Quebec

Towards the routine use of genome-based testing in Canada:

State of Readiness Report Card

Why does Quebec need to be prepared for a future of genomic medicine?

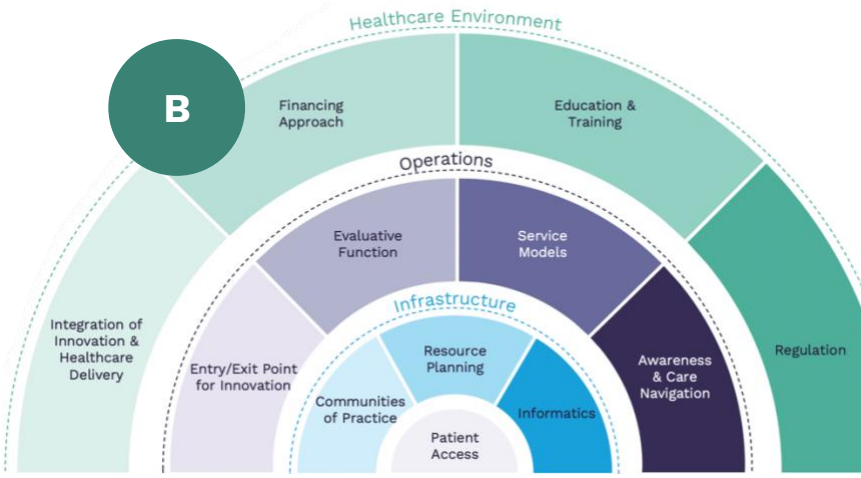
Improved care – including better health outcomes, reducing harm from therapy, and improving survival and quality of life.

Better patient and care provider experiences – reducing the need for referrals and other diagnostic tests, and improving time to diagnosis.

Better science and economic growth – aiding scientific discovery and clinical trial enrollment, creating commercial and investment opportunities as well as future-proofing Canada's healthcare workforce.

Healthcare efficiency – genomic medicine creates opportunities to reduce healthcare costs while creating the necessary infrastructure for delivering 21st century care.

Quebec has established many of the necessary conditions (1) required to deliver genome-based testing to best benefit patients through its single service organization, the DBBM. It championed laboratory governance reform and the use of a transparent and principled test evaluation process before other provinces.



Takeaway:
Quebec began taking necessary steps to reform its approach to genome-based testing over a decade ago. There are still opportunities to improve the optimal use of testing in Quebec.

Strengths:
- Single service organization (DBBM) that provides oversight and resource planning across integrated testing environment.
- Single point of entry and somewhat transparent evaluation process for new tests through the DBBM and INESSS.
- Nimble financing approach with funding available for test development.

Weaknesses:
- Navigation and education for care providers and patients limited but in development.
- Limited integration of innovation and healthcare delivery.
- Limited engagement and involvement of broader stakeholder community, particularly commercial innovators.

Evidence-based best practices	Action
High performing health systems require broad engagement of those impacted by testing. These include the patients, administrators, IT professionals, implementation and genome scientists, public and private sector innovators and others (scientists, legal and ethics experts, professional organizations, bioethicists, regulators) (2).	Expand opportunities for engagement with broader members of the healthcare/innovation community. The DBBM should consider a separate advisory council for commercial innovators.
Effective delivery of genetic testing requires educational standards as well as navigation tools for patients and the public including referral guidelines, a test directory, eligibility criteria, tools/education for ordering genetic testing, and a care clinic directory. (3)	Improve the processes of navigation for care providers and patients and develop standards for education and training.
While a translation research program exists, offering investigational tests to patients can play an important role in patient care: qualifying patients for clinical trial enrollment, as well as other research endeavors that further understanding of disease that will be increasingly relevant in the future. (4)	Quebec could benefit from further integrating innovative testing into the mainstream delivery of care.

More information about the State of Readiness Report Card for Genomic Testing in Canada can be found here: UR

Background

Canada's largest province by size and second largest by population (approx. 8.5 million) began reform on its system of laboratory governance in 2011. Molecular diagnostics including low- to medium-throughput sequencing is delivered across five "clusters" operating seven supra-regional laboratories (Capitale-Nationale [CHU de Québec – Université Laval]; Estrie [CHUS – Hôpital Fleurimont]; Montréal – CHUM [CHUM and Hôpital Maisonneuve-Rosemont]; Montréal – CUSM [CUSM and Hôpital général Juif]; Montréal – CHU Sainte-Justine [CHU Sainte-Justine]) as well as the Montreal Heart Institute (MHI). The Centre québécois de génomique clinique (CQGC) in 2018, physically situated at the Centre hospitalier universitaire Sainte-Justine (CHU Sainte-Justine), was established to conduct high-throughput (exome, transcriptome or whole-genome) sequencing. Testing is also referred to out-of-province providers for rarer conditions. The Direction de la Biovigilance et de la Biologie Médicale (DBBM) is the Ministry Program that has been tasked with coordinating the implementation of molecular diagnostic testing across all of these centres/clusters. The Institut national d'excellence en santé et en services sociaux (INESSS) is tasked with carrying out test evaluation.

	Topic	Established	Partially Established	Need for Improvement
Infrastructure	**Creating communities of practice and healthcare system networks**	• The RQDM acts as the supra-regional network and coordinating • Standards for analytic parameters or test proficiency are developed by the CQGC		• Processes for broader stakeholder engagement lacking
	Personnel, equipment, and resource planning	• Systematic oversight for resource planning through the DBBM		
	Informatics	• Integration of LIS across centres beginning fall, 2022	• Some integration of EHR with laboratory information	
Operations	**Entry/exit point for innovation**	• Single point of entry through DBBM • Explicit timelines for consideration		• Closed application process • No reassessment processes
	Evaluative Function		• Some stakeholder engagement	
	Service Models	• Service coordination across providers	• Need for further coordination in oncology	
	Awareness and care navigation		• Test list ("repertoire") available but lacks some information regarding available tests or access to tests	• Navigation for care providers and patients lacking
Environment	**Integration of innovation and healthcare delivery**		• Translational research through Genome Quebec and the CQGC	• Investigational testing not funded
	Financing approach	• Funding for test development, additional human resource costs • Funds available at the time of adoption • Clear funding formula		
	Education and Training		• Province-wide standards for education and training in development	
	Regulation	• DAP ISO 15189-province-wide accreditation and proficiency standards		• No analytic validation standards

References

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