

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

State of Readiness Progress Report



Why does Ontario 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.

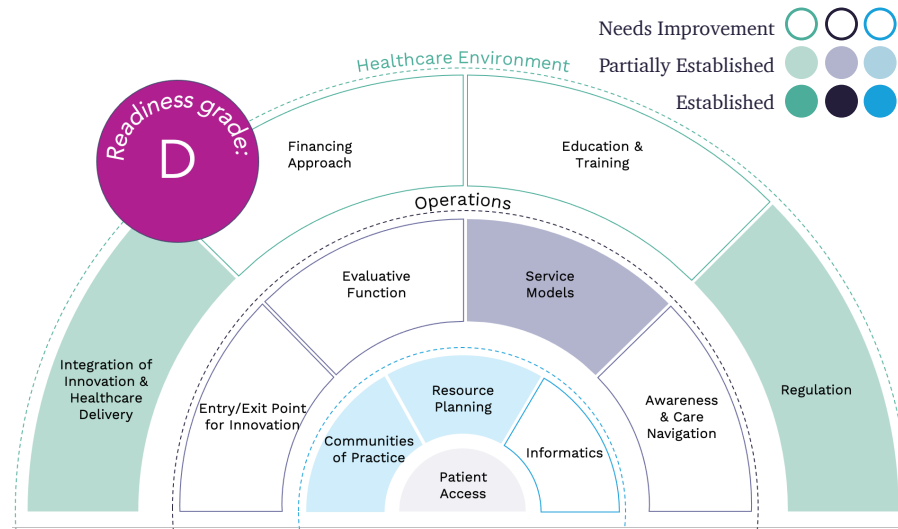
Better patient and care provider experiences – reducing the need for referrals and other diagnostic tests, and improving time to diagnosis.

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.

In 2021, Ontario made the establishment of many of the necessary conditions (1) to deliver genome-based testing a health system priority. Recent reforms, including, a more centralized health system, have created opportunities for improved coordination.

However, Ontario still lags behind other provinces in terms of readiness for genome-based testing.



Its current state of readiness has earned Ontario a grade of D

Takeaway:

Ontario has lagged behind and has only recently taken necessary steps to reform its approach to genome-based testing. It currently lacks many of the necessary conditions to be prepared.

Strengths:

- Recently created single service organization (PGP) intended to coordinate services and provide oversight and resource planning.
- Clear standards for accreditation and proficiency

Weaknesses:

- Funding not timely or transparent; no funding for test development or human resources
- No across-province integration of laboratory information
- Multiple evaluative frameworks- some not fit- for purpose.
- Limited engagement and involvement of broader stakeholder community.




Evidence-based best practices	Action
High functioning health systems must act as stewards, rather than decision-makers for individual purchasing.(2)	Ontario must shift away from the Ministry acting as a decision-maker for the funding of individual tests, and toward a system of Ministry as a steward. This will ensure expenditure, and care quality are driven by needs of the clinical community and avoid unnecessary patient delay.
Evaluation and adoption of testing must be responsive to innovation, transparent (3), timely and well connected to current investments in translational and discovery research as well as a community of care.(4)	Ontario has numerous, loosely connected systems of evaluation of testing. It must consolidate evaluation processes and adopt a single-entry approach, supported by horizon scanning.
Informatics is essential for test development, interpretation, and clinical decision support (5,6). Ensuring adequate integration of test results into electronic health records will also provide a key resource for real-world monitoring, disease management, quality assessment and assurance, and financing (7).	Ontario must create an integrated laboratory information system integrated with clinical health records to provide genetic testing that will most benefit patients and care providers while reducing unnecessary expenditure.

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

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Background

Ontario is the largest of Canada's 13 provinces and territories by population (approx. 14.8 million[1], with the vast majority of the province's inhabitants located in its southernmost regions) and third-largest by size. Provincial genetic testing is carried out in a decentralized fashion, across Ontario hospitals, including the Children's Hospital of Eastern Ontario for newborn screening. Some testing is commissioned to out-of-province providers as well. Somatic testing is conducted across 12 centres of varying sizes [Hamilton Health Sciences/ St. Joseph's Healthcare Hamilton; Health Sciences North; Kingston Health Sciences Centre; London Health Sciences Centre; Markham Stouffville Hospital; Mount Sinai Hospital; Sunnybrook Health Sciences Centre; The Ottawa Hospital; Trillium Health Partners; Unity Health – St. Michael's Hospital; University Health Network; William Osler Health System].

	Topic	Established	Partially Established	Need for Improvement	References
 Infrastructure	Creating communities of practice and healthcare system networks		<ul style="list-style-type: none"> Laboratories work independently coordination through PGP/PLMP Networks being developed through PLMP and PGP-led clinical leadership forum 	<ul style="list-style-type: none"> Processes for engagement with commercial innovators lacking 	<ol style="list-style-type: none"> 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? <i>Healthcare</i>. 2022 Oct 19;10(10):2086. World Health Organization. <i>Everybody's business : strengthening health systems to improve health outcomes : WHO's framework for action</i> [Internet]. Geneva: World Health Organization; 2007. Available from: https://apps.who.int/iris/bitstream/handle/10665/43918/9789241596077_eng.pdf 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. <i>Int J Technol Assess Health Care</i>. 2022 Jun 3;38(1):e37. 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. <i>Int J Technol Assess Health Care</i>. 2008;24(3):244-58; discussion 362-368. Louie B, Mork P, Martin-Sanchez F, Halevy A, Tarczy-Hornoch P. Data integration and genomic medicine. <i>Journal of Biomedical Informatics</i>. 2007 Feb 1;40(1):5-16. Shah S. Better bioinformatics will help labs manage genetic testing. <i>MLO Med Lab Obs</i>. 2AD;49(2):28, 31. Warner JL, Jain SK, Levy MA. Integrating cancer genomic data into electronic health records. <i>Genome Med</i>. 2016 Oct 26;8(1):113.
	Personnel, equipment, and resource planning		<ul style="list-style-type: none"> Working group report published in 2018 New PGP area of focus --completed for cancer genetics 		
	Informatics		<ul style="list-style-type: none"> Some integration of EHR with laboratory information New provincial program area of focus 	<ul style="list-style-type: none"> No cross-province integration of laboratory information 	
 Operations	Entry/exit point for innovation		<ul style="list-style-type: none"> Open proposal process newborn and prenatal testing; OGAC reviews 	<ul style="list-style-type: none"> No single point of entry No explicit timelines No reassessment process 	
	Evaluative Function		<ul style="list-style-type: none"> Some evaluation transparent (e.g., OGAC) with some stakeholder engagement Ongoing evaluation through PGP-led expert and advisory groups 	<ul style="list-style-type: none"> No consistent evaluative framework Multiple evaluation frameworks with some not timely 	
	Service Models		<ul style="list-style-type: none"> Partially established through PGP 		
	Awareness and care navigation		<ul style="list-style-type: none"> Test navigation re-source in development Test lists available 		
 Environment	Integration of innovation and healthcare delivery		<ul style="list-style-type: none"> Some testing regimes combine established and investigational testing Some large-scale implementation projects with industry partners 		
	Financing approach			<ul style="list-style-type: none"> Funds available on annual budget cycles or sometimes not available at time of adoption Funding formula not clear No funding for test development, additional human resource costs 	
	Education and Training			<ul style="list-style-type: none"> No province-wide standards for education and training in development 	
	Regulation	<ul style="list-style-type: none"> Accreditation and proficiency are based on the ISO15189 		<ul style="list-style-type: none"> No province-wide analytic validation standards 	

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