Free genetic testing is not free of clinical and ethical considerations

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In most medical subspecialties, genetic and genomic testing have become a routine part of clinical care. However, access to genetic testing at the patient, provider, and provincial levels is inequitable, with varying approval processes and public funding and, consequently, differences in access and wait times. Recently, sponsored genetic testing (clinical-grade genetic testing partially or fully subsidized by industry) has become more readily available in Canada and is often marketed to practitioners outside of medical genetics who may see advantages in pursuing testing in this way; this has increased availability of genetic testing overall. Whereas sponsored genetic testing can simplify access, broaden testing options for patients, and advance research into genetic diseases, unique and important ethical, legal, and health care system–related considerations must be carefully examined.

Like provincially funded genetic tests, sponsored genetic tests must be ordered by a medical professional; they are not offered as direct-to-consumer tests. Sponsored genetic testing is available for a range of conditions and disorders, from neuromuscular to skeletal to ophthalmologic indications.[1] Most sponsored tests offered to people in Canada are performed in American laboratories, with most offering gene panel tests, that is, testing on a collection of genes (ranging to as many as 700) that may be involved in the condition being screened. The aim is often to identify patients who might benefit from specific treatments, trials, gene therapies, or future research, together with the pharmaceutical or biotechnology industry partners who often subsidize the testing.[2–4] In the United States, these subsidized testing programs may increase access to genetic testing for those without health insurance,[5] whereas, in Canada, they may be more commonly used to allow patients who do not meet provincial criteria for publicly funded genetic testing to obtain some testing or, in some provinces, to bypass funding approval or wait-lists for referral to genetics or genetic counselling, and allow patients to obtain results faster.

Ethical, legal, and health care system–related concerns in the Canadian context include the following. Many of Canada's provinces have centralized laboratories or programs that ensure the quality and appropriateness of any publicly funded genetic testing; however, sponsored genetic testing may not be subject to similarly rigorous quality assurance. The technologies and testing methodologies used by various sponsored programs' laboratories can further differ from those used in Canada's publicly funded systems, which may translate to differences in the sensitivities and specificities of the testing. Tests that include larger gene panels are not necessarily "better" than smaller panel tests; they may include genes not clinically indicated for testing, which may lead to clinical uncertainty and harms of medical or family member follow-up when variants of unknown significance are identified. Some companies may even incentivize testing by offering their own genetic counselling service, which, while important for patient care, may be fraught with conflicts of interest[6] and may not include follow-up referrals to local specialists or screening programs, if indicated. Moreover, because sponsored genetic testing is often ordered outside the conventional processes, fewer

Key points

- Health care providers in Canada across all specialties are increasingly able to order industry-sponsored genetic testing at no cost to their patients or to the health care system, which seems like a solution to prevailing inequities in access to testing but comes with several important ethical, legal, and health care system–related considerations that must be addressed.
- Most sponsored tests offered to people in Canada are performed in American laboratories, with the majority offering gene panel tests.
- Whereas many of Canada's provinces have centralized laboratories or programs that ensure the quality and appropriateness of any publicly funded genetic testing, including those sent internationally, sponsored genetic testing may not be subject to similarly rigorous quality assurance.
- Despite benefits to patients in terms of simplifying access, broadening testing options, and potentially advancing research into genetic diseases, privacy risks related to data sharing and other downstream harms and costs require careful attention.
- The Canadian College of Medical Genetics and Canadian Association of Genetic Counsellors recently published a position statement to outline key considerations; now is the time for health care jurisdictions to consider this important issue and to support the development of comprehensive guidance to help practitioners navigate this next generation of genetic testing and data sharing.

safeguards exist to ensure that results are appropriately integrated into a patient's electronic medical record to allow other treating physicians to have access to this information.

Another important consideration is that patient data collected by sponsored genetic testing programs become a commodity, often in an international space. Privacy and data-sharing practices with industry may or may not be transparent despite policy recommendations,[7] and Canadian privacy laws such as the *Personal Information Protection and Electronic Documents Act*[8] would not apply in other countries where testing may be performed or data may be transferred. If patients cannot control who sees and uses their data, their privacy may be at risk if downstream re-identification occurs.[9] Provider data may also be made available, which creates an undefined potential relationship of a health care provider with industry. For patients to provide free and informed consent, the data privacy conditions described above and any available provincially funded testing alternatives should be adequately explained to them when they consider sponsored genetic testing. This will ensure patients are not agreeing to conditions with which they would normally be uncomfortable in exchange for easier access to testing. Also noteworthy is that patient perspectives on sponsored genetic testing are not currently known.

Canada's health care system leaders should consider that, since sponsored programs evolve and end at the discretion of the testing company, jurisdictions that depend largely on the services of industry-sponsored genetic testing programs — perhaps because of competing demands on available health care funding — may experience new gaps in care. They may lose any chance to negotiate and advocate for appropriate service improvements for sustained, equitable access to care. How sponsored programs may successfully coexist with the public system has not been fully explored.

Given these concerns, the Canadian College of Medical Genetics and Canadian Association of Genetic Counsellors recently published a position statement with the intention of guiding Canada's health care providers about the use of sponsored genetic testing,[1] particularly those who lack familiarity with navigating the consenting, ordering, and interpreting of genetic tests. The increasing availability of sponsored genetic testing options in Canada's health care landscape has appeared to simplify and expand patient and practitioner access to genetic testing, yet the potential clinical, ethical, and legal considerations warrant close scrutiny. Near- and long-term expansion in no-cost testing and industry partnership in genetics, with patient data as the commodity, is likely. Commodification of data is not the norm in health care systems in Canada and should not be introduced without due consideration. We call on health care jurisdictions to consider this important issue urgently and to support the development of comprehensive guidance to help practitioners navigate this next generation of genetic testing and data sharing.

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