care services to the public, exploring the need for regulation is timely. However, to date, no study has systematically examined the actual scope of practice of Canadian genetic counselors or its associated potential risk for harm.

Purpose and Significance

To evaluate whether current genetic counseling practices in Ontario meet the primary HPRAC criteria for risk of harm, by looking at the clinical practice patterns of genetic counselors and their perceptions of the potential for mental and physical harm to their patients. Results from this study will guide future discussions regarding public accountability, title protection and regulation for Ontario genetic counselors and could be extrapolated to genetic counselors in other Canadian provinces.

Table 2 DORA categories of potential harm to the public in genetic counseling practice (State of Colorado 2013)

1)	Incomplete risk assessment
2)	Inaccurate Test Interpretation
3)	Psychological and Financial Issues
4)	Inadequate training specializing in genetics
5)	Title misuse
6)	Medical Malpractice
7)	Alleged wrongful birth
8)	Inadequate training

Methods

Survey Design

The survey was developed and designed in accordance with the principles of Dillman's Tailored Survey method (Dillman 2007). Questions were based on the primary and secondary criteria set out by HPRAC and were designed to assess potential risk to the public by

1) Describing the professional activities that call upon judgment or decision-making
2) Exploring genetic counselors' perceptions and experiences regarding potential and actual risk to their patients.
3) Measuring levels of professional autonomy by evaluating
   a) Medical delegation patterns
   b) Independence levels in direct patient interactions
   c) Documentation practices with respect to signing requisitions and consultation summaries

Questions to ascertain demographic attributes, global practice patterns and clinical scope of practice were also included. Survey questions were then tested on a pilot group of Canadian genetic counselors from outside Ontario and further refined based on feedback and question performance. A formal scientific peer review of the study design was conducted

and ethics approval was obtained through The Hospital for Sick Children Research Ethics Board.

Participant Recruitment

We chose to recruit participants who work in the province of Ontario, as it contains the largest workforce of genetic counselors among all Canadian Provinces and Territories. Research participants were identified through the Canadian Association of Genetic Counselors (CAGC) and the National Society of Genetic Counselors (NSGC) directories, as well as direct contact with all known facilities in Ontario that provide genetic counseling services (including regional genetics centers, private medical clinics, public health units, tertiary care centers and mental health facilities). Given the lack of title protection in Ontario, a "genetic counselor" was defined as an individual who is a non-physician health care provider whose primary role is to provide genetic counseling services. All identifiable genetic counselors in Ontario were personally invited to participate in the study, both by mail and email invitations. Inclusion criteria included health professionals who were hired by their institution to provide genetic counseling services for at least part of their role. Participants who, at the time of recruitment, had been on leave of practice for more than 2 years were excluded from the study.

Data Collection and Analysis

Data were collected via a web-based survey system. Descriptive and comparative statistical analyses included Fisher's exact and t-tests to look for significant differences in measures between groups and subgroups. Participants were asked to respond to questions about demographic and training background, certification status, practice setting, specific clinical roles and activities, autonomy of practice and personal perceptions regarding risk of harm posed by their practice. They were asked to rate their level of independence for specific types of genetic counseling encounters, (with a "high-level" rating indicating a minimal level of medical oversight by the responsible physician), and to describe their documentation practices (signing testing requisitions and writing consultation summaries). We also invited them to share their personal anecdotes of risk for harm in genetic counselling practice.

Results

Response Rate

There were 120 Ontario genetic counselors that met inclusion criteria and were invited to participate. There was a 75 % response rate (N = 90), with a complete response rate of 65 % (N = 78), and a partial response rate of 10 % (N = 12).

Demographic Features and Practice Settings

All demographic and practice setting data are presented in Table 3. "Genetic Counselor" was the most commonly reported job title. The most frequent academic background reported was Master of Science degree in genetic counseling via an accredited training program. Certification by a recognized body was reported by the majority of the participants. Of those who were board-eligible with no plan to become certified (N = 18), the reasons given in order of frequency were "it did not impact employment", "personal reasons" and "financial constraints". The majority of participants reported a hospital medical genetics setting as at least one of their practice settings. The average estimated face-to-face patient encounters per month was 30.6 (range 5–90, median 27.5) (Table 4). Over ¼ of respondents (26 %) reported being employed exclusively in a specialized role (such as adult, cancer or prenatal genetics) and 16.5 % reported their professional practice to be limited exclusively to cancer genetics.

Professional Activities Requiring Clinical Judgment / Decision-Making

The scope of genetic counselor roles and activities is summarized in Table 4. The vast majority of participants (92.9 %) reported that greater than half of their role is allocated to direct patient care activities. Direct patient care activities requiring clinical judgment and decision-making included face-to-face consultations for a wide variety of clinical indications, ordering and interpreting genetic tests and providing health surveillance recommendations. Involvement in indirect patient care activities requiring clinical judgment ranged from 27 % to 97.7 % and included consulting to health professionals to provide information about genetic testing options, patient referral and screening recommendations and DNA test result interpretation.

Perceptions of Risk for Patient Harm and Attitudes toward Regulation

Over half of participants (52 %) agreed or strongly agreed that there "currently exists a significant risk to cause emotional or psychological harm to patients in the practice of genetic counseling". A minority of participants (12 %) reported having actually observed a few instances of harm.

A majority of participants agreed or strongly agreed that the policies, medical directives or delegated medical functions in place at their institutions are inadequate to protect their patients from harm (51 %) or themselves from medico-legal risk (52 %).

The frequency with which respondents observed a risk-for-harm scenario in at least a few instances ranged from 8.4 % to 37.3 %, for each case-type presented (Table 5).

Personal anecdotal observations of risk for harm in genetic counseling practice reported by participants were placed in

Table 3 Participant demographics and practice settings ($N = 90$)

Job title and years of experience ($N = 90$)	
Job Title	
Genetic Counsellor	75 (83.3 %)
Nurse or Public Health Nurse	13 (14.4 %)
Other[a]	2 (2.2 %)
Years of Experience	
Mean	8.0
Median	7.5
Range	< 1 to >25
Academic background ($N = 90$)	
Masters Level ABGC accredited genetic counselling training program	59 (64.8 %)
Masters Level Non-ABGC accredited genetic counselling training program	13 (15.4 %)
Masters Level Non-ABGC accredited genetic counselling training program AND Nursing BScN/RN	1 (1.1 %)
Nursing BScN/ RN	13 (14.4 %)
Non-Clinical M.Sc. / M.S. / M.A. in genetics	2 (2.2 %)
Other (Bachelor's degree and College-level nursing diploma)	2 (2.2 %)
ABCG and/or CAGC certification status ($N = 90$)	
Canadian AND American certified	26 (28.8 %)
American certified only	13 (14.4 %)
Canadian certified only	18 (20.0 %)
Board eligible – plan to take exam in upcoming cycle	13 (14.4 %)
Board eligible – no plan to achieve certification	18 (20.0 %)
Ineligible to be certified in Canada or the US	2 (2.2 %)
Settings in which subjects practice[b] ($n = 90$)	
Hospital medical genetics clinic	71 (78.8 %)
Public health unit genetics clinic	11 (12.2 %)
Pediatric clinic	8 (8.8 %)
Oncology clinic	8 (8.8 %)
Private Genetics Clinic	2 (2.2 %)
Ophthalmology clinic	2 (2.2 %)
Obstetrics/Maternal Fetal medicine clinic	2 (2.2 %)
Family medicine clinic	2 (2.2 %)
Gastroenterology	2 (2.2 %)
Surgical clinic	1 (1.1 %)
Other (research lab, cardiology clinic, GI cancer registry)	7 (7.7 %)

[a] The two "Other" job titles included Prenatal Screening Coordinator and Program Manager

[b] Some respondents reported practicing in more than one clinical setting

one of five categories of harm as outlined by the DORA Sunrise Review (State of Colorado 2013). There were three observations reported by participants that described incidents of actual harm to patients (Table 6).

Only a minority of respondents agreed that the current level of medical oversight they receive for their practice was inadequate and that this inadequacy *could* or actually did lead to patient harm (Table 7). However, over half the participants believed that their workplace policies and/or medical directives were not adequate to protect patients from harm. Overall, respondents showed support for regulation, with a majority reporting high likelihood to comply with regulations set out by a putative regulatory college, and agreement that regulation would promote a safer and more effective delivery of genetic counseling services (Table 5). A portion of respondents, however, did indicate they did not have enough knowledge to be able to agree or disagree with statements regarding support of regulation.

Autonomy of Practice

Autonomy of practice was assessed by three measures: medical delegation patterns, independence of practice in direct patient interactions and documentation practices.

Table 4 Genetic counselor roles and activities

Proportion of role allocated to direct patient care activities ($N = 88$)	
< 50 %	7 (7.9 %)
50–69 %	14 (15.9 %)
70–89 %	36 (40.9 %)
90 % or more	30 (34.1 %)
Estimated face-to-face patient contacts per month ($N = 88$)	
Average	30.6
Median	27.5
Range	5–90
Scope of professional activities (%)	
Direct patient care ($N = 88$)	88 (100 %)
Consulting other health providers ($N = 86$)	84 (95.4 %)
Clinical research coordination ($N = 79$)	51 (57.9 %)
Laboratory services ($N = 76$)	35 (39.7 %)
Newborn Screening ($N = 77$)	30 (34.0 %)
Health policy analysis ($N = 78$)	21(23.8 %)
Consulting to other health providers – specific activities ($N = 88$)	
Information about appropriate referrals	84 (95.4 %)
Information regarding available genetic testing	80 (90.9 %)
Information about specific genetic disease	78 (88.6)
Interpretation of genetic test results	77 (87.5 %)
Other[a]	6 (6.8 %)
Do not consult to other health providers	2 (2.3 %)

[a] Other: Screening/surveillance recommendations ($n = 5$), Ethical issues ($n = 1$)

Medical Delegation Patterns

The majority (84.1 %) of Ontario genetic counselors receive at least some of their medical delegation from a clinical or metabolic geneticist. Participants reported receiving medical delegation from a variety of physicians who specialize in other areas of medicine as well. Receiving medical delegation solely from a non-geneticist physician was reported by 14 (15.9 %, $N = 88$) of the participants (Table 7), all of whom reported direct patient care for part or all of their roles. Those non-geneticist physicians were reported to be specialists in oncology, surgery, gastroenterology, ophthalmology, pediatrics, respirology, hematology and laboratory medicine. Participants whose practice was exclusively limited to cancer genetic counseling ($n = 15$) were significantly less likely to receive their medical directives from a medical geneticist (40 % vs. 92 %, $p < <0.0001$).

Independence in Direct Patient Interactions

For prenatal cases, high-independence rates ranged from 18 % (genetic counseling regarding a fetal ultrasound abnormality) to 97 % (genetic counseling regarding aneuploidy risk). For general genetic counseling cases, high-independence rates ranged from 21 % (genetic counseling regarding an unbalanced chromosome rearrangement) to 74 % (genetic counseling regarding consanguinity risks). For cancer cases, high-independence rates ranged from 35 % (counseling for cancer-related health management/screening recommendations) to 79 % (genetic counseling regarding a negative DNA test result for a patient with a prior diagnosis of cancer) (Table 8).

Documentation Practices

All participants reported routinely signing at least one requisition type listed by our study on behalf of the responsible physician (100 %, $n = 85$). The frequency of signing requisitions on the responsible physician's behalf, ranged from 55.9 % for diagnostic DNA testing to 89.6 % for prenatal diagnostic procedures. The most common reasons given for genetic counselors signing the requisitions on behalf of the responsible physician were: better efficiency/more timely (73 %) and unavailability of the responsible physician (68 %) at the time of the patient encounter. Participants reported a high frequency of writing consultation summaries for their patient encounters; the majority (90 %) obtain co-signature from the responsible physician.

Cancer Genetic Counselors

Of interest, a subgroup that stood out in our analysis was the cohort of genetic counselors who specialize in cancer genetics. Fifteen (16.7 %) of the 90 participants were identified as having an exclusive role of cancer genetic counseling. Segmentation analysis revealed that this subgroup demonstrated significant difference in their practice and attitudes compared to the rest of the study group. They were more likely to have been trained by an ABGC accredited institution (86 % vs. 64 %, $p = 0.04$) and were more likely to report an Oncology Clinic as their work setting (40 % vs. 3 %, $p = 0.0002$).

Exclusive cancer genetic counselors were significantly more likely to practice with high autonomy when communicating a positive DNA result in a patient with a previous diagnosis of cancer (60 % vs. 30 %, $p = 0.02$). In fact, exclusive cancer genetic counselors practiced with greater autonomy across all cancer cases presented (approaching statistical significance), indicating a trend towards greater autonomy in this sector.

Exclusive cancer genetic counselors were significantly less likely than other participants to receive medical directives from a medical geneticist (40 % vs. 92 %, $p < 0.002$) and significantly more likely to receive directives from an oncologist or surgeon ($p = 0.0004$ and $p = 0.01$, respectively). Exclusive cancer genetic counselors were less likely than other participants to receive at least some of their directives from a medical geneticist (40 % vs. 94 %, $p < <0.01$).

Table 5 Risk-of-harm scenarios and attitudes toward regulation

Question regarding observed or experienced incidents of risk for harm: How frequently have you personally *observed* or *experienced* the following situations in your practice?	Many instances or routinely observed	A few instances	Never or only once instance	Unsure
A genetic counselor who did not offer ethnic-based carrier screening when indicated ($N = 83$)	5 (6.0 %)	31 (37.3 %)	32 (38.6 %)	15 (18.1 %)
A genetic counselor who did not address a significant positive finding in a pedigree ($N = 83$)	5 (6.0 %)	27 (32.5 %)	36 (43.4 %)	15 (18.1 %)
A genetic counselor who was unqualified to provide genetic counseling services ($N = 83$)	5 (6.0 %)	15 (18.1 %)	54 (65.1 %)	9 (10.8 %)
A genetic counselor who provided incorrect or inappropriate health screening advice ($N = 83$)	4 (4.8 %)	18 (21.7 %)	45 (54.2 %)	16 (19.3 %)
A genetic counselor who provided inappropriate psychosocial support to a patient ($N = 83$)	3 (3.6 %)	25 (30.1 %)	44 (53 %)	11 (13.2 %)
A genetic counselor who provided an incorrect risk calculation ($N = 83$)	2 (2.4 %)	22 (26.5 %)	(38) 45.7 %	22 (26.5 %)
A genetic counselor who did not obtain written or verbal consent for genetic testing ($N = 83$)	2 (2.4 %)	12 (14.4 %)	61 (73.5 %)	8 (9.6 %)
A genetic counselor who interpreted a molecular or cytogenetic result incorrectly ($N = 82$)	1 (1.2 %)	8 (9.8 %)	59 (72.0 %)	14 (17.1 %)
A genetic counselor who behaved inappropriately with a patient ($N = 83$)	1 (1.2 %)	7 (8.4 %)	70 (84.3 %)	5 (6.0 %)
A genetic counselor who behaved unethically in clinical practice ($N = 83$)	0	9 (10.8 %)	61 (73.5 %)	13 (15.7 %)
Statements posed to assess attitudes regarding professional regulation and risk of harm in genetic counseling practice		Agree/ strongly agree	Neutral or Do not know	Disagree/ strongly disagree
There currently exists a significant risk to cause psychological harm to patients in the practice of genetic counseling ($N = 82$)		43 (52.4 %)	21 (25.6 %)	18 (21.9 %)
There currently exists a significant risk to cause physical harm to patients in the practice of genetic counseling ($N = 81$)		17 (20.9 %)	17 (20.9 %)	47 (58.0)
Regulation of the genetic counseling profession would promote a safer/more effective delivery of services ($N = 84$)		54 (64.2 %)	24 (28.5 %)	6 (7.1 %)
If genetic counselors become regulated, I am likely to comply with the regulations set out by the regulatory body/ college ($N = 82$)		73 (89.0 %)	9 (11.0 %)	0
I am in support of regulation for genetic counselors ($N = 83$)		63 (75.9 %)	15 (18.0 %)	5 (6.0 %)

Table 6 Risk for harm in genetic counseling practice - anecdotal observations shared by subjects (sorted according to DORA categories) (State of Colorado 2013)

DORA category	Observations shared by participants	Possible or actual harmful effect on patient
Inaccurate test interpretation	Communicating a cancer gene mutation as pathogenic when it was in fact a benign variant	Unnecessary or inappropriate risk-reducing surgery[a]
Incomplete / inaccurate risk assessment	Missing a significant cancer history in a pedigree	Inadequate screening or testing recommendations[a]
	Pregnancy termination based on a gross overestimate of risk to a fetus	Inappropriate termination of pregnancy[a]
		Psychological harm[b]
Inadequate training specializing in genetics	Lacking knowledge needed to provide accurate medical education and counseling for a specific referral indication	Patient making misinformed decision regarding testing or disease management[b]
Inadequate Training	Health professional from another field receiving limited genetic counseling training, and failed to recognize and explore significant finding in family history	Patient is unaware of increased risk for genetic disease and is not given option to access preventative measures[b]
Title Misuse	An individual assuming the title of Genetic Counselor with no formal training in the field	Misrepresentation to public and a threat due to lack of competency[b]
		Patients unknowingly receive incomplete or inaccurate risk assessment or recommendations[b]
Medical malpractice	Performing controlled acts (such as ordering tests and communicating diagnoses) with insufficient medical oversight due to unavailability of responsible physician	Medical error in interpretation or care that leads to psychological or physical harm to patient[b].
Psychological and financial issues	None reported	
Alleged wrongful birth	None Reported	

[a] Anecdotal report of actual incidents by the participants

[b] Postulated as potential harmful outcomes by the authors

Discussion

Our study demonstrates that most (67.8 %, $N = 90$) Ontario genetic counselors have a clearly defined entry to practice (via accredited Master's degree training programs), and significant involvement in direct patient care activities. They typically perform their duties with high levels of independence with respect to clinical judgment and decision-making, patient care, test ordering and interpretation and case management activities. There appears to be a tendency for case-types with a higher potential for abnormal or medically actionable outcomes to be associated with lower rates of high-level independence. For example, genetic counselling for a negative carrier test or for consanguinity (where the outcome is unlikely to be abnormal) was associated with high-level independence rates of 78.9 % and 74.2 % respectively. Conversely, genetic counselling for a fetal ultrasound abnormality or a positive DNA result for a predictive test was associated with high-level independence rates that were lower (17.8 % and 19.7 % respectively) (Table 8).

Ontario genetic counselors also have significant roles in consulting to other health care providers about the interpretation and implications of genetic test results, evidencing their expertise and potential value to inter-professional practice beyond direct patient care activities.

A minority of genetic counselors (15.9 %, $N = 88$) reported working in non-medical genetics settings, where they have limited or no access to a medical geneticist for supervision or consultation. In these cases, the genetic counselor may be the only health professional with formal medical genetics training, and thus be relied upon to guide colleagues in test choice and interpretation. This level of autonomy may increase the potential risk for public harm. As a means of ensuring that only highly qualified individuals are permitted to provide genetic counseling with this high level of autonomy, tighter controls (via regulation or other accountability measures) should be considered.

Cancer genetic counselors represent one of the first examples of sub-specialization of the genetic counseling field. Cancer genetic counselors (and other expert genetic counselor specialists) are likely to act as the genetics experts in their clinical settings, and may be more likely to be relied upon to interpret results, consult to other health professionals, execute genetic testing and communicate positive results to patients. The fact that cancer genetic counselors were significantly more likely to be ABGC-trained, and reported higher levels of practice autonomy may be a reflection of the value that non-genetics-trained physicians place on accredited training routes to practice entry, and the unique skill set and knowledge gained from such graduate education programs.

Table 7 Clinical oversight for controlled acts performed by the genetic counselor

Physician-type providing clinical oversight and medical delegation to participant[a] ($N = 88$)	
Medical geneticist	74 (84.1 %)
Metabolic geneticist	15 (17.0 %)
Oncologist	9 (10.2 %)
Obstetrician	9 (10.2 %)
Family physician	8 (9.1 %)
Surgeon	6 (6.8 %)
MD laboratory director	6 (6.8 %)
Pediatrician	5 (5.7 %)
Gastroenterologist	5 (5.7 %)
Other medical specialist	3 (3.4 %)
Hematologist	3 (3.4 %)
Ophthalmologist	2 (2.3 %)
Endocrinologist	2 (2.3 %)
At least some medical geneticist delegation	74 (84.1 %)
No medical geneticist delegation	14 (15.9 %)
Agreement frequencies[b] for statements regarding adequacy of clinical oversight and medical delegation of controlled acts ($N = 84$)	
The level of clinic oversight received *does not* adequately protect patients from harm	15 (17.8 %)
There have been circumstances in which the level of clinical oversight was insufficient and *may have* caused harm to patients	25 (29.7 %)
There have been circumstances in which the level of clinical oversight was insufficient and *did* cause harm to patients	3 (3.5 %)
The institutional policies, medical directives and/or delegation in my place of work are not adequate to protect genetic counseling clients from harm	49 (58.3 %)

A controlled act is defined as a restricted medical act that may only be performed by a regulated health professional with legal authorization to perform it, or by a person to whom that act has been delegated by a regulated health professional authorized to do so. In the case of this study, "communicating a diagnosis" and "ordering a diagnostic test" were the two relevant controlled acts examined

[a] Some subjects reported receiving medical delegation from more than one source

[b] Number of participants who either "agreed" or "strongly agreed" to statements

Ontario genetic counselors also perceive that there are potential risks for both psychological and physical harm to patients, intrinsic to their practice, as evidenced by subjective measures of hypothetical case scenarios and anecdotal reports. Given the relatively low frequency with which each scenario was reported to have been observed, and the very few true incidents actually reported, the *potential* risk for harm appears to be greater than any realized risk to date. The majority of Ontario genetic counselors also appear to be supportive of regulation of the profession.

Study Limitations

A concerted effort was made to identify and invite the participation of all genetic counselors in Ontario. However the researchers were required to use a loose definition of genetic counselor, given the diverse training and backgrounds of individuals in Ontario who provide genetic counseling services. This may have contributed to unintended inclusion or exclusion of some participants. The data generated from this study should be interpreted with caution, and are subject to response and ascertainment biases that are often inherent to this research modality. Most responses relied heavily on participant recollection and subjective estimates. At the time the survey was administered, whole exome sequencing and next generation sequencing panels were not standard of care. Thus we were unable to accurately measure clinical practices related to counseling for and interpreting variants of uncertain clinical significance. Finally, although Ontario may be thought of as a paradigm for medical genetics practice in other Canadian provinces, we may not be able to generalize all of our results, given the provincial-based health care and legislation for professional regulation in our country (similar to the U.S. state-based licensure).

Practice Implications

Genetic counselors are growing as a professional body at a rapid rate. Many are migrating from traditional medical genetics team practices towards specialty practices (including

Table 8 Self-reported high-level independence cases for subjects by case-type and category

Genetic counseling case type and category[a]	Those reporting routine involvement in case-type	Those with routine involvement who report high-level independence
Prenatal genetic counseling		
Aneuploidy risk ($N = 87$)	60 (68.9 %)	58 (96.6 %)
Positive prenatal multiple marker ($N = 86$)	59 (68.6 %)	55 (63.9 %)
Fetal ultrasound marker/soft sign ($N = 86$)	56 (65.1 %)	40 (46.5 %)
Pregnancy termination counseling ($N = 86$)	61 (70.9 %)	24 (27.9 %)
Aneuploidy detected on prenatal diagnosis ($N = 86$)	58 (67.4 %)	17 (19.7 %)
Prenatal diagnosis of a single gene disease ($N = 86$)	63 (73.2 %)	17 (19.7 %)
Fetal ultrasound abnormality ($N = 85$)	56 (65.8 %)	10 (17.8 %)
General genetic counseling		
Consanguinity ($N = 85$)	66 (77.6 %)	49 (74.2 %)
Family history of single gene disease ($N = 85$)	71 (83.5 %)	46 (64.8 %)
Balanced chromosomal rearrangement ($N = 85$)	66 (77.6 %)	39 (59.0 %)
Counseling for previously confirmed DNA dx ($N = 85$)	68 (80.0 %)	27 (39.7 %)
Pre-symptomatic counseling for adult-onset disease ($N = 85$)	51 (60.0 %)	13 (25.4 %)
Unbalanced chromosome rearrangement in a patient ($N = 85$)	66 (77.6 %)	14 (21.2 %)
Cancer genetic counseling		
NEG DNA result for a patient with a prior CA dx ($N = 86$)	57 (66.2 %)	45 (78.9 %)
NEG DNA result for a patient with no prior CA dx ($N = 87$)	58 (66.6 %)	45 (78.9 %)
POS FH of a CA predisposition syndrome ($N = 87$)	59 (67.8 %)	41 (47.1 %)
POS FH of CA with unknown genetic etiology ($N = 87$)	55 (63.2 %)	33 (37.9 %)
POS DNA result for a patient *with no* prior CA dx ($N = 87$)	57 (65.5 %)	21 (24.1 %)
POS gene result for a patient *with* a prior CA dx ($N = 87$)	58 (66.6 %)	21 (24.1 %)
CA-related screening recommendations ($N = 87$)	46 (52.8 %)	16 (18.4 %)
Communicating genetic testing results		
NEG result for a single gene disorder carrier test ($N = 86$)	80 (93.0 %)	67 (83.8 %)
POS result for a single gene disorder carrier test ($N = 86$)	82 (95.3 %)	53 (64.6 %)
NEG diagnostic test result in a symptomatic patient ($N = 86$)	74 (86.0 %)	32 (43.2 %)
NEG predictive test result for an adult onset disease ($N = 86$)	65 (75.6 %)	24 (36.9 %)
POS predictive test result for an adult onset disease ($N = 86$)	66 (76.7 %)	13 (19.7 %)
POS diagnostic test result in a symptomatic patient ($N = 86$)	74 (86.0 %)	20 (27.0 %)

A high-level independence case is defined as a consultation for which there is typically no face-to-face contact between the patient and the responsible physician on the day of the specified visit

[a] *NEG* negative, *POS* positive, *CA* cancer, *FH* family history, *Dx* diagnosis

commercial laboratories) and functioning with high levels of independence. As this trend continues and the demand for and availability of genetic testing continues to grow, so will the need for trained genetic counselors who can work as genetics experts in non-traditional settings. The demand for trained genetic counselors currently outweighs the number of new graduates available for hire. The risk is that without title protection or public accountability measures, unqualified individuals may be hired to provide genetic counseling services. Given that there is a risk of harm inherent to our practice, considering the feasibility of regulation or other accountability and title protection measures is incumbent upon us. A dialogue with policy makers and other stakeholders to explore accountability measures as a means to ensure that genetic counseling is provided only by appropriately trained professionals is timely.

Research Recommendations

With evidence that genetic counseling practice within Canada poses a risk for harm, it would be important to assess such risks, as they relate to the role of genetic counselors in the era of genomic and personalized/precision medicine. Looking at the current barriers to hiring qualified genetic counselors in Canada may help to identify opportunities in the system to

promote safe patient care. Assessing the public's experiences with genetic counseling services in the province may uncover vulnerabilities with respect to potential harm. Finally, better-quantifying Canadian genetic counselors' understanding of and support for professional regulation will help guide efforts to improve accountability in the profession.

Conclusion

The practice trends that we have elucidated support further investigation into the need and feasibility of professional regulation of Ontario genetic counselors. This will ensure the continued provision of high-quality, safe and accessible genetic counseling services for patients, families and as well as expert and accurate input for non-geneticist health care providers. It will also pave the way for genetic counselors to integrate into new interprofessional healthcare teams in order to respond effectively to the anticipated future demands of genomic medicine.

Acknowledgments The authors wish to acknowledge and thank the Canadian Association of Genetic Counselling for funding via a special project grant, Ms. Cheryl Shuman for her thoughtful and thorough scientific review of our research proposal and manuscript, and Ms. Gabrielle Herman for her assistance in preparing this manuscript.

Compliance with Ethical Standards

Funding This research project received funding via a Canadian Association of Genetic Counsellors special project grant awarded to the authors, who were co-investigators.

Conflict of Interest Authors Andrea Shugar, Nada Quercia and Christopher Trevors declare that they have received a special project grant from the Canadian Association of Genetic Counsellors to conduct this research as part of a larger project.

Author Marina M. Rabideau declares that she has no conflict of interest.

Author Sohnee Ahmed declares that she has no conflict of interest.

Human Studies and Informed Consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). Informed consent was obtained from all patients for being included in the study.

Ethical Approval Ethics approval was sought and granted for this research project through the Hospital for Sick Children Research Ethics Board and in accordance with the Canadian government's Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans.

References

Andermann, A., & Blancquaert, I. (2010). Genetic screening: a primer for primary care. *Canadian Family Physician, 56*(4), 333–339.

Andermann, A., & Narod, S. A. (2002). Genetic counselling for familial breast and ovarian cancer in Ontario. *Journal of Medical Genetics, 39*(9), 695–696.

Austin, J., Semaka, A., & Hadjipavlou, G. (2014). Conceptualizing genetic counseling as psychotherapy in the era of genomic medicine. *Journal of Genetic Counseling, 23*(6), 903–909.

Bensend, T. A., Veach, P. M., & Niendorf, K. B. (2014). What's the harm? Genetic counselor perceptions of adverse effects of genetics service provision by non-genetics professionals. *Journal of Genetic Counseling, 23*(1), 48–63.

Botkin, J. R., Belmont, J. W., Berg, J. S., Berkman, B. E., Bombard, Y., Holm, I. A., et al. (2015). Points to consider: ethical, legal, and psychosocial implications of genetic testing in children and adolescents. *American Journal of Human Genetics, 97*(1), 6–21.

CAGC, C. A. O. G. C. (2012a). *2011 CAGC Professional Status Survey*, from https://www.cagc-accg.ca/doc/2011%20PSS%20report%20-%20English%20(1).pdf.

CAGC, C. A. O. G. C. (2012b). *Knowledge-Based Competencies for Canadian Genetic Counsellors*, from https://www.cagc-accg.ca/doc/knowledge_based_competencies_final_french_translation%20-%20june%2026%2C%202012.pdf.

CAGC, C. A. O. G. C. (2012c). *Practice-Based Competencies for Canadian Genetic Counsellors*, from https://www.cagc-accg.ca/doc/cagc%20practice%20based%20competencies.pdf.

Cameron, L. D., & Muller, C. (2009). Psychosocial aspects of genetic testing. *Current Opinion in Psychiatry, 22*(2), 218–223.

Canada, S. (2015). *Estimates of population*, *Canada*, *provinces and territories*, *quarterly* (*persons*), from http://www5.statcan.gc.ca/cansim/a26?lang=eng&retrLang=eng&id=0510005&&pattern=&stByVal=1&p1=1&p2=31&tabMode=dataTable&csid=.

Carroll, J. C., Rideout, A. L., Wilson, B. J., Allanson, J. M., Blaine, S. M., Esplen, M. J., et al. (2009). Genetic education for primary care providers: improving attitudes, knowledge, and confidence. *Canadian Family Physician, 55*(12), e92–e99.

Christian, S., Lilley, M., Hume, S., Scott, P., & Somerville, M. (2012). Defining the role of laboratory genetic counselor. *Journal of Genetic Counseling, 21*(4), 605–611.

Clarke, A., & Thirlaway, K. (2011a). Genetic counselling for personalised medicine. *Human Genetics, 130*(1), 27–31.

Clarke, A., & Thirlaway, K. (2011b). 'Genomic counseling'? Genetic counseling in the genomic era. *Genome Medicine, 3*(1), 7.

Dillman, D. A. (2007). *Mail and internet surveys: The tailored design method* (2nd ed.). Hoboken: Wiley.

Egalite, N., Groisman, I. J., & Godard, B. (2014). Genetic counseling practice in next generation sequencing research: implications for the ethical oversight of the informed consent process. *Journal of Genetic Counseling, 23*(4), 661–670.

Eisenstein, M. (2015). Genetics: fluent in DNA. *Nature, 526*(7571), 151–152.

Featherstone, C., Colley, A., Tucker, K., Kirk, J., & Barton, M. B. (2007). Estimating the referral rate for cancer genetic assessment from a systematic review of the evidence. *British Journal of Cancer, 96*(2), 391–398.

Frelick, K., & McFadden, J. (2009). Significant changes to Ontario's regulated health professions act, 1991 in effect. *Health Law in Canada, 30*(1), 24–27.

Gordon, E. S., Griffin, G., Wawak, L., Pang, H., Gollust, S. E., & Bernhardt, B. A. (2012). "It's not like judgment day": public understanding of and reactions to personalized genomic risk information. *Journal of Genetic Counseling, 21*(3), 423–432.

Green, E. D., Guyer, M. S., & Institute, N. H. G. R. (2011). Charting a course for genomic medicine from base pairs to bedside. *Nature, 470*(7333), 204–213.

Guttmacher, A. E., McGuire, A. L., Ponder, B., & Stefánsson, K. (2010). Personalized genomic information: preparing for the future of genetic medicine. *Nature Reviews. Genetics, 11*(2), 161–165.

Hawkins, A. K., & Hayden, M. R. (2011). A grand challenge: providing benefits of clinical genetics to those in need. *Genetics in Medicine, 13*(3), 197–200.

Hooker, G. W., Ormond, K. E., Sweet, K., & Biesecker, B. B. (2014). Teaching genomic counseling: preparing the genetic counseling workforce for the genomic era. *Journal of Genetic Counseling, 23*(4), 445–451.

Horowitz, M., Sundin, E., Zanko, A., & Lauer, R. (2001). Coping with grim news from genetic tests. *Psychosomatics, 42*(2), 100–105.

Houwink, E. J., Henneman, L., Westerneng, M., van Luijk, S. J., Cornel, M. C., Dinant, J. G., et al. (2012). Prioritization of future genetics education for general practitioners: a Delphi study. *Genetics in Medicine, 14*(3), 323–329.

HPRAC, H. P. R. A. C. (2011). *Regulation of a New Health Profession Under the Regulated Health Professions Act*, from http://www.hprac.org/en/reports/resources/RegulatingaNewProfession_CriteriaProcess_Nov2011.pdf.

Ingles, J., Yeates, L., & Semsarian, C. (2011). The emerging role of the cardiac genetic counselor. *Heart Rhythm, 8*(12), 1958–1962.

Korf, B. R., Berry, A. B., Limson, M., Marian, A. J., Murray, M. F., O'Rourke, P. P., et al. (2014). Framework for development of physician competencies in genomic medicine: report of the competencies working Group of the Inter-Society Coordinating Committee for physician education in genomics. *Genetics in Medicine, 16*(11), 804–809.

Machini, K., Douglas, J., Braxton, A., Tsipis, J., & Kramer, K. (2014). Genetic counselors' views and experiences with the clinical integration of genome sequencing. *Journal of Genetic Counseling, 23*(4), 496–505.

Martin, D. K., Greenwood, H. L., & Nisker, J. (2010). Public perceptions of ethical issues regarding adult predictive genetic testing. *Health Care Analysis, 18*(2), 103–112.

Matloff, E. T., & Barnett, R. E. (2011). The growing role for genetic counseling in endocrinology. *Current Opinion in Oncology, 23*(1), 28–33.

McCabe, E., Guttmacher, A., Hegele, R., Holtzman, N., & McKenzie, A. (2001). Genetic Services in Ontario: Mapping the Future. A Report of the Provincial Advisory Committee on New Predictive Genetic Technologies. In O. M. O. H. A. L. T. Care (Ed.)).

McGowan, M. L., Glinka, A., Highland, J., Asaad, G., & Sharp, R. R. (2013). Genetics patients' perspectives on clinical genomic testing. *Personalized Medicine, 10*(4), 339–347.

Mendes, A. F., Santos, T. A., & Sousa, L. (2011). Experiencing genetic counselling for hereditary cancers: the client's perspective. *European Journal of Cancer Care (Engl), 20*(2), 204–211.

Mills, R., & Haga, S. B. (2014). Genomic counseling: next generation counseling. *Journal of Genetic Counseling, 23*(4), 689–692.

MOHLTC, O. (2016). *Health Workforce Planning and Regulatory Affairs Division*: *Regulated Professions*, from http://www.health.gov.on.ca/en/pro/programs/hhrsd/about/regulated_professions.aspx.

MOHLTC, O. M. O. H. A. L. T. C. (2002). Genetics, Testing and Gene Patenting:*Charting New territory in Healthcare*, from http://www.ontla.on.ca/library/repository/mon/3000/10301166.pdf.

O'Daniel, J. M. (2010). The prospect of genome-guided preventive medicine: a need and opportunity for genetic counselors. *Journal of Genetic Counseling, 19*(4), 315–327.

Ontario, G. O. (1991, 2015). *Regulated Health Professions Act*, *1991*, from https://www.ontario.ca/laws/statute/91r18.

Ontario, C. C. (2008). *Ensuring access to high quality molecular oncology laboratory testing and clinical cancer genetic services in Ontario*: *Report of the Molecular Oncology Task Force*, from https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=31935.

Ontario, C. o. P. a. S. o. (1999, 2012). *Delegation of Controlled Acts*, from http://www.cpso.on.ca/policies-publications/policy/delegation-of-controlled-acts.

Ormond, K. E. (2013). From genetic counseling to "genomic counseling". *Molecular Genetics & Genomic Medicine, 1*(4), 189–193.

Powell, K. P., Hasegawa, L., & McWalter, K. (2010). Expanding roles: a survey of public health genetic counselors. *Journal of Genetic Counseling, 19*(6), 593–605.

Radford, C., Prince, A., Lewis, K., & Pal, T. (2014). Factors which impact the delivery of genetic risk assessment services focused on inherited cancer genomics: expanding the role and reach of certified genetics professionals. *Journal of Genetic Counseling, 23*(4), 522–530.

Resta, R. G. (2006). Defining and redefining the scope and goals of genetic counseling. *American Journal of Medical Genetics. Part C, Seminars in Medical Genetics, 142C*(4), 269–275.

Resta, R., Biesecker, B. B., Bennett, R. L., Blum, S., Hahn, S. E., Strecker, M. N., et al. (2006). A new definition of genetic counseling: National Society of genetic counselors' task force report. *Journal of Genetic Counseling, 15*(2), 77–83.

Rosen, L. J., & Sunshine, E. (2010). Amendments to the regulated health professions act, 1991: major implications for health care professionals. *Health Law in Canada, 30*(4), 227–228.

Shields, A. E., Burke, W., & Levy, D. E. (2008). Differential use of available genetic tests among primary care physicians in the United States: results of a national survey. *Genetics in Medicine, 10*(6), 404–414.

Somers, A. E., Ware, S. M., Collins, K., Jefferies, J. L., He, H., & Miller, E. M. (2014). Provision of cardiovascular genetic counseling services: current practice and future directions. *Journal of Genetic Counseling, 23*(6), 976–983.

Somerville, M. J., & Allingham-Hawkins, D. (2010). Regulation of genetic testing/service in Canada. In U. Kristoffersson, J. Schmidtke, & J. J. Cassiman (Eds.), *Quality issues in clinical genetic services* (pp. 83–90). Dordrecht, Heidelberg, London, New York: Springer.

State of Colorado, D. (2013). *2013 Sunrise Review*: *Genetic Counselors*, from http://hermes.cde.state.co.us/drupal/islandora/object/co%3A12704/datastream/OBJ/download/2013_sunrise_review__genetic_counselors.pdf.

Swanson, A., Ramos, E., & Snyder, H. (2014). Next generation sequencing is the impetus for the next generation of laboratory-based genetic counselors. *Journal of Genetic Counseling, 23*(4), 647–654.

Vanstone, M., Chow, W., Lester, L., Ainsworth, P., Nisker, J., & Brackstone, M. (2012). Recognizing BRCA gene mutation risk subsequent to breast cancer diagnosis in southwestern Ontario. *Canadian Family Physician, 58*(5), e258–e266.

Vig, H. S., & Wang, C. (2012). The evolution of personalized cancer genetic counseling in the era of personalized medicine. *Familial Cancer, 11*(3), 539–544.

Weil, J. (2002). Genetic counselling in the era of genomic medicine. As we move towards personalized medicine, it becomes more important to help patients understand genetic tests and make complex decisions about their health. *EMBO Reports, 3*(7), 590–593.

Zetzsche, L. H., Kotzer, K. E., & Wain, K. E. (2014). Looking back and moving forward: an historical perspective from laboratory genetic counselors. *Journal of Genetic Counseling, 23*(3), 363–370.

Zhou, Y. Z., Wilde, A., Meiser, B., Mitchell, P. B., Barlow-Stewart, K., & Schofield, P. R. (2014). Attitudes of medical genetics practitioners and psychiatrists toward communicating with patients about genetic risk for psychiatric disorders. *Psychiatric Genetics, 24*(3), 94–101.

Zierhut, H., & Austin, J. (2011). How inclusion of genetic counselors on the research team can benefit translational science. *Science Translational Medicine, 3*(74), 74cm77.