

General Medical Practitioners Acting as Geneticists, a Risky Business?

Aurélie Dauge, Yann Joly, Beatrice Kaiser, Jocelyne Chiquette, Julie Lapointe, Jacques Simard, Michal Dorval and Hermann Nabi

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Article abstract

The availability of precision medicine tools and approaches has increased considerably over the past decades, propelled by rapid scientific advances in genomics and the popularity of direct-to-consumer genetic testing. Genetic specialists working within public healthcare systems are struggling to meet the growing demand for clinical genetic services. Some experts have suggested that doctors who are not specialized in genetics could take on some of the tasks performed by genetic specialists since they are regularly the first point of contact for people with a genetic predisposition to cancer. However, expanding doctors' roles may heighten their standard of practice and concomitant medical liability risk to that of genetic specialists. This paper reviews the medical liability regime applicable to this situation through the lens of Canada's unique bijural legal system. We then compare the state of the law in Canada to that of the United States. According to our findings, unless there is an improvement in the quality of genetic services provided by general practitioners, we could see a growing number of successful liability suits in clinical genetics and precision medicine in the coming years. To prevent this unsatisfactory outcome, additional professional training in core genetic tasks should be made increasingly available to general practitioners and the creation of communities of practice in genetics encouraged. Furthermore, courses introducing medical students to genetics, including its ethical and legal challenges, should be made available and actively promoted within medical curricula.



GENERAL MEDICAL PRACTITIONERS ACTING AS GENETICISTS, A RISKY BUSINESS?

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RÉSUMÉ

La disponibilité d'outils et d'approches de médecine de précision a considérablement augmenté au cours des dernières décennies, propulsée par des avancées scientifiques rapides en matière de génomique et la popularité des tests génétiques directement accessibles aux consommateurs. Les généticiens travaillant au sein de systèmes de santé publics peinent à répondre à la demande croissante de services de génétique clinique. Certains experts ont suggéré que la prise en charge de certaines tâches accomplies par les généticiens, soit effectuée par les médecins généralistes, étant régulièrement le premier point de contact avec des personnes ayant une prédisposition génétique au cancer. Toutefois, l'élargissement de leur rôle pourrait accroître leur champ de pratique et le risque de responsabilité médicale associé. Cet article examine le régime de responsabilité médicale applicable à cette situation à travers le prisme du système bijuridique unique du Canada. Nous comparons ensuite l'état du droit au Canada à celui des États-Unis. Selon nos conclusions, à moins d'une amélioration de la qualité des services génétiques fournis par les médecins généralistes, nous pourrions assister, dans les prochaines années, à un accroissement du nombre de poursuites en responsabilité civile dans le domaine de la génétique clinique et de la médecine de précision. Afin d'éviter cette situation insatisfaisante, il faudrait que la formation professionnelle complémentaire aux tâches génétiques soit de plus en plus accessible aux médecins généralistes et que la création de communautés de pratique en matière de génétique soit encouragée. Par ailleurs, des cours initiant les étudiants en médecine à la génétique, y compris les enjeux éthiques et juridiques qu'elle pose, devraient être proposés et activement promus dans le cadre des programmes d'études médicales.

MOTS-CLÉS : Droit de la santé ; services génétiques ; tests génétiques ; responsabilité médicale ; norme de pratique du médecin

ABSTRACT

The availability of precision medicine tools and approaches has increased considerably over the past decades, propelled by rapid scientific advances in genomics and the popularity of direct-to-consumer genetic testing. Genetic specialists working within public healthcare systems are struggling to meet the growing demand for clinical genetic services. Some experts have suggested that doctors who are not specialized in genetics could take on some of the tasks performed by genetic specialists since they are regularly the first point of contact for people with a genetic predisposition to cancer. However, expanding doctors' roles may heighten their standard of practice and concomitant medical liability risk to that of genetic specialists. This paper reviews the medical liability regime applicable to this situation through the lens of Canada's unique bijural legal system. We then compare the state of the law in Canada to that of the United States. According to our findings, unless there is an improvement in the quality of genetic services provided by general practitioners, we could see a growing number of successful liability suits in clinical genetics and precision medicine in the coming years. To prevent this unsatisfactory outcome, additional professional training in core genetic tasks should be made increasingly available to general practitioners and the creation of communities of practice in genetics encouraged. Furthermore, courses introducing medical students to genetics, including its ethical and legal challenges, should be made available and actively promoted within medical curricula.

KEYWORDS : Health law ; genetic services ; genetic tests ; medical liability ; physician standard of practice.

1. INTRODUCTION

[1] Medical genetics has only been recognized as a medical specialty in Canadian provinces since the mid-1990s. In 2019, it was estimated that Canada had around 111 genetic specialists for a population of more than 35 million inhabitants (Medical Genetics Profile, 2019, p. 6). The Canadian College of Medical Geneticists and the Royal College of Physicians and Surgeons Canada have warned Canadian stakeholders about the lack of genetic specialists (Silversides, 2007, pp. 315-316). Due to scientific progress, which has notably increased the capacity to transfer genetic innovations in clinical care, and the growing demand for genetic consultations and testing, especially in the field of oncology, there has been a significant disparity in accessing genetic services and increases in wait times (Borle et al., 2022).

[2] In response to the escalating need for genetic services, alternative service delivery models have been called for. One such model is the Collaborative Oncogenetic Model (COM) developed by Quebec City's Université Laval Hospital (CHU Québec-Université Laval) in the Canadian province of Quebec that uses interprofessional and inter-institutional collaborations (e.g., by involving medical and surgical oncologists along with genetic professionals) to reduce delays in accessing genetic services (Lapointe et al., 2021). This initiative, established by health professionals, highlights the growing importance of clinical genetics in the cancer field, especially in genetic counselling and testing (*Ibid.*). In this context of growing demand and collaborative medical practice, stakeholders agree that there should be authorization for doctors non-specialized in genetics (thereafter non-genetic specialist MDs) to take up some of the tasks of genetic specialists to help relieve the system. However, this shifting of responsibility from genetic specialists to non-genetic specialist MDs raises legal and ethical issues, including those of medical liability.

[3] Take for example the fictitious case of Ms. Williams, 32, with three close female relatives (mother, sister, and aunt) who succumbed to ovarian cancer before the age of fifty. Once made aware of this information, should her family physician provide pre-counselling for a genetic test themselves and order the test? It may impact their willingness to provide such services to know that in case of a legal recourse, their actions will be assessed according to the standard of what a genetic specialist would have done in similar circumstances. Then again, the alternative option is that Ms. Williams will be referred to a genetic specialist and made to wait an additional 6 months or more, with the risk of health and psychosocial repercussions that this additional waiting period could create (Piedimonte et al., 2020).

[4] Common mistakes in genetics likely to trigger the liability of non-genetic specialists MDs and genetic specialists alike involve 1) failure to recommend a genetic test that would be relevant based on known family history, symptoms or biomarkers to a patient; 2) communication of erroneous or incomplete information in pre-test counselling; 3) choosing an inappropriate test or gene panel for the patient; 4) faulty interpretation of test results and/or inappropriate treatment plan recommended; 5) inadequate communication of results and post-test counselling. While both genetic specialists and non-genetic specialist MDs can make these mistakes, the lack of genetic training

received by non-genetic specialist MDs makes them much more likely to be the ones providing faulty services (Bouchard & al., 2023 ; Ouellet & al., 2023).

[5] According to the Canadian standard of practice, physicians are expected to meet the reasonable professional's standard. In the case law, physicians are compared to other physicians with the same skills and responsibilities, practicing in similar circumstances (*Ter Neuzen v Korn*, [1995] 3 RCS 674, par. 33-34; *Reeg v Shaughnessy*, [1978] 570 F2d 309, pp. 312-313). However, a clinical geneticist's expertise in the field of precision medicine far exceeds that of a physician not specialized in this field. Therefore, holding physicians with little training in genetics to the liability standards of clinical geneticists may create too great a liability risk for them and discourage them from providing genetic services. However, not doing so and comparing them to a non-genetic specialist MD risks having the adverse effect of encouraging the development of a substandard genetic practice on the part of general practitioners.

[6] Having healthcare practitioners perform some of the more accessible tasks of genetic specialists, such as risk assessment for highly penetrant monogenic conditions or performing pre-test counselling and ordering tests, until there are more genetic specialists available to work in public healthcare systems, seems like a reasonable solution. However, considering our previous discussion, this solution could have adverse consequences on both the quality of genetic services and the medical liability risks of these general practitioners.

[7] This paper reviews the unique bijural system of Canada to provide a clear understanding of both the law of Quebec (where the COM was implemented) and the rest of Canada regarding the applicable standard of medical liability for non-genetic specialist MDs performing tasks usually done by genetic specialists. To do so, the paper examines statutes and case law in Quebec and the rest of Canada. The Canadian liability regime is then compared to the U.S. law on this matter. After establishing the state of the law in both countries, we propose considerations to ensure that non-genetic specialist MDs are not taking on unnecessary legal risks and continue to offer quality genetic services to patients.

2. SCOPE

[8] Before proceeding with our legal analysis, it is important to mention that the expressions "genetic healthcare professionals" and "genetic specialists" can be considered to include both clinical geneticists and genetic counsellors. Genetic counsellors are not part of a professional order in Canada and their profession is not regulated (Patrinos & al., 2020). For this reason and because they play a different role in the healthcare system than that of a clinical geneticist, their liability standard is likely different (Zawati, 2014). In the remainder of this paper, we will focus only on clinical geneticists.

[9] Non-genetic specialist MDs who may be called upon to perform genetic healthcare professionals' acts can include general practitioners, oncologists, and pediatricians, among others (Gould & Seven, 2022 ; Harding & al., 2019).

[10] The role of genetic healthcare professionals is to make a diagnosis and to manage and treat a patient's condition (Association of Geneticists of Quebec). They also collect family history, perform and interpret genetic tests and perform risk assessments of patients and their families (*Ibid.*). It has been suggested that tasks that could potentially be delegated to non-genetic specialist MDs include providing risk assessment for monogenic conditions to identify eligibility for testing, consenting for testing, pre-test counselling, ordering and assisting in coordinating sample collection for genetic testing, and returning results/providing post-test counselling (Cohen & Nixon, 2016; Lapointe & al., 2021). For our comparative legal analysis, it is not necessary to distinguish between these various tasks. Therefore, in our analysis, we will be referring to non-genetic specialist MDs that perform genetic tasks without singling out specific tasks.

3. LEGAL ANALYSIS

3.1 FOUNDATION AND CHALLENGES AFFECTING MEDICAL MALPRACTICE LIABILITY

[11] Medical malpractice liability developed as an area of law to support societal objectives of compensating injuries suffered by victims of medical errors and deterring healthcare providers from engaging in substandard and unreasonable healthcare practices. It is thought that meeting this last objective will lead to a more seamless uptake of improved medical technologies and practices by healthcare workers. These goals are laudable, but legal concepts and norms are often challenged by fast-moving technologies and rapid scientific developments. This is particularly true in the medical field where both professional practices and medico-legal norms are challenged to respond sufficiently rapidly to the fast pace of medical genetics innovation.

[12] Indeed, when physicians and other healthcare providers are unfamiliar with innovative technologies, they are likely to make more frequent mistakes. There is thus often a lag before newly approved practices and technologies can be used optimally by practitioners. While communication strategies and tools (information brochures, scientific journals, up-to-date equipment and trade publications, professional standards, etc.) are devised to alleviate this situation, we have yet to find solutions to fully overcome this gap problem. Considering this challenge, in the context of genetics, we note that most non-genetic specialist MDs practicing today receive insufficient formal training in genetics in medical school (Ouellet & al., 2023). Thus, they are underprepared to function in an environment where genetics and genomics will assume increasing importance in health care delivery (Marchant & al., 2020).

3.2 THE JUDICIAL SYSTEM IN CANADA

[13] Canada is a federal state with three levels of government – federal, provincial and municipal; with legislative powers distributed between federal and provincial jurisdictions under the *Constitution Act, 1867* (*Constitution Act*, 30 & 31 Vict 1867, ss, pp. 91-92). The Constitution also creates a division between two legal orders: private law, which “sets the rule between individuals” and public law, which “sets the rules for the relationship between the individual and society” (Department of Justice Canada). While Canada has a harmonized common law system to address public law matters, its legal

system is unique thanks to the bijuralism of its private law, where two legal traditions co-exist. Common law applies in every province and territory to matters of private law, except in Quebec, where civil law applies to private law issues.

[14] These two legal systems each have a distinct history and relationship with the sources of law (Glenn, 2014). In common law, statutes are the primary sources for legal decisions. However, according to the *stare decisis* principle, lower courts are bound to follow higher courts' interpretation of those statutes. Decisions of equal or lower-level courts may be departed from if they are deemed to have incorrectly interpreted the statute. Legislative supremacy (with some exceptions regarding the Constitution) is deeply entrenched in the common law tradition⁹. In the civilian tradition, statutes are still the highest authority. Historically, courts were not bound to past decisions. However, especially in Quebec, this is not practically the case. Lower courts follow higher courts' decisions and precedents carry roughly equivalent weight (Ontario Justice Education Network, *Common Law and Civil Law*, 2013).

[15] To avoid the establishment of distinct rules of law between provinces and conflicting judgments, the Supreme Court of Canada, as the highest court in the country, has the role of harmonizing lower courts' judgments. Thus, it can overturn rulings or affirm a consistent case law (Brun, Tremblay & Brouillet, 2014) Given this role and the importance of the *stare decisis* doctrine in Canadian law, lower courts, such as courts of appeal, federal courts, provincial superior courts, and provincial courts must adhere to the Supreme Court's judgments, subject to extremely rare exceptions, such that the system remains fluid and consistent (Rowe & Katz, 2020, pp. 12-13).

3.3 THE EVOLUTION OF MEDICAL LIABILITY LAW IN CANADA

[16] When considering the legal implications of non-genetic specialist MDs performing genetic tasks, the primary concern relates to the standard of practice that will apply in a medical liability suit. As medical liability falls under private law, it is an issue that will be addressed by either common or civil law depending on the Canadian province concerned. This raises the question of whether the standard application would be similar in both jurisdictions.

[17] The Supreme Court of Canada alluded for the first time to the applicable professional standard for physicians in the landmark case of *Sylvester v Crits et al.* in 1956. It upheld the judgment of the Court of Appeal of Ontario, where Justice Schroeder stated that:

"Every medical practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. He is bound to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing and, holds himself out as a specialist, a higher degree of skill is required of him than one who does not profess to be so qualified by special training and ability." (*Sylvester v Crits & al.*, [1956] SCR 991, p. 434)

⁹ *R v Kirkpatrick*, 2022 SCC 33 at para 178. Thus, "vertical *stare decisis* requires lower courts to follow decisions of higher courts, with limited exceptions" while "horizontal *stare decisis* binds courts of coordinate jurisdiction in a similar, but not identical, manner".

[18] In this case, the Supreme Court distinguished between what is accepted as a “standard practice” or “general practice” across professionals in the field from practice that is a personal standard of the physician (*Ibid.*). The Supreme Court stated that, in cases of standard practice, it would not be appropriate for courts to intervene (*Ibid.*, p. 996). However, in this case, the Supreme Court decided that the physician did not act within their professional standard and thus deemed his actions to be “improper” (*Ibid.*, p. 997).

[19] In civil law, a person is held liable when the four conditions set out in article 1457 of the *Civil Code of Quebec* are met: capacity, fault, damage and causation. For this purpose, Baudouin wrote:

“Unlike the common law, [...] the civil law system does not recognize specific torts but rather a general and universal principle of civil responsibility [...]. Whether the case involves situations of malpractice, defamation, battery, trespass, assault or wrongful death, etc, is immaterial, as long as the wrongdoer has committed a fault and there exists a direct causal connection between his or her act or omission and the prejudice suffered by the victim¹⁰.”

[20] The Quebec Superior Court confirmed in *Lévesque v Hôpital Notre-Dame Ste-Croix*, that there was a clear distinction between the situation of a specialized physician, such as an orthopaedist, and a general practitioner (*Lévesque v Hôpital Notre-Dame de Ste-Croix*, [1993] RRA, p. 93). The *Lévesque* judgment outlines the need to differentiate the standard of practice depending on a physician’s specialty since the courts cannot expect a generalist working in an area of medicine that does require specialization to have the same knowledge and skills as a specialist (Baudouin, Deslauriers & Moore, 2021). The courts will compare health professionals from the same specialty to assess if there was negligence or fault as different specialties require distinct expertise in terms of training and methods (Robertson & Picard, 2017).

[21] Importantly, in *Hawke v Hornstein*, the Quebec Superior Court further clarified that a generalist providing specialized care would be held to the same liability standards as a specialist if acting beyond his domain of expertise. In that particular case which pertained to the work of a dentist, which the Court affirmed falls under the same legal principles as medical care. The dentist’s work was deemed inadequate for the patient’s condition: he did not refer his patient to a specialist, in this instance a periodontist, for a consultation when he should have (*Hawke c Hornstein*, [1994] RJQ 965, pp. 8, 10-11). The defendant made an erroneous diagnosis by installing bridges and crowns for the patient when he had a “complex generalized periodontitis,” resulting in pain that persisted after the treatment (*Ibid.*). The decision in this case also reflects the requirements of the Quebec *Code of Ethics of Physicians* which is a legally enforceable regulation in this Canadian province. Section 42 of the Code provides that a physician must know his limitations and should consult “any competent person” if their patient’s condition requires it and the issue is out of their scope of practice (*Code of ethics of*

10 Jean-Louis Baudouin, “Law of Delict in Quebec” in *The Canadian Encyclopedia* (2016); See also *Roberge v Bolduc*, [1991] 1 SCR 374, pp. 434-435: In 1991, The Supreme Court stated in a case involving a different professional order, that standard professional practice does not exonerate liability if it does not meet the general standard of liability, in other words, acting reasonably and diligently.

physicians, CQLR 2002, ch M-9, r 17, art. 32; Perreault, 1996). Thus, in civil law, if a physician were to perform a task outside of their fields of activity, they would have to meet the same liability standard as a specialist physician regularly carrying out these acts (Baudouin, Deslauriers & Moore, 2021; Philips-Nootens, Kouri & Lesage-Jarjoura, 2016,).

[22] In Quebec, the Superior Court clarified that a physician's specialization should be determined before applying the relevant standard of practice to them (*Fiocco v De Varennes*, 2017 QCCS 5042, par. 64; *Chouinard c Robbins*, [1999] RRA 65, p. 8). Therefore, a generalist would be compared to another generalist and a specialist to another specialist. However, a generalist acting as a specialist should be held to the same responsibility standard as that applicable within this specialty (*Ibid.*; *X v Whelan*, 2011; *Topliceanu v Bojanowski*, 2018). Thus, Quebec civil law would hold physicians to a higher professional standard of practice if they practiced outside of their field of expertise. The justification is that a physician should refer their patient to a specialist who could have done a specific procedure instead of providing specialist treatments they may not be familiar with themselves (*Baker v Silver*, 1998 ; Deslauriers & Chebin, 1999 ; Emmet & al., 2018; Kirmse, 2020).

[23] In common law provinces, judges have established through case law four elements to take into consideration when assessing liability and particularly negligence: 1) a duty of care, 2) whether the standard of practice was breached, 3) whether the person suffered an injury or loss and, 4) whether this conduct was the actual and legal cause of the injury (Robertson & Picard, 2017). The doctor-patient relationship has been recognized as a relationship in which an established duty of care exists, thus, physicians must also take all the reasonable measures possible to treat their patients. In these circumstances, seeking advice from specialized physicians when their expertise is required, is necessary to avoid liability (Perreault, 1996). It was not until 1995, in *Ter Neuzen v Korn* (1995), that the Supreme Court of Canada formally adopted the modified objective test to assess whether a physician acted as dictated by the "reasonable man" concept¹¹. This test determines whether an expert or specialist acted "reasonably" by considering whether they acted in the same way that others with similar expertise would have in the same circumstances. For instance, according to the Court, a specialist "who holds himself out as possessing a special degree of skill and knowledge, must exercise the degree of skill of an average specialist in this field" (*Ibid*, par. 33). Moreover, in the medical field, the courts will consider the circumstances at the time when assessing the reasonability standard such as "the education, experience and other qualifications of the doctor, the degree of risk involved in the procedure or treatment and the equipment, facilities and other resources available to the doctor" (Robertson & Picard, 2017).

[24] In Canada, since the recognition of medical genetics as a profession, non-genetic specialist MDs performing some of the tasks of medical geneticists is a relatively new occurrence (Guttmacher, Jenkins & Uhlmann, 2001, pp. 216-17). This explains the

¹¹ See : *Ter Neuzen v. Korn*, [1995] 3 RCS 674, par. 32-34, 38, 44, 51

absence of specific case law in genetics on the applicable liability threshold¹². However, an inference can safely be made from the above-mentioned case law and principles to the effect that general practitioners acting as genetic specialists would be held to the higher professional standards of this group of specialists. To sum this up, if a case falls outside the doctor's field of expertise, a separate duty exists to refer the patient to a specialist. If the standard of care requires referral to a specialist, the non-specialist who does not refer but undertakes to treat the patient within that specialty would be held to a higher specialist standard.

3.4 MEDICAL LIABILITY FOR GENERAL PRACTITIONERS CARRYING OUT SPECIALIZED ACTS OF A GENETIC SPECIALIST IN THE UNITED STATES

[25] The United States has a common law judicial system with two levels: the federal level and the local (state) level. Tort cases are heard by state courts, and the legislation may differ from one state to another although the principles are similar (White House). In this section, we present case law chronologically to showcase the evolution of medical negligence in the United States. In doing so, we focus on landmark cases where physicians acted outside of their field of practice to determine which threshold was applied by courts and whether there was a different standard of practice applied based on the medical specialty. According to doctrine, U.S. decisions regarding medical negligence are also based on the standard of practice (Gilmour, 1994, p. 189). Indeed, some authors have provided a historical review of the latter and highlighted that two specific cases have had a significant impact on the definition that exists today on which U.S. courts rely (Moffett & Moore, 2011).

[26] In the *T.J. Hooper* case, the U.S. Court of Appeals for the Second Circuit indicated that simply because a practice is not universally "customary", does not mean that it could not be considered reasonable enough to be a standard of practice (*The T.J. Hooper*, 1932). It laid the foundations for the judgment in the second leading case, *Helling v Carey*, which ruled that the standard of practice should be assessed by legal professionals and the courts (*Helling v Carey*, 1974, pp. 517, 519). They had to consider whether it is reasonable or not for a medical professional to be insulated from liability where he complied with the standard of the profession (*Ibid.*). Medical and legal experts claim this case "prompted state legislatures to pass statutes that defined the standard of care in their jurisdiction" (Moffett & Moore, 2011). Thus, the modern definition of the standard of practice used to assess medical liability in the U.S. remains that a reasonably prudent person in their line of work would exercise. Although most states generally agree on this definition, what constitutes the conduct of a "reasonably prudent person" can largely differ depending upon the location, facts and circumstances of the treatment. Several of the more recent medical liability court cases have in fact favoured a lower application of the standard of practice, only requiring physicians to conduct themselves as a "minimally competent physician in the same field would do under the same circumstances" (*Ibid.*).

12 *MJR c Girard*, 2019 QCCS 1937: the only such case is this recent medical liability case involving several medical professionals in the context of the birth of a child with Wolf-Hirschhorn Syndrome. While the case confirms the general standard applicable to medical liability cases in Canada it does not specifically discuss the case of non-specialist MDs performing some of the tasks of medical geneticists. Nevertheless, some interesting elements of the case will be presented in our discussion section.

[27] In 1978, in *Reeg v. Shaughnessy*, the U.S. Court of Appeals for the Tenth Circuit specified that the applicable standard of practice to be employed depends on the physician's specialty (*Reeg v. Shaughnessy*, 1978). The Court held that a general surgeon's standard of practice was less demanding than the standard of an orthopedic surgeon but higher than that required of a general practitioner (*Ibid.*, p.315). Based on this judgment, it appears the applicable standard of practice depends on the physician's specialty in the U.S., similar to what applies in Canada. Specialists, including clinical geneticists, are held to a higher standard of practice because of their specific training and experience (Goguen).

[28] In *Foster v. Klaumann*, the Supreme Court of Kansas did not have to assess whether "the general physician standard of care instruction was legally appropriate" as the parties agreed that the surgeon "held herself out as a specialist" and consequently, the specialist standard of practice was applied (*Foster v. Klaumann*, 2013, pp. 300-305). The Court also stated that the duty of care "depends on the patient's situation and the physician's medical specialty, if applicable" (*Ibid.*, pp. 302-303). In *Baker v. DeRiso*, the Ohio Court of Appeals quoted the Ohio Supreme Court judgment that distinguished the standard of practice for specialists from that for non-specialist physicians (*Bruni v. Tatsumi*, 1976 ; *Baker v. Silver*, 2015). Their distinct standards were incorporated into the Ohio Jury Instructions: non-specialist physicians have a duty to act as "a physician of reasonable skill, care, and diligence [...]", whereas a specialist standard of practice is that of "a reasonable specialist practicing medicine exercising reasonable skill, care and diligence under like and similar circumstances [...]" (Ohio Jury Instructions, 2010, s. 417.01). These judgments from the past decade ruled on this question similarly to Canadian judgments highlighting distinct standards for specialist and non-specialist physicians. The instructions given in *Baker v. DeRiso* do not differentiate specialists among themselves, stating that "a specialist in any branch has the same standard of care as all other specialists in that branch" (*Ibid.*, s. 417.01; *Baker v. DeRiso*, 2015). Though our overview of U.S. decisions is not comprehensive due to the variability that exists between states' application of liability principles, a consensus can be identified between states on our specific question, as they all seem to distinguish between the generalist and specialist standards of care when assessing physicians' medical liability. Furthermore, U.S. courts of justice would likely apply the specialist's standard to a generalist carrying out an act from that specialty¹³. Therefore, we conclude that Canada and the U.S. use comparable reasoning to decide medical liability cases. However, we note that the standard applied recently by some of the U.S. courts consisting of holding physicians to the conduct of a reasonably yet minimally competent physician appears lower than that applied in Canada.

[29] Both Canada and the U.S. determine the liability by considering whether physicians held themselves as specialists or generalists. If they held themselves as generalists, their liability would be the same as generalists. However, if they held themselves as specialists, for instance as genetic specialists, whereas they are non-genetic specialist MDs, they would be held to the same standard as genetic specialists.

¹³ *Reeg v. Shaughnessy*; *Foster v. Klaumann*; & *Baker v. DeRiso*.

4. DISCUSSION AND FURTHER REMARKS

[30] Our legal analysis revealed an increased legal liability risk for non-genetic specialist MDs performing acts normally carried out by genetic healthcare professionals because of the growing demand for genetic testing services. The various liability risks relating to genetics tasks are difficult to assess given that the outcome of such claims will often depend on the specific facts, parties and legal professionals involved. Previous court decisions will likely influence the future requirements and frequency of these claims. However, if proper caution is not exercised, especially in the U.S., it is likely that litigation in this realm will follow the historical trend of new medical technologies being conducive to malpractice liability lawsuits. Yet, there is a need for more physicians capable of performing some genetic tasks to allow more timely access to such services for patients. In this context, there is a need for clarification on the exact tasks in genetics practice that could be performed safely by these non-genetic specialist MDs (Harding & al., 2019). Importantly, given that they would be held to a higher liability standard for those tasks, non-genetic specialist MDs should benefit from proper training in clinical genetics before systemically proceeding in this direction. Otherwise, this practice could result in lower quality of services for patients and an increasing number of successful legal liability suits against non-genetic specialist MDs in this context. Eventually, this outcome may lead to a growing number of non-genetic specialist MDs refusing to offer services in genetics that are needed by patients.

[31] The academic literature reports the concerns of primary care providers who have to manage the emergence of precision medicine which includes the provision of genetic counselling and testing (Bellcross & al., 2011; Bonter & al., 2011 ; Carroll & al., 2016 ; Vassy & al., 2018). A systematic review revealed that the current lack of professional education and guidelines about genetics negatively affects the integration of genetics into patient care, which is an issue as primary care providers are frontline health professionals regularly meeting with people with a genetic predisposition to cancer (Hamilton & al., 2017). Examples of this include that frontline health professionals rarely discuss genetics or will refer a patient for a genetic consultation without specifying the level of emergency associated with this consultation. The follow-up of carriers may not be made according to updated recommendations and standards.

[32] This problem is not specific to Canada and has also been identified in the United States and in the Netherlands (Cornel, 2019; McGrath & al., 2021). Another Canadian study illustrated the necessity for better coverage of medical genetics and genomics in the medical profession curriculum. For instance, learning objectives linked to medical genetics for themes, such as “communicate genetics information for informed decision” and “obtain specialist help on inherited conditions”, only reach 2 and 1% of students respectively in the pre-clerkship curriculum (Ouellet & al, 2023).

[33] Following our analysis of the relevant legal standards in Canada and the U.S., we believe the law as it currently stands does not require modification (Thorogood & al., 2019 ; Presseault, 1997). From a legal standpoint, there is no strong rationale to consider the question of the liability of non-genetic specialist MDs acting as specialists differently in the context of genetics than in other specialized contexts. Not holding these general practitioners to the higher liability threshold of genetic specialists could

encourage the development of a substandard clinical practice in genetics and different quality of care for patients able to see a genetics specialist from those who are not.

[34] Some authors have proposed the creation of multidisciplinary healthcare teams as a solution to prevent medical errors of non-genetic specialist MDs. Such committees would “serve as a treasure trove of resources for dealing with uncertainty and with situations comporting technical or clinical limitations” (Pasquier & al. 2022). According to some studies, resorting to multidisciplinary healthcare teams has increased the number of patients seen and enhanced the quality of services (Hamilton & al., 2017; Carroll & al., 2011). To the same extent, practice agreements between genetic specialists and general practitioners or specialists can limit the potential for error, with the community of practice being a relevant tool for collaborative work (Institut National de Santé Publique du Québec, 2018). Such studies propose communities of practice are a promising way forward “to better cope with the complexity of medical education” and serve as a “guide to the development of interventions designed to make the educational process in medicine more effective” (Cruess, Cruess & Steinert, 2018). Implementing these communities of practice would improve general practitioners’ practice, as well as medical students, as they will be working more regularly with genetics teams. This kind of integration could have beneficial impacts on physicians’ work efficiency but especially on the follow-up of at-risk populations (*Ibid*; Burgess & al., 2019 ; Seibert, 2015)

[35] In 2019, the University of Pittsburgh Medical Centre launched a multidisciplinary care model to deliver improved genomic testing and services in the primary care setting. The model Clinic comprises a primary care physician with training in genetics, a pharmacist specializing in pharmacogenomics, and two genetic counsellors (Massart & al., 2022). However, others contend that since most genetic specialists are concentrated in metropolitan areas and academic centres, this solution could have limited practical application in rural regions of the United States and Canada (Battista & al., 2011; Jenkins & al., 2021). In the province of Quebec, one such community CDTC's (Comité du diagnostic et du traitement du cancer) meetings are now held online via the Microsoft Teams platform, as a way to circumvent issues of geographical distances between cities and regions (CIUSSS du Nord-de-l'île-de-Montréal. 2022).

[36] *M.J.R. v Girard*, a recent case, warrants discussion here, as it may illuminate the path for future cases in genetics (*M.J.R. c. Girard*, 2019). In this Quebec Superior Court case, reviewing the facts associated with a medical liability claim against several medical professionals for the birth of an infant with Wolf Hirschhorn syndrome, the court agreed with an expert opinion that considered a work protocol established by the Montreal Jewish Hospital that divided the work between genetic specialists and genetic counsellors, under which genetic specialists did not have to meet patients directly as adequate (*Ibid.*). Furthermore, commenting on the work of both the genetic and non-genetic professionals involved in the case, the court found that without working in a single team, everyone nevertheless lent their assistance, to the degree relative to their knowledge and capacity, asking the opinion of more specialized colleagues as the medical case developed and raised additional questions (*Ibid.*). This analysis shows that a decentralized community of practice, where tasks and delegations to specialists are carefully established to play on one another's strengths, could help avoid medical malpractice lawsuits.

[37] While the creation of more such communities should be considered, in the short term, a priority objective remains to implement genetic professional education programs as a larger component of generalist training, adapted to current knowledge in this area (Blaine & al., 2008 ; Carroll & al., 2009 ; Falah & al., 2022 ; Plunkett-Rondeau, Hyland & Dasgupta, 2015 ; Talwar & al., 2016). One study showed that training nurse specialists in the scientific, psycho-social and ethical aspects of genetics and utilizing them as substitute genetic counsellors to provide risk assessment and offer genetic testing with the collaboration of genetic counsellors to supervise the sessions resulted in a four-fold increase in the number of patients seen (Cohen & Nixon, 2016).

[38] Considering the needs of the next generation of physicians, university programs in medicine should be adapted to integrate emerging health discoveries and practices more rapidly. Since genetics and precision medicine are rapidly evolving fields, it would be highly beneficial that genetic components of medical programs be revised on a regular basis (Talwar & al., 2016). We also believe that creating openly accessible guidelines for general practitioners who perform acts of genetic specialists could help consolidate a more diligent practice and prevent costly mistakes (Skinner & al., 2021).

[39] Ultimately, promoting good practice of non-genetic specialist MDs performing specialized tasks in genetics should be viewed as part of an ecosystem approach dedicated to improving the performance of a medical institution as a whole in genetics and precision medicine. In such an approach, different healthcare practitioners work in an interdependent complementary manner to provide quality genetic services to patients and are supported by adequate technical (e.g., satisfactory electronic health records (EHR) representation of genetic and genomic test results) and administrative practices at the institutional level.

5. CONCLUSION

[40] With the growth of clinical genetics and precision medicine, it is crucial to determine whether physicians' liability has evolved to reflect recent advances in genetic counselling and testing. The standard of practice applied to determine a non-genetic specialist MD's liability for medical incidents clearly depends on both their degree of knowledge of genetics and how they represent themselves to the patients (*Fiocco c De Varennes*, 2017; *X v Whelan*, 2011; *Topliceanu c Bojanowski*, 2018 ; *Foster v Klaumann*, 2013 ; *Baker v DeRiso*, 2015. According to our legal research, in Canada and the U.S., for a non-genetic specialist MD carrying out a medical act usually performed by a genetic healthcare professional, the standard of practice applicable would likely be that of a reasonably prudent clinical geneticist (Baudouin, Deslauriers & Moore, 2021; Robertson & Picard, 2017).

[41] Considering the importance of promoting accessible, high-quality healthcare, changing the liability standard to make it more lenient does not appear to be a responsible solution. Instead, what is required is a better implementation of genetic and genomic courses from pre-clerkship programs in faculties of medicine and professional settings to help physicians gain the appropriate knowledge and capacity to take on genetic healthcare professionals' tasks (Ouellet & al., 2023 ; Plunkett-Rondeau, Hyland & Dasgupta, 2015 ; Talwar & al., 2016). Developing standards and guidelines on clinical geneticists' tasks most likely to be carried out by non-genetic specialist MDs and

promoting the development of communities of practice would also help streamline and improve the practice of generalists in this context (Skinner & al., 2021).

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