PROFESSIONAL ISSUE



Genetic counselors and legal recognition: A made-for-Canada approach

Deborah M. Lambert¹ Dimitri Patrinos² | Bartha Maria Knoppers² | GenCOUNSEL Study* | Ma'n H. Zawati²

¹National Rare Diseases Office, Mater Misericordiae University Hospital, Dublin, Ireland

²Centre of Genomics and Policy, Department of Human Genetics, Faculty of Medicine and Health Sciences, McGill University, Montreal, QC, Canada

Correspondence

Ma'n H. Zawati, Centre of Genomics and Policy, Department of Human Genetics, Faculty of Medicine and Health Sciences, McGill University, Montreal, OC, Canada. Email: man.zawati@mcgill.ca

Abstract

Genetic counseling is a fast-growing profession in Canada. Yet, despite its growth, genetic counseling lacks legal recognition in the majority of Canadian provinces. Legal recognition serves to regulate professions, including genetic counseling, that if not properly regulated, expose the public to the risk of harm. Under Canadian law, there are three models of legal recognition: 1) the constitution of a professional order, 2) inclusion in a professional order, and 3) delegation. This paper explores the practical implications of these different models of legal recognition for genetic counselors. It focuses on the balancing act between protecting the public and the resources required to seek legal recognition under the three different models. With a small number of genetic counselors (n = 484, with 89% found in 4 provinces) compared to other professions, the route toward professional regulation for genetic counselors can be challenging. Though legal recognition occurs at the provincial rather than federal level in Canada, we nonetheless advocate for pan-Canadian discussions that may benefit future pursuits of legal recognition.

KEYWORDS

genetic counseling, genetic counselors, policy, professional development, regulation

1 | INTRODUCTION

In 2018, there were an estimated 350 genetic counselors in Canada, with an estimated 270 actively practicing at the time (Abacan et al., 2019). Further workforce expansion is anticipated, with Canadian employers of genetic counselors generally willing to increase hires should financing permit (Costa et al., 2020). While the majority work in clinical genetics settings alongside clinical (or

medical) geneticists, an increasing number of genetic counselors are employed in a diverse range of settings and are becoming increasingly autonomous, taking on expanding roles in the health care system (Leeming, 2013; Shugar et al., 2017). Despite such expansion of practice beyond the tertiary genetics clinic, access to genetic counseling services remains largely limited. Alongside the evolving scope of the profession, the need for regulation of the practice of genetic counseling has been highlighted to assure safe practice (Shugar

[†]GenCOUNSEL was funded through the Large Scale Applied Research Project (LSARP) Genome Canada competition with co-funding from: Canadian Institutes for Health Research (CIHR). Genome BC, Genome Ouebec, Provincial Health Services Authority, BC Children's Hospital Foundation and BC Women's Hospital Foundation. The GenCOUNSEL Study is led by Alison M. Elliott, Jehannine Austin, Bartha Maria Knoppers, and Larry D. Lynd with Project Manager Alivia Dey, and includes the following co-investigators: Shelin Adam, Nick Bansback, Patricia Birch, Lorne Clarke, Nick Dragojlovic, Jan Friedman, Deborah M. Lambert, Daryl Pullman, Alice Virani, Wyeth Wasserman, and Ma'n H. Zawati

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made. © 2021 The Authors. Journal of Genetic Counseling published by Wiley Periodicals LLC on behalf of National Society of Genetic Counselors

Deborah M. Lambert and Dimitri Patrinos should be considered joint first author.

50 WILEY Counselors

et al., 2017) and there have been several calls in the literature for legal recognition in Canada (Shugar et al., 2017; Zawati, 2012, 2018).

In Canada, legal recognition serves to protect the public by regulating the safe and competent practice of health care professionals (Aldridge, 2008; Shugar et al., 2017). Legal recognition is determined at the provincial or territorial rather than federal level, and is generally reserved for professions that pose a risk of harm to the health and safety of the public if not properly regulated. While the term 'profession', in the legal sense, is generally reserved for occupations that have become legally recognized, we employ the term here in its general sense. Genetic counseling is largely unregulated in Canada, where only the province of Manitoba has legally recognized it by allowing delegation from physicians (Government of Manitoba, 2018; Patrinos et al., 2020). This lack of legal recognition is typical of the genetic counseling profession internationally, as only a few countries have legally recognized genetic counseling (Abacan et al., 2019; Ormond et al., 2018).

It is therefore timely to further pursue the question of legal recognition and explore its implications for genetic counselors in Canada. Genetic counselors in several Canadian provinces are actively pursuing legal recognition (Abacan et al., 2019). Issues of legal recognition are further being explored through the large-scale research project GenCOUNSEL, which aims to optimize genetic counseling services across Canada (Genome Canada, 2017). Though plausible models of legal recognition have been identified for genetic counselors in Canada (Patrinos et al., 2020), it would be an advantage to the profession to balance the practical advantages and disadvantages of each model. In particular, we will consider protecting the public from the risk of harm versus the wherewithal necessary to implement legal recognition under these different models. We have determined the number of genetic counselors within each province and territory to better inform the feasibility of each of these models. This article will therefore serve as an organizational framework for genetic counselors in Canada as they move toward legal recognition. Our analysis may also be a model for genetic counselors in other jurisdictions where legal recognition is being sought.

2 | DISCUSSION

2.1 | Genetic counseling practice in Canada

The practice of genetic counseling in Canada corresponds to the definition of genetic counseling: 'the process of helping people understand and adapt to the medical, psychological, and familial implications of the genetic contributions to disease' (Resta et al., 2006, p. 79). The emphasis on the different elements of this model – interpretation of family and medical histories, patient education, and counseling (Resta et al., 2006) – varies depending on the genetic counselor's area of specialization and their role within their multi-disciplinary team or independent practice. Canada-based respondents to the Canadian Association of Genetic Counsellors (CAGC)/National Society of Genetic Counselors (NSGC) professional survey

report that 60% provide direct patient care while 25% provide a mix of direct patient care and non-patient care (CAGC, 2020).

As in other countries, the status and role of the genetic counselor in Canada continue to evolve, and the history of genetic counseling in Canada has been well documented by the CAGC (Zeesman & Creighton, 2000) and by Leeming (2013). The CAGC's Professional Status Surveys provide valuable information about trends over time in the roles and responsibilities of Canadian genetic counselors. While in 1991, 26.2% of practicing genetic counselors used the official job title 'genetic counsellor' (Leeming, 2013), over 94% used the title in 2016 (CAGC, 2016). In 2016, 9.9% of genetic counselors surveyed were laboratory based, while by 2020, 13% of genetic counselors surveyed were laboratory-based, either in public or in private laboratories (CAGC, 2020). In 2016, 1.6% were in private practice (CAGC, 2016), while in 2020, 15% of were working in a private institution, private practice, or commercial company, with 54% of them working in diagnostic laboratories (CAGC, 2020).

The majority of health care providers hiring clinical genetic counselors in Canada will stipulate that candidates should be boardeligible or board-certified with either the CAGC or the American Board of Genetic Counseling (ABGC) (Abacan et al., 2019; Shugar et al., 2017). Since 2021, a new certification board called the Canadian Board of Genetic Counselling (CBGC) has assumed the role of certifying genetic counselors practicing in Canada from the CAGC (CAGC, 2021). Certification may not be required by employers of genetic counselors practicing in research or other nonclinical roles. Seven percent of respondents to the 2020 CAGC/ NSGC Professional Status Survey Summary had neither CAGC nor ABGC certification, either having never certified or not renewed their certification (CAGC, 2020). Although the genetic counselors without certification were mostly recent graduates, the reasons for not obtaining certification included 'board certification not necessary for job' and 'did not recertify' (CAGC, 2020). The 2016 CAGC Professional Status Survey Summary found that, of members surveyed, 70% were CAGC certified, 21% were CAGC certificationeligible, and 61% held ABGC certification (CAGC, 2016). In 2011, non-certified genetic counselors reported 14% less pay than certified genetic counselors; however, only 2% received pay increase and none had received promotion upon certification (CAGC, 2012).

Other published estimates of the number of genetic counselors in Canada have been based on membership in the CAGC (CAGC, 2012, 2016), membership in the CAGC and/or NSGC (CAGC, 2020), or an estimated number of employed genetic counselors (Abacan et al., 2019). It is important to ascertain, in the context of regulation in Canada, the number of individuals per province or territory who might reasonably be considered genetic counselors for purposes of legal recognition, independent of current employment status or professional association membership.

Genetic counselors participating in the CAGC provincial professional regulation interest group, who are collaborators on the GenCOUNSEL project, from each Canadian province and territory were asked: (1) Whether there is a provincial association of genetic counselors in their province and (2) The estimated number of genetic counselors in the province: individuals, whether full- or part-time, employed in any setting or unemployed. The number of genetic counselors per 100,000 population was calculated using Q1 2020 provincial population estimates (Statistics Canada, 2020). We estimate that there are 484 individual genetic counselors in Canada. The number of genetic counselors per province or territory ranges from 0 in New Brunswick, the Northwest Territories, and Nunavut to 235 in Ontario. The number of genetic counselors per 100,000 population in Canada is 1.28, with the distribution by province shown in Table 1.

Our figure of 484 genetic counselors, or 1.28 per 100,000 population, is higher than Abacan et al.'s (2019) estimate of 350 genetic counselors. With 89% of these genetic counselors residing in the four provinces of British Columbia, Alberta, Ontario, and Quebec (representing 86.5% of the Canadian population), progression toward legal recognition may be more straightforward in some provinces and territories than others.

2.2 | Legal recognition in Canada

Canada is a federation and a parliamentary democracy composed of 10 provinces and 3 territories with a publicly funded health care system. Jurisdiction of health care-related matters is constitutionally determined and shared between the federal and the provincial and territorial governments. Federal responsibilities include providing funding for provincial health care insurance programs, health research, and health promotion (Government of Canada, 2019). The provinces and territories are responsible for the majority of

TABLE 1Demographics of Canadiangenetic counselors (GCs) by province andterritory. Provincial population estimatesare for Q1 2020 (Statistics Canada, 2020)

the provision and administration of health care services, including the planning and funding of hospital services and the regulation of health care professions (Government of Canada, 2019). The legal recognition of genetic counselors in Canada therefore falls under provincial or territorial rather than national (i.e., federal) jurisdiction.

Legal recognition in Canada involves the enactment of legislation to regulate the practice of occupations that are considered to pose a risk of harm to the health and safety of the public if not regulated correctly (Shugar et al., 2017). Genetic counselors routinely provide direct patient care activities susceptible of exposing the public to the risk of harm, such as risk assessments, ordering genetic tests, interpreting genetic test results, communicating diagnoses, and providing psychosocial counseling (Shugar et al., 2017). Moreover, the risk of harm extends not only to the patient, but also to family members for whom an error or omission in the patient's care could result in an altered or missed diagnosis (Brierley et al., 2012). Legal recognition would therefore ensure safer, high-quality provision of genetic counseling services to the public by establishing educational and professional standards for genetic counselors, limiting the use of the title 'genetic counselor' to qualified practitioners, and affording public protection through fitness-to-practice assessment when necessary.

Protecting the public from risk of harm is the primary consideration in regulating healthcare professions in Canada. The Quebec Association of Genetic Counsellors' submission to the Quebec Office des professions (the province's professional supervisory body) (Fox & Secord, 2016) outlines anecdotal accounts of harm highlighted by their members. These accounts of potential or actual harm concern either substandard practice from a genetic counselor, or provision of inadequate erroneous genetic information from non-genetic health

Province/Territory	No. of GCs	Population (in 1,000s)	GCs per 100,000 population	Provincial GC association? (Y/N)
British Columbia	90	5,111	1.76	Y (joint association with the Yukon Territory)
Alberta	45	4,413	1.02	Υ
Saskatchewan	8	1,182	0.68	Ν
Manitoba	14	1,358	1.03	Ν
Ontario	235	14,712	1.60	Υ
Quebec	60	8,538	0.70	Y
New Brunswick	0	780	0.00	Ν
Nova Scotia	21	977	2.15	Ν
Prince Edward Island	1	157	0.64	Ν
Newfoundland and Labrador	9	521	1.73	Ν
Northwest Territories	0	45	0.00	Ν
Yukon Territory	1	41	2.44	Y (joint association with British Columbia)
Nunavut	0	39	0.00	Ν
Total	484	37,874	1.28	



care professionals. The accounts (Fox & Secord, 2016) encompass harm in the areas of wrongful termination or sterilization, inappropriate surgery or management, harm to relatives, inappropriate testing of minors, insurance and employment discrimination, and psychological distress. This demonstrates the wide-ranging competencies in communication, ethical practice, and highly specialized knowledge necessary in genetic counseling practice.

Legal recognition would also entail numerous other benefits for the public and the health care system in Canada besides protection of the public from harm. Genetic counselors are a scarce resource in Canada, with employers generally willing to increase hires should financing permit (Costa et al., 2020). Lack of legal recognition largely restricts genetic counseling services to genetics clinics alongside clinical geneticists in tertiary health care settings found in major cities (Elliott & Friedman, 2018). It is also important to note that clinical geneticists are also an under-resourced medical specialty with 111 practitioners in Canada (Canadian Medical Association, 2019). This limited number of clinical geneticists may restrict the expansion of non-regulated genetic counseling practice in tertiary health care genetics clinics. As well, 18.5% of the Canadian population does not reside in an urban area (World Bank Data, 2021), limiting their access to genetic counseling in tertiary settings. Given the increasing demand for genetic services, limited access remains a major problem for patients requiring genetic counseling in Canada. In Ontario, the province with the largest number of genetic counselors (Table 1), average wait times for genetic counseling services range from approximately 1 month to 2 years (Cancer Care Ontario, 2018). Wait times are even longer in provinces with very few genetic counselors, such as Newfoundland and Labrador, where the waitlist for genetic counseling services is nearly 3 years long (Hynes et al., 2020). Legal recognition can help increase accessibility and equitable access to genetic counseling services, improving patient care outcomes. Indeed, legal recognition as independent health care practitioners may allow for further expansion beyond the tertiary care genetics clinic.

Additionally, legal recognition of genetic counseling can help decrease financial costs to the health care system. Genetic tests ordered by primary health care providers unfamiliar with genetic testing can result in incorrect or unnecessary testing being ordered, increasing cost expenditures (Brierley et al., 2012). Genetic counselors, through their specialized knowledge and training, have been shown to decrease expenditures to the health care system and increase cost efficiencies, especially as the health care system moves toward genomic medicine (Branda, 2017; Dragojlovic et al., 2020; Suarez et al., 2017; Wakefield et al., 2018).

2.3 | Lack of legal recognition of genetic counseling and the role of the CBGC

To date, Manitoba is the only jurisdiction in Canada to legally recognize genetic counseling, whereby genetic counselors may legally communicate a diagnosis relating to a genetic disease or disorder under certain conditions through delegation from physicians (Patrinos et al., 2020). Consequently, the majority of genetic counselors in Canada practice as unregulated health care providers.

In the near-total absence of legal recognition ensuring the safer practice of genetic counseling in Canada, the CBGC has taken on an organizational role, ensuring that members of the Canadian public receive genetic counseling services from individuals who have demonstrated a high level of competency (CBGC, 2021a). To do so, the CBGC has adopted four pathways toward certification for candidates who have graduated from a Master's program in genetic counseling (CBGC, 2021b). Certification is valid for a period of 10 years, after which certified genetic counselors must become recertified through either reexamination or through an accumulation of continuing practice credits (CPCs) and continuing education credits (CECs) (CBGC, 2021c).

Despite its organization of genetic counseling in Canada, there are several differences between the CBGC's certification system and legal recognition. CBGC certification is voluntary and not a legal requirement to practice genetic counseling in Canada or use the title of genetic counselor. The CBGC does not currently offer any formal complaints or disciplinary processes against its diplomates. Even in the event a genetic counselor is decertified, the CBGC does not have the legal authority to prevent the former member from continuing to practice genetic counseling. Moreover, many genetic counselors practice in Canada on the basis of their certification with the ABGC and a minority on the basis of certification with other international certification boards, rather than with the CBGC. The CBGC does not have jurisdiction over these individuals, even though many employers hire genetic counselors in Canada based on their ABGC certification. The CBGC also does not have jurisdiction over the 7% (CAGC, 2020) who are neither Canadian nor American board-certified, nor is it able to prevent individuals who do not have a Master's degree in genetic counseling from providing genetic counseling services to the public.

Thus, despite its organizational role, none of the mechanisms put in place by the CBGC are legally binding and do not protect the public to the same degree as legal recognition would. This is further compounded by the fact that oversight over the practice of genetic counselors is not uniform and is shared between different certification bodies (or none at all). Legal recognition would ensure that all individuals offering genetic counseling services to the public within a given province or territory have the appropriate qualifications to do so and are all subject to the same requirements for practice. Given that genetic counseling is a rapidly evolving field, as knowledge of genetics is continually changing, the need to be qualified to practice with the appropriate safeguards is crucial. An exploration of the models of legal recognition available in Canada is therefore timely.

2.4 | Models of legal recognition in Canada

In our previous work, we identified three models of legal recognition available for genetic counselors in Canada through a comparative analysis of provincial professional legislation: (1) the constitution of a professional order, (2) inclusion in a professional order, and (3) delegation (Patrinos et al., 2020). The first two models involve a regulatory body, called an order or college (depending on the province), which governs the practice of its members in the public interest. Regulation under a professional order is similar to the concept of licensure in the United States (Shugar et al., 2017). Professional orders in Canada are self-regulating, through delegation by the provincial governments, and are responsible for the establishment and administration of educational and admissions requirements, rulemaking, and the setting and enforcement of practice and ethical standards (Lahey & Fierlbeck, 2016). They also provide public accountability mechanisms through formal complaints and disciplinary procedures (Shugar et al., 2017). Under the first model, an independent professional order is created, whereas in the second model an occupation becomes regulated through integration in an existing professional order. This is usually done where there is a sufficient overlap in scope of practice between an unregulated occupation and a regulated profession.

Legal professional status is granted in these two models. Membership within the professional order is obligatory to be able to practice the profession or use a professional title or designation. Entry into the professional order is controlled and individuals are legally prohibited from practicing the profession or using its title or designation without being a member of the order.

The third model, delegation, does not involve the creation of a professional order for an occupation and, therefore, does not grant legal professional status. Rather, delegation regulates the performance of certain specific health care acts, referred to as controlled, reserved, or restricted acts (depending on the province). These types of acts, such as communicating a diagnosis or prescribing medication, may only be performed by legally designated health care professionals (Ries, 2016). Individuals must fulfill various criteria to be able to perform these delegated acts (Patrinos et al., 2020). Manitoba's regulatory model falls within this category: physicians may delegate the reserved act of communicating a diagnosis relating to a genetic disease or disorder to genetic counselors, under certain conditions, including only delegating to genetic counselors certified with either the CAGC (now CBGC) or the ABGC (Government of Manitoba, 2018; Patrinos et al., 2020). It is interesting to observe that, although certification is generally voluntary, it is a legal requirement in Manitoba to be able to carry out the aforementioned delegation.

For a more in-depth legal analysis of these models of legal recognition, as well as the discussion of their respective advantages and disadvantages, we refer readers to our original article (Patrinos et al., 2020). While the legal considerations of each model should be taken into account in future pursuits of legal recognition, the practical and logistical factors of each model also warrant close consideration.

2.5 | Models of legal recognition: Practical considerations

Seeking legal recognition can be a complex process and comes at the expense of time, money, and effort. As such, it entails a balancing act

between best protecting the public interest and the 'need to be fiscally responsible with public resources' (Aldridge, 2008, p. 5).

Genetic

2.5.1 | Constitution of a professional order

The constitution of a professional order offers the highest degree of public protection from risk of harm, while also serving to increase the profession's public visibility and credibility (Aldridge, 2008). Nonetheless, the constitution of a professional order is a complex and lengthy process. Occupations seeking to create an order must apply to the provincial government and demonstrate they meet the prescribed criteria for this model. If so, the legislature must adopt statutes to create the professional order (Patrinos et al., 2020). This process can take years to accomplish.

Once constituted, the operation of a professional order is both labor- and resource-intensive (Aldridge, 2008). To carry out their legal duties, the orders must create and operate several committees, including those responsible for public inquiries and complaints, disciplinary proceedings, and quality assurance. While this grants a high level of independence and control to a profession, its economic impacts are significant. Sufficient financial and human resources are required to discharge these functions.

This may be a challenge to occupations with fewer members, for which this form of regulation may not be financially viable. The number of practitioners is often indicative of the potential viability of a self-regulating order. The relatively low numbers of genetic counselors and the costs associated with regulation have been important factors in the lack of legal recognition in Canada (Abacan et al., 2019). Our estimated figure of 484 genetic counselors is far lower than that of any legally recognized health care providers in Canada, where midwives are the smallest group at 1,590 individuals (Canadian Institute for Health Information, 2020). Canada's largest workforce of genetic counselors – in the province of Ontario – counts 235 individuals; by comparison, the College of Dental Technologists of Ontario, the province's smallest regulatory college by membership, includes 544 members (Office of the Fairness Commissioner, 2020).

While an important factor, the number of practitioners is not determinative and does not necessarily preclude the constitution of a professional order. Occupations with fewer members may demonstrate their competence and ability to operate a professional order through other means. The example of the legal recognition of midwifery in Ontario is particularly informative, where the 'insufficient numbers' of midwives had been raised as a potential concern for legal recognition in the province (Bourgeault, 2000, p. 98). However, midwives were able to overcome this through demonstrating their ability and competency in taking on the duties of self-regulation. In particular, Ontario midwives had 'voluntarily taken on the tasks of setting standards, conducting peer review, and establishing a complaints and discipline procedure' (Kaufman, 1991, p. 101). Efforts to achieve self-regulation were also aided through strong lobbying efforts from professional associations of midwives, such as the Midwives Coalition and the Association of Ontario Midwives (Bourgeault, 2000).

This is illustrative of how an organized effort is required by occupational groups seeking statutory self-regulation. Professional associations, which advocate on behalf of their members, play a key role in this process, through demonstrating leadership, the ability to assume the responsibilities and duties of self-regulation, as well as rallying consumer support for legal recognition (Bourgeault, 2000).

2.5.2 | Inclusion in a professional order

Though less often employed than the constitution of an independent professional order, inclusion in an existing professional order requires consideration. Sharing the duties of regulation with another profession can help offset the economic impacts of regulation, while still reaping the benefits of being regulated under a professional order. In several provinces, occupational groups applying for regulation under an independent professional order must first consider whether they may become regulated under an existing order with which its body of knowledge and practice overlaps (e.g. Health Professions Regulatory Advisory Council, 2011). This may be especially relevant where the number of practitioners within an occupation may be insufficient to create an independent professional order.

Given the relatively low number of practicing genetic counselors in Canada, possible integration within an existing professional order may be a feasible option. While complete regulatory autonomy is not afforded by this model of legal recognition, it may be more practical in some provinces where the number of genetic counselors is low and resources are limited. It may also be a relevant model to consider in the province of British Columbia, which is now streamlining its health care professions system to decrease the number of professional colleges from 25 to 6. This change will include two unified regulatory colleges (Government of British Columbia, 2020). It is recognized that this will be advantageous to professions with fewer members, for whom the costs of operating an independent professional order may be too onerous. This restructuring of the health professions landscape will also result in cost reduction and increased efficiency of the provincial regulatory framework, as it will eliminate the costs required to establish an independent college for each new profession that becomes regulated (Government of British Columbia, 2020). As such, this will be advantageous not only to the professions themselves but to the provincial or territorial governments as well. Legal recognition through a multi-professions regulatory body has been successful for genetic counselors in South Africa (Kromberg et al., 2013) and Australia (Hoskins et al., 2020), and for genomic counselors in the United Kingdom (National Health Service, 2020).

One major challenge in pursuing this model of legal recognition is the choice of professional order within which to be integrated. The professional order must be sufficiently related to genetic counseling so as to constitute a logical choice. Austin et al. (2014) have proposed that genetic counseling can be viewed as a narrowly delineated form of psychotherapy, which might form the basis for professional alignment. Given the unique status of genetic counseling, combining both counseling skills and specialist scientific knowledge, this may be a particular challenge.

An additional challenge in pursuing this model is that in certain jurisdictions, such as Quebec, the order into which inclusion is sought must be consulted with prior to the integration (Government of Quebec, 2020). Resistance to the inclusion of a new sub-group may occur from the professional order, which may be a limiting factor in the implementation of this model of legal recognition.

2.5.3 | Delegation

Under the delegation model, a legally regulated health care professional may authorize the performance of a reserved act to either another regulated health care professional or to an unregulated practitioner (Patrinos et al., 2020). Delegation has the key advantage of being the most time- and cost-efficient model of legal recognition to implement, as it is done so through the adoption of regulations or bylaws rather than the adoption of statutes (Patrinos et al., 2020). In Manitoba, the decision to delegate the act of diagnosing a genetic disease or disorder to genetic counselors was made following meetings from representatives of the provincial order of physicians, the provincial genetics program, and genetic counselors, where it was noted that genetic counselors were routinely providing diagnoses - an act they were not legally permitted to perform. The decision was then made to adopt a regulation permitting physicians to legally delegate this act to genetic counselors under certain conditions. This is particularly illustrative of the streamlined process involved in the implementation of delegation as a model of legal recognition.

It should be noted that delegation is considered a form of legal recognition where it is circumscribed within a regulatory framework, as was done in Manitoba (Patrinos et al., 2020). Delegation can be accomplished on a more informal basis, though, in these cases, it does not constitute a form of legal recognition. For instance, in 2003 in the province of Nova Scotia, the College of Physicians and Surgeons authorized the delegation of medical functions to genetic counselors by medical geneticists (Zawati, 2012). This authorization is specific to the sole public genetics center, whereby genetic counselors are reviewed individually by the center's geneticist team in order to permit them to perform a specific medical function, subject to yearly quality review (Natasha Van Iderstine, Maritime Medical Genetics Manager, personal communication, May 2021). Genetic counselors employed elsewhere in Nova Scotia than Maritime Medical Genetics do not have delegated functions from the College of Physicians and Surgeons. In Ontario, Shugar et al. (2017) found that the majority of genetic counselors in the province had received some type of medical delegation from clinical or metabolic geneticists in their institutions. However, this is restricted to the institutional level and occurs on an ad hoc basis, as Ontario does not have a legal framework in place for delegation (Patrinos et al., 2020).

While many genetic counselors in Canada have been informally delegated the authority to perform acts that are legislatively reserved for physicians, delegation can only be considered a form of legal recognition where it is implemented within the province or territory's legal framework.

Despite being readily implementable, delegation does not offer the full spectrum of public protection that a professional order provides. Rather, it extends to the oversight of the performance of specific acts (Patrinos et al., 2020). In this regard, all other aspects of genetic counseling practice remain unregulated, with no other mandatory measure of public protection in place and no title protection for practitioners. To be able to carry out a delegated act, a genetic counselor must have a supervisor. If the delegatory authorization is only from clinical geneticists, the number of clinical geneticists in Canada (n = 111) may be insufficient to supervise the number of genetic counselors (n = 484). However, with the mainstreaming of genetic and genomic testing, delegatory authority may be considered from non-genetics specialists, such as obstetricians, oncologists, and cardiologists, to genetic counselors. While this would widen the scope of practice in which genetic counselors could practice under delegated authority, it has the potential for the non-geneticist to be acting in a supervisory capacity outside of their professional expertise and training. Nevertheless, in light of the limited resources available for regulation under a professional order, delegation should not be ruled out as a plausible option for legal recognition. Being more cost effective than the other two models of legal recognition, delegation could be pursued as a first step in the legal recognition process and may be a stepping-stone in the pursuit of recognition under the other two identified models.

2.6 | Considerations on the path to legal recognition

Each model of legal recognition presents key advantages and disadvantages. All three models, to varying degrees, serve to ensure high-quality and safe provision of genetic counseling services to the public. While the constitution of a professional order is the most advantageous from this perspective, it has the disadvantage of being the most resource- and time-intensive of the three models. Inclusion in a professional order provides the same public protection benefits in a less resource- and time-intensive process, though this comes at the expense of complete regulatory autonomy. Delegation is the easiest of the three models to achieve, though it does not offer the same public protection benefits. For simplicity, we have summarized the practical advantages and disadvantages of the above models in Table 2 as a reference for groups of genetic counselors starting to contemplate legal recognition in their jurisdiction.

Genetic

An enabler toward reaching legal recognition may be the formation of a provincial or territorial association of genetic counselors, for several reasons. The first is to assess who is a genetic counselor in one's province; it may be that a very small number of practitioners will limit the legal models that are open to consideration. Secondly, a professional association may help to establish the range of practice of genetic counselors in the jurisdiction to ensure that all their roles are respected by the proposed legal recognition model. For example, it would be inadvisable to seek the delegation of genetic testing by a clinical geneticist if a large proportion of genetic counselors in the jurisdiction do not work with a clinical geneticist. Finally, a professional association will also provide a unified, and potentially powerful lobbying voice for the chosen regulatory model, as demonstrated by the regulation of midwifery in Ontario (Bourgeault, 2000). There are presently only 5 Canadian jurisdictions in which there is a genetic counseling professional association (Table 1). Genetic counselors in remaining jurisdictions should consider forming such an association to facilitate future pursuits of legal recognition.

3 | CONCLUSION: IMPORTANCE OF PAN-CANADIAN DISCUSSIONS

The regulation of health care professions in Canada is a matter of provincial and territorial jurisdiction. As such, the legal recognition of genetic counselors will be an inherently fragmented process in Canada, unlike other countries where the legal recognition of genetic counselors occurred at the national level, such as France (Cordier et al., 2013) and South Africa (Abacan et al., 2019). Each

TABLE 2 Practical advantages and disadvantages of the models of legal recognition in Canada

Model	Advantages	Disadvantages
Constitution of a Professional Order	 High degree of public protection Legal professional status High level of autonomy through self-regulation Increased public visibility and credibility 	 Presents the most challenges Lengthy to achieve Requires sufficient human resources and finances to achieve and operate
Inclusion in a professional order	 Grants same degree of public protection as constitution of a professional order May be more feasible for smaller groups 	• Lack of regulatory autonomy and unique professional identity
Delegation	 Smaller groups can be legally recognized Does not require the same amount of resources as a professional order Most straightforward to establish 	 Locus of control remains with the delegating professional No legal professional status Level of public protection (limited to performance of certain acts)

province and territory will ultimately decide whether to regulate genetic counseling and, if so, which model represents the best option within its jurisdiction.

Genetic 🚮

ILEY-

We believe that inter-jurisdictional discussions in future pursuits of legal recognition across Canada would be greatly beneficial to genetic counselors. Genetic counselors in each province and territory will have unique circumstances and factors that must be considered in these undertakings, such as the number of practitioners and resources necessary to pursue legal recognition. However, agreement on a core set of elements, such as a proposed scope of practice and arguments for legal recognition, which may be used in applications for legal recognition to provincial and territorial health ministries or departments, would be helpful for all provinces and territories.

Discussion of other practical factors, such as billing for genetic services, which differ between provinces and territories, would support pursuits of legal recognition. A national campaign to rally consumer support, with a shared approach, may be useful to build awareness of genetic counselors and public support for legal recognition. As early as 2006, the CAGC recognized the need for uniform practice standards for genetic counseling practice across Canada, in light of the rapid progress of genetic technologies, the expanding practice of genetic counselors, and the increasing demand for genetic services (Ferrier et al., 2013). Pan-Canadian discussions may help contribute to uniformity in the practice of genetic counseling across the country, notwithstanding the inherently piecemeal approach to legal recognition in Canada, through the sharing of experiences and information between jurisdictions.

The need for pan-Canadian discussions does not end once legal recognition is in place. By way of example, the Canadian Free Trade Agreement (CFTA), an agreement between the federal, provincial and territorial governments, aims to eliminate barriers to labor mobility within Canada (Canadian Free Trade Agreement, 2021). It requires its signatories to adopt 'to the extent possible and where practical [...] common interprovincial standards, including occupational standards' in order to facilitate mobility between jurisdictions (Canadian Free Trade Agreement, 2021, p. 86). The Labour Mobility Working Group coordinates the application of the labor mobility provisions of the CFTA and supports professional regulatory bodies, while recognizing that provinces and territories may differ in the educational and training prerequisites for regulation, thereby creating a framework for reciprocity of provincial and territorial regulation (Labour Mobility Coordinating Group, 2021). An established pan-Canadian group providing support toward legal recognition in provinces and territories is well placed to work with Labour Mobility Coordinators toward establishing common occupational standards that can help reciprocity between jurisdictions. However, due to Canada's legal framework for professional regulation, this would only apply for jurisdictions that have achieved the same model of legal recognition. Nonetheless, continuing these discussions at the national level will ensure that patients and their families across Canada benefit from optimal genetic counseling services and enhanced patient care.

AUTHOR CONTRIBUTIONS

D.L. and D.P. contributed substantially to the design of the work and drafted the manuscript. D.L., D.P., B.M.K., and M.H.Z. revised the manuscript critically for important intellectual content, approved the final version for publication, and agree to be accountable for all aspects of the work.

ACKNOWLEDGMENTS

The GenCOUNSEL Study is led by Alison M. Elliott, Jehannine Austin, Bartha Maria Knoppers, and Larry D. Lynd with Project Manager Alivia Dey, and includes the following co-investigators: Shelin Adam, Nick Bansback, Patricia Birch, Lorne Clarke, Nick Dragojlovic, Jan Friedman, Deborah Lambert, Darvl Pullman, Alice Virani, Wveth Wasserman, and Ma'n H. Zawati. GenCOUNSEL was funded through the Large Scale Applied Research Project (LSARP) Genome Canada competition with co-funding from: Canadian Institutes for Health Research (CIHR), Genome BC, Genome Quebec, Provincial Health Services Authority, BC Children's Hospital Foundation, and BC Women's Hospital Foundation. We wish to thank the following genetic counselors who provided data regarding the demographics of Canadian genetic counselors (GCs) by province and territory: Kennedy Borle (BC), Sajid Merchant (AB), Janet Lucas (SK), Jessica Hartley (MB), Christine Davies (ON) Shannon Ryan (YT, NT, NU), Jennifer Fitzpatrick (QC), Laura Dempsey Nunez (QC), Tina Babineau-Sturk (NB, NS, PE), Andree McMillan (NL), and Natasha van Iderstine (NS). Ma'n H. Zawati would like to acknowledge the generous contribution of the Fonds de recherche du Québec - Santé through the Junior 1 Research Career Award.

COMPLIANCE WITH ETHICAL STANDARDS

CONFLICT OF INTEREST

All authors declare that they have no conflict of interest.

HUMAN STUDIES AND INFORMED CONSENT

No human studies were carried out by the authors for this article.

ANIMAL STUDIES

No non-human animal studies were carried out by the authors for this article.

DATA SHARING AND DATA ACCESSIBILITY

All data is shown in Table 1.

ORCID

Deborah M. Lambert D https://orcid.org/0000-0003-0967-0476 Ma'n H. Zawati https://orcid.org/0000-0002-8905-6259

REFERENCES

Abacan, M., Alsubaie, L., Barlow-Stewart, K., Caanen, B., Cordier, C., Courtney, E., Davoine, E., Edwards, J., Elackatt, N. J., Gardiner, K., Guan, Y., Huang, L.-H., Malmgren, C. I., Kejriwal, S., Kim, H. J., Lambert, D., Lantigua-Cruz, P. A., Lee, J. M. H., Lodahl, M., ... Wicklund, C. (2019). The global state of the genetic counseling profession. *European Journal of Human Genetics*, 27(2), 183–197. https:// doi.org/10.1038/s41431-018-0252-x

- Aldridge, S. (2008). The regulation of health professionals: An overview of the British Columbia experience. *Journal of Medical Imaging and Radiation Sciences*, 39(1), 4–10. https://doi.org/10.1016/j. jmir.2008.01.001
- 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. https://doi.org/10.1007/s1089 7-014-9728-1
- Borle, K., Kopac, N., Ellis, U., Birch, P., Adam, S., Friedman, J. M., Nisselle, A., Elliott, A. M., & Lynd, L. D., GenCOUNSEL Study. (2020). The composition and capacity of the clinical genetics workforce in highincome countries: A scoping review. *Genetics in Medicine: Official Journal of the American College of Medical Genetics*, 22(9), 1437–1449. https://doi.org/10.1038/s41436-020-0825-2
- Bourgeault, I. (2000). Delivering the 'new' Canadian midwifery: The impact on midwifery of integration into the Ontario health care system. *Sociology of Health & Illness*, 22(2), 172–196. https://doi. org/10.1111/1467-9566.00198
- Branda, K. (2017). The role of the genetic counselor in utilization management of genetic testing. In K. Lewandrowski & P. M. Sluss (Eds.), Utilization management in the clinical laboratory and other ancillary services (pp. 261–266). Cham: Springer.
- Brierley, K. L., Blouch, E., Cogswell, W., Homer, J. P., Pencarinha, D., Stanislaw, C. L., & Matloff, E. T. (2012). Adverse events in cancer genetic testing: Medical, ethical, legal, and financial implications. *The Cancer Journal*, 18(4), 303–309. https://doi.org/10.1097/PPO.0b013 e3182609490
- Canadian Association of Genetic Counsellors (CAGC). (2012). 2011 Professional status survey. Retrieved from https://www.cagc-accg.ca/ doc/2011%20PSS%20report%20-%20English%20(1).pdf
- Canadian Association of Genetic Counsellors (CAGC). (2016). CAGC 2016 Professional status survey summary. Retrieved from https:// www.cagc-accg.ca/doc/CAGC%202016%20PSS%20Summary. pdf
- Canadian Association of Genetic Counsellors (CAGC). (2020). Professional status survey 2020: Canada. Retrieved from https://www.cagc-accg. ca/doc/2020%20Canadian%20PSS%20Executive%20Summary%20 Oct%202020.pdf
- Canadian Association of Genetic Counsellors (CAGC) (2021). Genetic Counsellor Certification. Retrieved from https://www.cagc-accg. ca/?page=359
- Canadian Board of Genetic Counselling (CBGC). (2021a). Certification. Retrieved from https://www.cbgc-cccg.ca/?page=5
- Canadian Board of Genetic Counselling (CBGC). (2021b). Introduction and application pathways. Retrieved from https://www.cbgc-cccg. ca/?page=22&id=
- Canadian Board of Genetic Counselling (CBGC). (2021c). *Recertification*. Retrieved from https://www.cbgc-cccg.ca/?page=9
- Canadian Free Trade Agreement. (2021). Consolidated version. Retrieved from https://www.cfta-alec.ca/wp-content/uploads/2021/03/ CFTA-Consolidated-Text-Final-English_March-23-2021.pdf
- Canadian Institute for Health Information. (2020). Canada's health care providers, 2014 to 2018 Data tables. CIHI.
- Canadian Medical Association (2019). *Medical genetics profile*. Retrieved from https://www.cma.ca/sites/default/files/2019-01/medicalgenetics-e.pdf
- Cancer Care Ontario. (2018). Recommendation report for Ontario's clinical genetic services. Retrieved from https://www.cancercareontario.ca/sites/ccocancercare/files/assets/ClinicalGeneticServicesRecomme ndationReport.pdf
- Cordier, C., Taris, N., De Pauw, A., Sobol, H., Philip, N., & Voelckel, M. A. (2013). French professionals in genetic counselor careers. *Journal of*

Genetic Counseling, 22(6), 844-848. https://doi.org/10.1007/s1089 7-013-9599-x

Genetic 🕥

Counselors

- Costa, T., Gillies, B., Oh, T., & Scott, J. (2020). The Canadian genetic counseling workforce: Perspectives from employers and recent graduates. *Journal of Genetic Counseling*, 30(2), 406–417. https://doi. org/10.1002/jgc4.1326
- Elliott, A. M., & Friedman, J. M. (2018). The importance of genetic counselling in genome-wide sequencing. *Nature Reviews Genetics*, 19(12), 735-736. https://doi.org/10.1038/s41576-018-0057-3
- Ferrier, R. A., Connolly-Wilson, M., Fitzpatrick, J., Grewal, S., Robb, L., Rutberg, J., Lilley, M., & CAGC Core Competencies Working Group. (2013). The establishment of core competencies for Canadian genetic counsellors: Validation of practice based competencies. *Journal* of Genetic Counseling, 22(6), 690–706. https://doi.org/10.1007/s1089 7-013-9651-x
- Fox, S., & Secord, A. (2016). A professional order for genetic counsellors in Quebec: A request for the Office des Professions to consider the creation of a new professional order for this growing group of health professionals. Retrieved from https://www.cagc-accg.ca/doc/A%20Professi onal%20Order%20for%20Genetic%20Counsellors%20in%20Que bec%20May%202016_FinalEng(1).pdf
- Genome Canada. (2017). GenCOUNSEL: Optimization of genetic counselling for clinical implementation of genome-wide sequencing. Retrieved from https://www.genomecanada.ca/en/gencounsel-optimization-genet ic-counselling-clinical-implementation-genome-wide-sequencing
- Government of British Columbia. Steering Committee on Modernization of Health Professional Regulation. (2020). *Recommendations to modernize the provincial health profession regulatory framework*. Retrieved from https://www2.gov.bc.ca/assets/gov/health/practitioner-pro/ professional-regulation/recommendations-to-modernize-regulatory -framework.pdf
- Government of Canada (2019). *Canada's health care system*. Retrieved from https://www.canada.ca/en/health-canada/services/healthcare-system/reports-publications/health-care-system/canada.html
- Government of Manitoba. (2018). College of physicians and surgeons of Manitoba general regulation. Retrieved from https://web2.gov.mb.ca/ laws/regs/current/_pdf-regs.php?reg=163/2018
- Government of Quebec. (2020). Professional code. Retrieved from http:// legisquebec.gouv.qc.ca/en/ShowDoc/cs/C-26
- Health Professions Regulatory Advisory Council. (2011). Regulation of a new health profession under the regulated health professions Act (RHPA), 1991. Retrieved from https://www.hprac.org/en/reports/resources/ RegulatingaNewProfession_CriteriaProcess_Nov2011.pdf
- Hoskins, C., Gaff, C., McEwen, A. et al (2020). Professional regulation for Australasian genetic counselors. *Journal of Genetic Counseling*, 00, 1– 9. https://doi.org/10.1002/jgc4.1344
- Hynes, J., MacMillan, A., Fernandez, S., Jacob, K., Carter, S., Predham, S., & Dawson, L. (2020). Group plus "mini" individual pre-test genetic counselling sessions for hereditary cancer shorten provider time and improve patient satisfaction. *Hereditary Cancer in Clinical Practice*, 18(1), 1–7. https://doi.org/10.1186/s13053-020-0136-2
- Kaufman, K. J. (1991). The introduction of midwifery in Ontario, Canada. Birth, 18(2), 100–103. https://doi.org/10.1111/j.1523-536X.1991. tb00068.x
- Kromberg, J. G. R., Sizer, E. B., & Christianson, A. L. (2013). Genetic services and testing in South Africa. *Journal of Community Genetics*, 4(3), 413–423. https://doi.org/10.1007/s12687-012-0101-5
- Labour Mobility Coordinating Group. (2021). Labour mobility working group. Retrieved from http://workersmobility.ca/mqrwg/
- Lahey, W., & Fierlbeck, K. (2016). Legislating collaborative self-regulation in Canada: A comparative policy analysis. *Journal of Interprofessional Care*, 30(2), 211–216. https://doi.org/10.3109/13561820.2015.1109501
- Leeming, W. (2013). Looking back on the future of genetic counselling in Canada. Canadian Bulletin of Medical History, 30(1), 101–122. https:// doi.org/10.3138/cbmh.30.1.101

58 WILEY Counselors

- National Health Service. (2020). *Genomic counselling*. Retrieved from https://www.healthcareers.nhs.uk/explore-roles/healthcare-scien ce/roles-healthcare-science/life-sciences/genomic-counselling
- Office of the Fairness Commissioner. (2020). College of Dental Technologists of Ontario. Retrieved from http://www.fairnesscommissioner.ca/index_ en.php?page=professions/college_of_dental_technologists_of_ontario
- Ormond, K. E., Laurino, M. Y., Barlow-Stewart, K., Wessels, T., Macaulay, S., Austin, J., & Middleton, A. (2018). Genetic counseling globally: Where are we now? American Journal of Medical Genetics Part C: Seminars in Medical Genetics, 178(1), 98–107. https://doi.org/10.1002/ajmg.c.31607
- Patrinos, D., Caron, R., & Knoppers, B. M., GenCOUNSEL Study, Zawati, M. H. (2020). Genetic counsellors, legal recognition, and the road less travelled. *McGill Journal of Law and Health*, 14(1), 109–158.
- Resta, R., Biesecker, B. B., Bennett, R. L., Blum, S., Estabrooks Hahn, S., Strecker, M. N., & Williams, J. L. (2006). A new definition of genetic counseling: National Society of Genetic Counselors' task force report. *Journal of Genetic Counseling*, 15(2), 77–83. https://doi.org/10.1007/s10897-005-9014-3
- Ries, N. M. (2016). Innovation in health care, innovation in law: Does the law support interprofessional collaboration in Canadian health systems. Osgoode Hall Law Journal, 54, 87–124.
- Shugar, A. L., Quercia, N., Trevors, C., Rabideau, M. M., & Ahmed, S. (2017). Risk for patient harm in Canadian genetic counseling practice: It's time to consider regulation. *Journal of Genetic Counseling*, 26(1), 93–104. https://doi.org/10.1007/s10897-016-9983-4
- Statistics Canada. (2020). Population estimates, quarterly. Retrieved from https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1710000901
- Suarez, C. J., Yu, L., Downs, N., Costa, H. A., & Stevenson, D. A. (2017). Promoting appropriate genetic testing: The impact of a combined

test review and consultative service. Genetics in Medicine, 19(9), 1049–1054. https://doi.org/10.1038/gim.2016.219

Wakefield, E., Keller, H., Mianzo, H., Nagaraj, C. B., Tawde, S., & Ulm, E. (2018). Reduction of health care costs and improved appropriateness of incoming test orders: The impact of genetic counselor review in an academic genetic testing laboratory. *Journal of Genetic Counseling*, 27(5), 1067–1073. https://doi.org/10.1007/s10897-018-0226-8

World Bank Data. (2021). Rural population (% of total population) - Canada | Data (worldbank.org). Retrieved from https://data.worldbank.org/ indicator/SP.RUR.TOTL.ZS?locations=CA Accessed June 2021.

- Zawati, M. H. (2012). Les conseillers en génétique et les professions médicales et infirmières au Québec: Des frontières brouillées? McGill Journal of Law and Health, 6(1), 137–187.
- Zawati, M. H. (2018). Chapitre 8: La responsabilité civile des conseillers en génétique. In M. Bourassa-Forcier, & A.-M. Savard (Eds.), *Droit de la santé*, 2nd ed. (pp. 337-393). LexisNexis Canada.
- Zeesman, S., & Creighton, S. (2000). The CAGC: A history in progress. Oakville.

How to cite this article: Lambert, D. M., Patrinos, D., Knoppers, B. M., & Zawati, M. H. (2022). Genetic counselors and legal recognition: A made-for-Canada approach. *Journal of Genetic Counseling*, 31, 49–58. <u>https://doi.org/10.1002/</u> jgc4.1468