Towards the routine use of genome-based testing in Canada:
State of Readiness Report Card

Why does Alberta 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.

Alberta has established many of the necessary conditions (1) required to deliver genome-based testing to best benefit patients. It is leading Canada in its readiness for the coming era of genomic medicine.

However, there are still opportunities to improve readiness.

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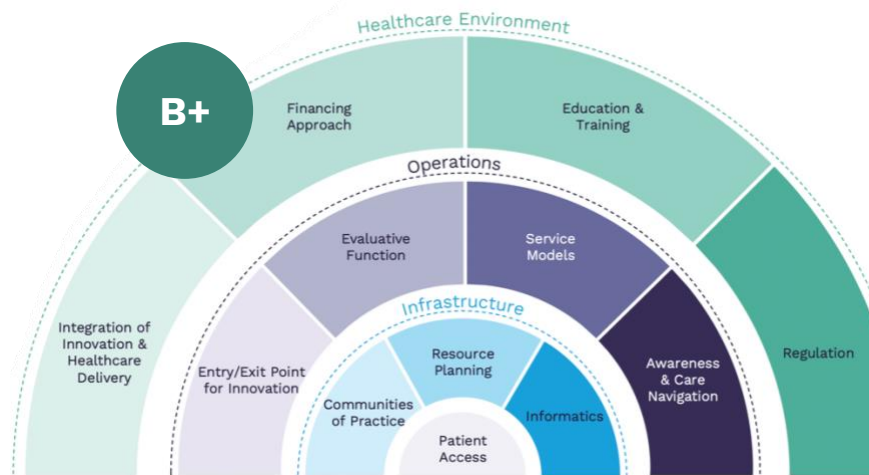
Takeaway:
Alberta has many of the necessary conditions for being ready for a coming era of genomic medicine. It is currently leading Canada in its readiness for the coming era of genomic medicine.

Strengths:
- Single service organization (APL) that provides oversight and resource planning.
- Integration of laboratory information across province is established.
- Integration and exchange with innovators through dedicated translational research programs and mainstream use of investigational testing.

Weaknesses:
- The test review process, timelines and criteria used are not publicly available.
- There are still opportunities to improve test navigation and educational standards for patients and providers.

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. This may be of particular use for health care planning.
More transparency around the test review process, timelines and criteria, will benefit a broader group of stakeholders. In doing so, it will also more closely adhere to current principles of technology assessment and deliberation (3,4) and improve perceptions of legitimacy for test adoption and create more opportunities for valuable innovation.	Improving the process of deliberation that surrounds the consideration and adoption of tests. Alberta's "one test-at-a-time" approach may be problematic for operationalizing uptake.
Unlike traditional tests, funding formulas for genetic testing must consider the need for additional human resources associate with development and proficiency testing (5) The current reliance on the private sector to fund test development may be counterproductive as priorities are influenced by who is paying, rather than unmet need, equity, or efficiency (6)	Improving the financing approach to include funding for test development and to account for the associated costs of testing.

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

Background

Alberta is Canada's fourth largest province by size and by population (approx. 4.2 million). Responsibility for testing is provided by a single organization, Alberta Precision Labs (APL), which is a wholly-owned subsidiary of Alberta's single health authority, Alberta Health Services (AHS). Highly specialized testing is largely delegated to teaching hospitals within Alberta's largest centres (Edmonton Zone and Calgary Zone) depending on program of care, including the University of Alberta, Alberta Children's Hospital, Stollery Children's Hospital, and university of Calgary, Foothills Medical Centre. Testing is also referred to out-of-province providers for rarer conditions.

	Topic	Established	Partially Established	Need for Improvement
Infrastructure	**Creating communities of practice and healthcare system networks**	• Accreditation and proficiency are based on the ISO15189		• Processes for engagement with external stakeholders lacking
	Personnel, equipment, and resource planning	• Systemic oversight for resources planning through the APL		
	Informatics	• Integrated LIS	• Projects underway to integrate laboratory and clinical data	
Operations	**Entry/exit point for innovation**			• No explicit timelines for consideration
	Evaluative Function	• Clinical stakeholder engagement through Laboratory Test Formulary committee and Strategic Clinical Networks		• External stakeholder engagement lacking • Evaluative criteria and process not made public
	Service Models	• Service coordination across providers		
	Awareness and care navigation		• Test directory and ongoing communication to providers but not all tests (e.g., oncology) listed	
Environment	**Integration of innovation and healthcare delivery**	• Investigational testing funded as part of larger multigene panels • Translational research through Genome AB, and the HIPP/ADEPT program		
	Financing approach	• APL has flexibility to release additional funds for testing on a per-case basis		• Funding formula not clear • No funding for test development
	Education and Training		• Training occurs but no province-wide standards for education and training	
	Regulation	• ISO 15189-based province-wide accreditation standards • Councils for creating analytic standards		

References

1. Husereau D, Steuten L, Muthu V, Thomas DM, Spinner DS, Ivany C, et al. Effective and Efficient Delivery of Genome-Based Testing-What Conditions Are Necessary for Health System Readiness? Healthcare. 2022 Oct 19;10(10):2086.

2. Health C for D and R. Collaborative Communities: Addressing Health Care Challenges Together. FDA [Internet]. 2021 Oct 12 [cited 2022 Jun 23]; Available from: https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together

3. Oortwijn W, Husereau D, Abelson J, Barasa E, Bayani DD, Santos VC, et al. Designing and Implementing Deliberative Processes for Health Technology Assessment: A Good Practices Report of a Joint HTAi/ISPOR Task Force. Int J Technol Assess Health Care. 2022 Jun 3;38(1):e37.

4. Drummond MF, Schwartz JS, Jönsson B, Luce BR, Neumann PJ, Siebert U, et al. Key principles for the improved conduct of health technology assessments for resource allocation decisions. Int J Technol Assess Health Care. 2008;24(3):244-58; discussion 362-368.

5. Christensen KD, Phillips KA, Green RC, Dukhovny D. Cost Analyses of Genomic Sequencing – Lessons Learned from the MedSeq Project. Value Health. 2018 Sep;21(9):1054–61.

6. Greer SL, Wismar M, Figueras J, European Observatory on Health Systems and Policies, editors. Strengthening health system governance: better policies, stronger performance. Maidenhead, Berkshire, England: Open University Press; 2016. 272 p. (European Observatory on Health Systems and Policies series).