



Recommendation Report for Ontario's Clinical Genetic Services

May 2018

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Executive Summary

In 2017, Cancer Care Ontario formed two working groups to develop recommendations for improving genetic services across Ontario, specifically in the areas of clinical cancer genetic services, and hereditary cancer testing.

This report, developed through the Clinical Genetic Services Working Group, outlines a set of recommendations for improving clinical cancer genetic services in Ontario. While the primary focus of this report is on adult hereditary cancer genetics, many of the recommendations could be applied to other areas of genetic services.

A second working group, the Hereditary Cancer Testing Working Group (HCT WG), was formed in parallel to the first. The HCT WG developed recommendations for oversight and implementation of hereditary cancer testing in Ontario. Recommendation reports from both working groups were submitted to the Ministry of Health and Long Term Care on May 8, 2018.

Background

Hereditary cancer accounts for approximately 5-10% of all cancer incidenceⁱ. The number of genes identified that can play a role in the diagnosis and management of hereditary cancer syndromes (HCS) has increased steadily over time. Traditionally, genetic counselling has been a prerequisite to genetic testing for hereditary cancer. Increase in demand for genetic testing has significantly impacted the need for genetic counselling, leading to inequity in patient access, long wait times, and variation in the delivery and quality of care. In an effort to understand the extent of these issues, the Clinical Genetics Working Group (Working Group) was convened to lead a current state assessment of clinical cancer genetic services in Ontario, and develop recommendations for oversight, service delivery and practice, and improved access to genetic services.

The current state assessment included engagement with the genetics field and associated health care providers, an environmental scan of genetic services, a baseline survey completed by genetics clinics, and a cancer genetic counselling Health Human Resources (HHR) modelling analysis.

Highlights of key findings from current state assessment:

- 25 of 31 genetics clinics (81%) in Ontario provide cancer genetic services; approximately half accept cancer referrals only, the other half accept a variety of referral types (general, prenatal, etc.) in addition to cancer.
- The majority of cancer referrals are for breast/ovarian (78%), followed by colorectal/endometrium/gastric (15%); a combination of other types make up the remainder (7%).
- Cancer referrals to genetic services have almost tripled between 2007 and 2016, from ~6378 to ~18084. A comparison of FTE counts across Ontario for the same timeframe shows a slight decrease in the number of medical geneticists (-1.6 FTE) and oncologists (-1.4 FTE), and a slight increase in genetic/nurse counselling FTEs (+8.9 FTE).
- It is estimated that Ontario requires 78.1 FTE genetic counsellors to meet the current needs of hereditary cancer patients. Results from the baseline survey show there are currently 43.4 cancer genetic counsellor FTE's, meaning there is an estimated unmet need of 34.7 FTE cancer genetic counsellors. An increase in medical geneticists/medical oncologists is also required, not only to supervise and advise the genetic

counsellors, but to also provide direct patient care. There are not enough resources in the system to fill this gap; alternate models of care and innovative process improvements must be included in the solution.

- Average wait times for accessing genetic counselling services in Ontario range from ~1 month to ~2 years.

Recommendations for Ontario

The following recommendations build on key elements of the Ontario cancer system, including:

- A network of clinical genetics centres and laboratories to coordinate access and delivery of high quality genetic services
- Increased understanding of the role of genetic services in the detection and prevention of cancer
- Advances in technology that allow more genes to be investigated for the same (or lesser) costs as single gene testing
- Increased need for genetic information to be available in the province to support patient treatment decision making over time and across practice settings
- Increased use of molecular tumour testing to identify patients with a possible hereditary cancer syndrome
- The development and refinement of high-risk cancer screening recommendations and/or guidelines

There is a need for increased coordination, oversight and resourcing to enhance patient access, to ensure the delivery of high quality services, and integration with new and developing cancer programs.

Recommendation 1. Establish governance and oversight

Establish provincial oversight for cancer genetic services to develop and oversee strategic planning and funding, and to develop standards and guidelines to ensure quality, educate providers and patients, reduce practice variation, increase capacity and provide patients with timely access to services.

The oversight functions should include:

- Planning related to:
 - System capacity and projections for hereditary cancer testing, clinical cancer genetic services, and high risk screening and prevention resources
 - The role for out of country hereditary genetic testing
 - Identifying human resource and information technology requirements
 - Developing models of care to ensure services are delivered by the right provider at the right time in the right place
 - Horizon scanning tied to new evidence and emerging actionable genes of clinical utility
 - Monitoring, reporting and evaluating key performance indicators related to access and quality
 - Education of providers and public
- Broad engagement with stakeholders to:
 - Foster and develop strong partnerships to support the development and delivery of comprehensive and coordinated services
 - Move new knowledge, evidence, and translational research to patient care

- Include a variety of perspectives of those who will impact and be impacted by these services, such as genetic services providers, oncologists, surgeons, primary care providers and patients and family members
- Provide advice on funding mechanisms to support sustainable access to Ontario patients

Recommendation 2. Improve patient access to genetic services through strategic planning

Conduct comprehensive strategic planning to assess/address capacity and service gaps in clinical and laboratory cancer genetic services, and develop policies to close those gaps to improve patient access to services.


Strategic planning activities should:

- Utilize system capacity estimates and demand projections for hereditary cancer testing to perform Health Human Resource (HHR) modelling to identify the resources needed to meet growing demand for testing, including laboratory genetic services and corresponding clinical cancer genetic services.
- Investigate alternate models of care that would alleviate wait times and improve patient access and experience, such as:
 - Oncology-based/rapid genetic testing ('mainstreaming' - facilitates cancer patients to access germline testing at one of their routine cancer clinic appointments, eliminating a step in the traditional referral process)
 - Group counselling
 - Province-wide system coordinated access (referral, scheduling)
 - Virtual/web/telephone counselling and consultation
 - eConsult
- Leverage technology to support the referral process and alleviate the administrative workload of genetic counsellors, such as:
 - Electronic Medical Record (EMR)
 - Provincial/Regional Clinical Viewer(s) (e.g. ConnectingOntario, ClinicalConnect)
 - Electronic pedigree software, family history questionnaire, referral, booking, and ordering of tests
 - Integration between systems (e.g. integration with laboratory information systems)
- Develop, implement, and monitor performance measures and establish provincial targets related to access and quality.
- Leverage technology to collect, store and transfer data related to key performance indicators

Recommendation 3. Standardize practice to reduce variation and ensure high quality services for patients across the province

Develop and implement evidence based tools, advice, and clear guidelines (for referral, testing, and care) to standardize practice while ensuring equitable and timely access to genetic services for patients across the province. This may include:

- Developing, maintaining and mandating clear guidelines, or pathways, outlining standardized eligibility criteria for genetic counselling and genetic testing to consistently identify the appropriate referral, test, and/or care for patients
- Endorsing standardized definitions for identifying someone as 'high risk' for developing cancer, along with associated surveillance or risk-reducing options, based on current evidence, and developing a mechanism to review and update the clinical guidance

- 
- Establishing standardized definitions for prioritizing referrals (urgent vs. routine), together with consistent provincial wait time targets for each prioritization category
 - Evaluating information needs for referrals, streamlining patient information requirements to create a set of standardized provincial referral criteria and associated forms (by referral type)

Create a network for sharing knowledge utilizing multiple methods including communities of practice, continuing education opportunities and the ability to access and share resources.

The recommendations in this report are a product of the engagement, knowledge and feedback of the genetics field, and propose concrete suggestions for addressing the type of change needed to increase patient access to high quality genetic services throughout Ontario.

Introduction

This report outlines a set of recommendations for oversight and service delivery of clinical cancer genetic services in Ontario, including key suggestions to reduce practice variation, increase capacity and improve patient access to services. While the primary focus of this report is on adult hereditary cancer genetics, many of the recommendations could be applied to other areas of genetic services.

In 2017, Cancer Care Ontario formed two working groups to develop recommendations for improving genetic services across Ontario, specifically in the areas of clinical cancer genetic services, and hereditary cancer testing.

This report, developed through the Clinical Genetic Services Working Group, outlines a set of recommendations for improving clinical cancer genetic services in Ontario. While the primary focus of this report is on adult hereditary cancer genetics, many of the recommendations could be applied to other areas of genetic services.

A second working group, the Hereditary Cancer Testing Working Group (HCT WG), was formed in parallel to the first. The HCT WG developed recommendations for oversight and implementation of hereditary cancer testing in Ontario. Recommendation reports from both working groups were submitted to the Ministry of Health and Long Term Care on May 8, 2018.

Background

Genetic counselling is the process of helping people understand and adapt to the medical, psychological and familial influences of genetic contributions to disease. Clinical Genetic Services use family and medical histories to assess initial risk, and/or recurrence, of disease; provide education about inheritance, testing, management, prevention, resources and research; and counselling to promote informed choices and adaptation to disease riskⁱⁱ. Healthcare providers who specialize in genetic counselling are predominantly genetic counsellors, genetic nurse counsellors, and medical geneticists; but may also include other healthcare providers with training in genetics (e.g. oncologists, primary care).

Focusing on the cancer system, while all cancer is genetic, 5-10% of cancer incidence is caused by inherited mutationsⁱⁱⁱ. The number of genes identified as causing hereditary cancer syndromes (HCS) has increased significantly over time. Traditionally, the pathway to cancer genetic testing is initiated with referral to a Genetics Clinic, with appropriateness for testing determined through genetic counselling. Management options for individuals with HCS have expanded in recent years with the advancement of personalized medicine^{iv,v}. These advancements, together with increased patient awareness of genetic testing^{vi}, have led to an increase in genetic counselling referrals. With lack of a provincial plan to adapt to these increases, wait times for genetic services are high (exceeding two years in some cases), delaying testing, management options, and care.

Through CCO's engagement channels¹, the field communicated these concerns, identifying the following key issues affecting clinical genetic services in Ontario:

¹ Initial engagement with CCO Clinical Leads, Provincial Leadership Council, Regional Vice Presidents, and working group members.

- Lack of a provincial system
- Increasing need for genetic services and corresponding testing
- Increasing wait times
- Resources not keeping pace with demand

The Clinical Genetics Working Group (Working Group) was brought together to lead a current state assessment of clinical cancer genetic services in Ontario, and develop recommendations for oversight, service delivery and practice, and improving access to genetic services. The working group brought together genetics experts from across the province, and included representatives from genetic counselling, clinical genetics, laboratory genetics, medical oncology, primary care, research, and administration. The working group also included a patient and family advisor to represent the patient voice. Specific deliverables of the working group were to:

- Review and discuss the current state of genetic services in Ontario with a primary focus on adult cancer related services, identify system gaps and challenges, as well as potential improvement strategies
- Analyze the findings of the baseline survey and environmental scan on genetic services
- Review the genetic services modelling analysis, completed in collaboration with CCO's Cancer System & Infrastructure Planning Program
- Develop recommendations for oversight and service delivery to reduce practice variation, increase capacity and improve access to genetic services

Results of these activities, as well as stakeholder feedback were used in the development of the recommendations.

Current State

To understand the current state of clinical cancer genetic services the baseline survey was designed to collect information from genetics clinics across Ontario using an electronic online survey program. The content was modelled after the Molecular Oncology Task Force Survey of Clinical Cancer Genetic Services, 2008^{vii}, with updates made to capture additional information requirements. The baseline survey² focused on assessing the current state of clinical genetic services under the following categories:

- Demographics
- Referral volumes and patient visits
- Patient access to genetic services (wait times)
- Resources and funding
- Supporting technologies, referral and scheduling processes
- Recommendations for improving genetic services in Ontario

² A copy of the baseline survey is available upon request via email at: PLMP@cancercare.on.ca

Overview of Survey Responses

In July 2017 the baseline survey was administered to 31 genetics clinics. 28 clinics completed the survey, achieving a response rate of 90%. Additional responses were received via email regarding the cancer genetic counsellor (GC) full time equivalent (FTE) count only (response rate 100% for cancer GC FTE count³). The complete list of clinics can be found in Appendix C.

Description of Clinical Unit

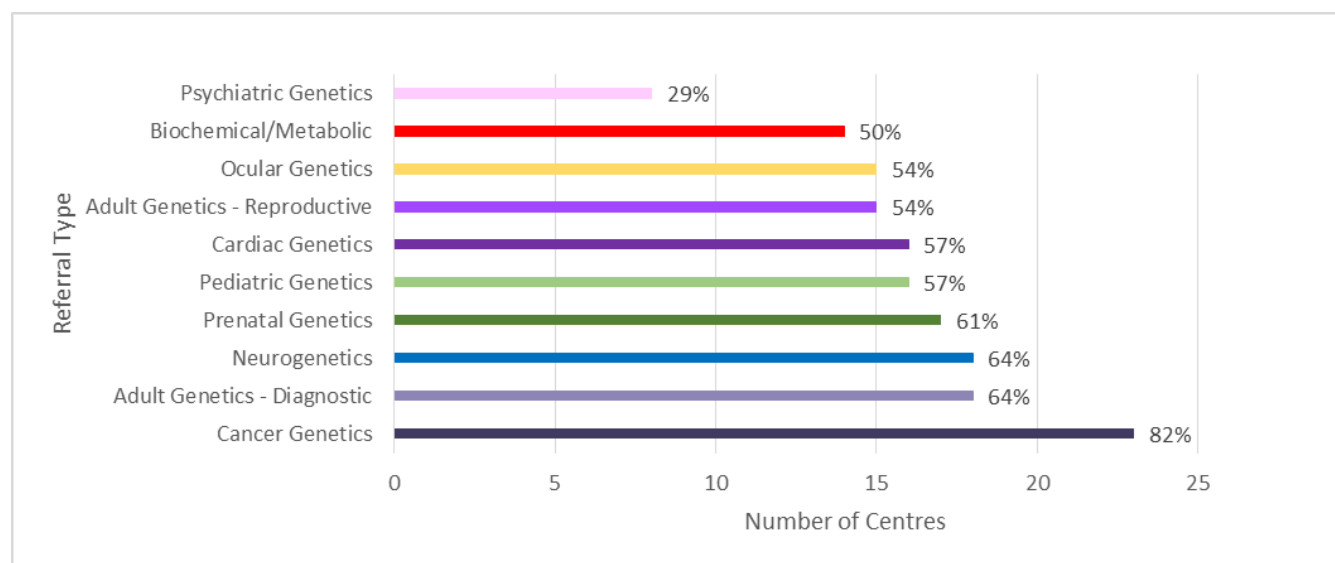
Respondents were asked to describe their clinical unit. Where possible and applicable, survey results will be displayed based on the following clinic categories:

Clinic Category	Description	#
Cancer and General Genetics Clinic	Accept cancer and non-cancer genetics referrals	9
Cancer and General Northern Genetics Clinic – Northern Regional Genetics Program (NRGP)	Accepts cancer and non-cancer genetics referrals, located in northern Ontario as part of the NRGF	5
Cancer Specialized Genetics Clinic	Accepts cancer genetics referrals only	9
Specialized Genetics Clinic (no cancer):	Accepts referrals only related to specialty, excludes cancer (i.e. pre-natal, neurogenetics)	3
General Genetics Clinic (no cancer)	Accepts a variety of genetics referrals, excluding cancer	2

25 of 31 (81%) clinics provide cancer genetic services. Of those, the majority of cancer referrals are for personal and/or family history of breast/ovarian cancer (78%), followed by colorectal/endometrium/gastric (15%), and a combination of other types making up the final 7%. 22 of 31 clinics (71%) accept genetics referrals not directly related to cancer. Figure 1 summarizes the genetic services provided by clinics (based on results from the 28 survey respondents, denominator = 28).

³ The cancer GC FTE count was used for determining current capacity, and projections, for cancer genetic counselling services. See Appendix D.

Figure 1. Summary of genetic services provided in Ontario



Referrals and Patient Visits

Respondents were asked to provide retrospective information about the numbers of referrals that were received and the number of patients that were seen between 2014 and 2016. Some respondents reported difficulties in extracting these data due to limitations in the way the data were captured or stored in their system, lack of an analytic resource to pull the data, and/or lack of data altogether. Overall, a slight increase in referral and patients seen is observed over the three year period for both cancer and non-cancer related referrals. Table 1 below provides a summary of the values received, based on a combination of exact values and best estimates.

Table 1. Number of new patients referred for genetic counselling, and seen by a GC between 2014 and 2016

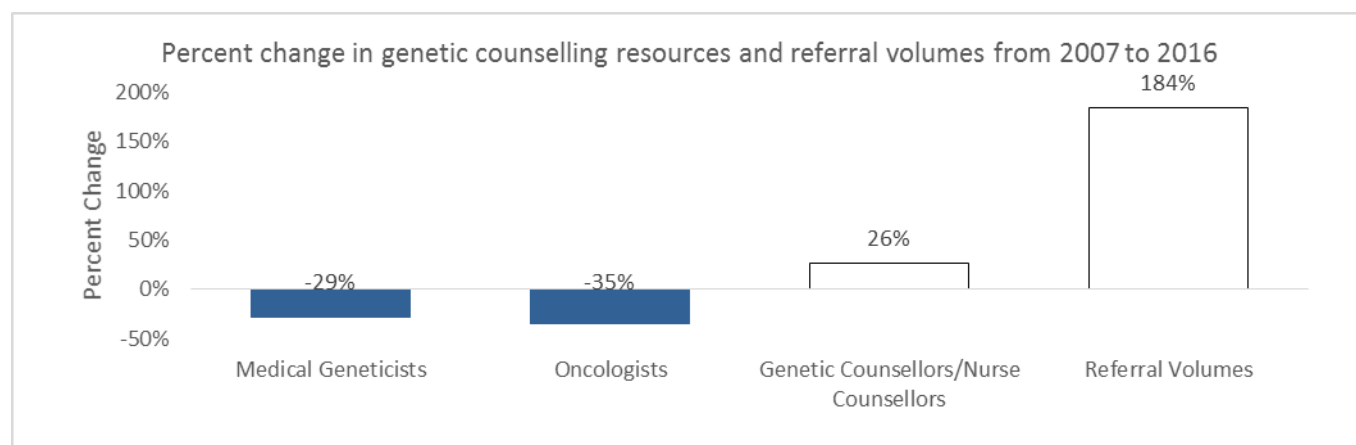
	Non-cancer						Cancer						OBSP					
	2014		2015		2016		2014		2015		2016		2014		2015		2016	
R = Referred, S = Seen	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S
NRGP	1259	1094	1223	1078	1109	906	941	822	918	810	1082	919	557	387	470	350	405	345
Cancer Specialized	N/A	N/A	N/A	N/A	N/A	N/A	8980	6436	8646	6565	8789	6630	3978	3651	4577	3964	4234	3705
Cancer and General	11388	12784	12198	12892	12483	12700	7083	6066	7031	5488	8213	6334	1825	1820	1931	1860	1888	1836
Genetic Clinic - no cancer	4315	4036	4607	4367	4872	4491	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total	16555	17507	17621	17930	18464	18097	17004	13324	16595	12863	18084	13883	6360	5858	6978	6174	6527	5886
Subtotal for year to year comparison*	16555	17507	17621	17930	18057	17690	17004	13324	16595	12863	17708	13507	6360	5858	6978	6174	6457	5816

Imputation was used for 9 of 28 clinics due to missing 'referred from' data.

*One clinic was only able to provide data from 2016, and was removed for the year to year comparison.

In a comparison of results reported in the 2008 MOTF report⁴, cancer referrals to genetic services have almost tripled between 2007 and 2016, from 6378 to 18084. A comparison of FTE counts for the same timeframe shows a slight decrease in the number of medical geneticists (-1.6 FTE) and oncologists (-1.4 FTE), and a slight increase in genetic/nurse counselling FTEs (+8.9 FTE). (Figure 2.)

Figure 2. Change in cancer genetic counselling resources and referral volumes, 2007 vs 2016



Patient Access to Genetic Services (Wait Times)

Wait times measure the timeframe between a request for service being made and the service taking place and is an important indicator of how quickly patients can access care. 75% of clinics measure wait times for genetic counselling referrals. The method(s) used for measuring wait times varied significantly across respondents, with 41% using a database, 23% tracking in a spreadsheet, 23% relying on a 'mental record', and 13% using a paper based method. Respondents were then asked to provide the average wait times (or best estimate) for cancer related referrals, Ontario Breast Screening Program (OBSP) eligible referrals, and non-cancer referrals received at their clinic. Aggregate results are listed in Table 2.

⁴ Data source: The 2007 data set was obtained from the Molecular Oncology Task Force Survey of Clinical Cancer Genetic Services, 2008ⁱ

Table 2. Wait times in calendar days from referral to first appointment with a GC

Wait times in calendar days from referral to first appointment (self-reported survey data)					
		Average (by clinic)		Range	
Referral Type	Average*	Highest	Lowest	High end	Low end
Routine/Non-urgent cases					
Cancer	183	590	30	730	30
OBSP Eligible	122	590	30	730	30
Non-Cancer Referrals (excluding prenatal)	232	510	45	700	40
Urgent cases					
Cancer	24	91	5	90	0
OBSP Eligible	16	48.5	5	90	0
Non-Cancer Referrals (excluding prenatal)	22	75	3	90	1
Prenatal Only (all cases urgent)	7	7	7	14	1

*Weighted provincial average based on referral volumes

Weighted averages vary by referral type, with non-cancer related referrals averaging a 232 day wait from referral to initial appointment, cancer related referrals averaging a 183 day wait, and OBSP eligible referrals averaging a 122 day wait. By clinic, the shortest reported wait times average 30 days for cancer genetics and 45 days for non-cancer genetics, while the longest average 590 days for cancer genetics, and 510 days for non-cancer genetics.

Twelve clinics responded to this question by providing a range. The midpoint of the range was used in the calculation of averages. The range was also kept for reference, and the highest and lowest ranges are reported in the table above.

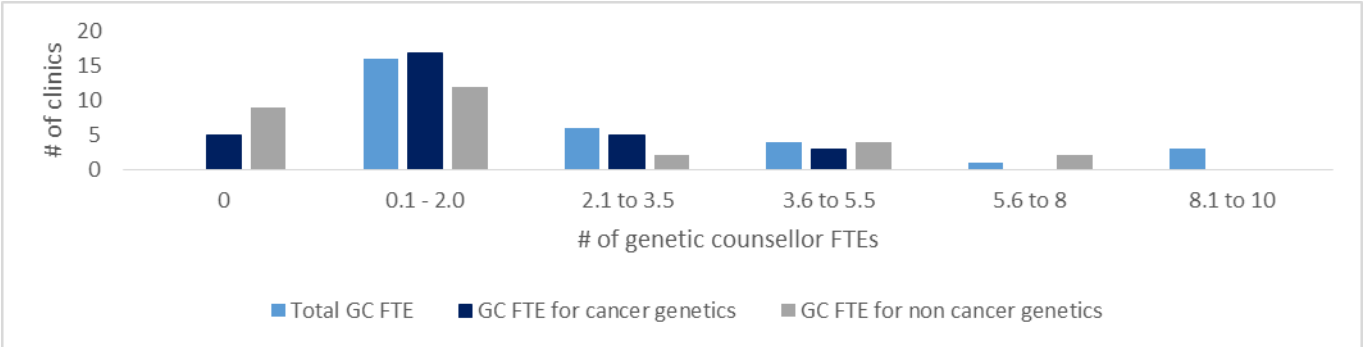
Urgent referrals:

All clinics provide an option for identifying referrals as urgent⁵. When asked if they had a documented policy for identifying 'urgent cases', 63% reported having an informal (undocumented) policy, 22% reported having a formal written policy in place, and 15% did not have a policy. In 82% of clinics, the person most responsible for identifying and triaging urgent referrals is a genetic counsellor, 36% of those clinics report triaging urgent cases in consultation with a medical geneticist or advisor.

89% of clinics reported having a target wait time for urgent cases. The target wait time for urgent cases varied across the province and ranged from 7 to 90 days for both cancer and general referrals and 0 (same day) to 21 days for prenatal referrals (see Appendix E, Figure 10).

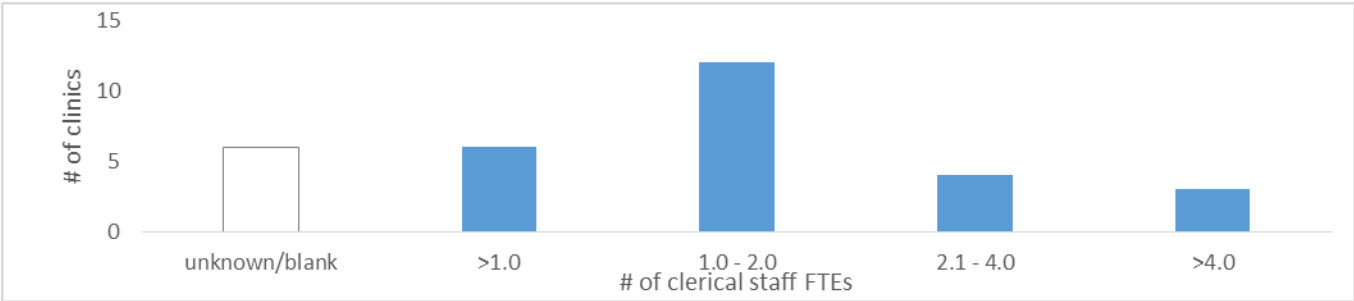
⁵ For prenatal clinics, all referrals are considered urgent.

Figure 3. The number of genetic counsellor FTEs reported per clinic



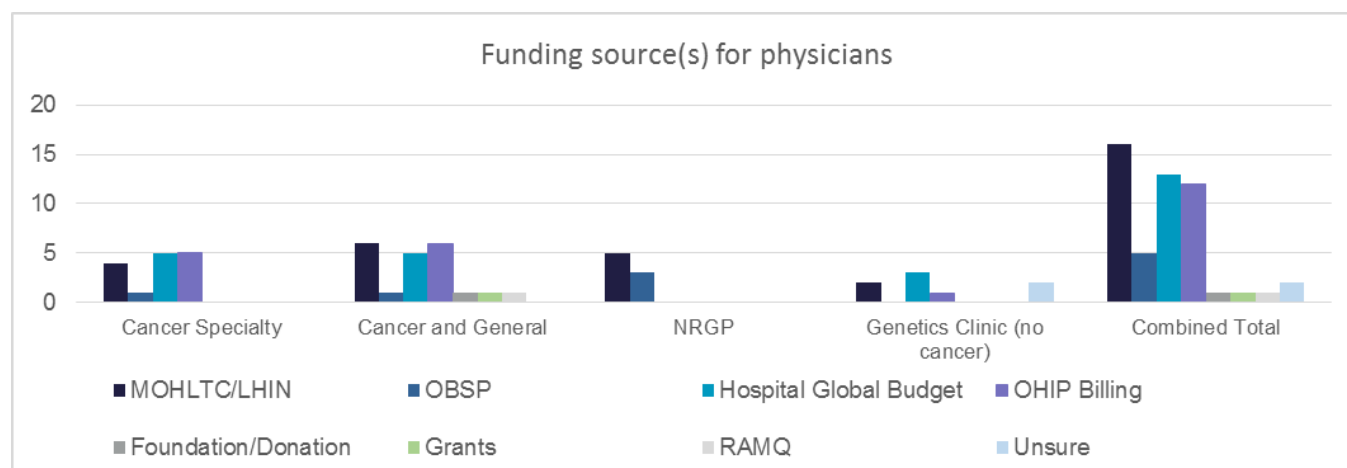
Most clinics are staffed with two or fewer genetic counsellor FTEs. The zero FTE count for cancer genetic counsellors and non-cancer genetic counsellors corresponds with clinics that do not accept the respective referral type.

Figure 4. The number of clerical staff FTEs reported per clinic



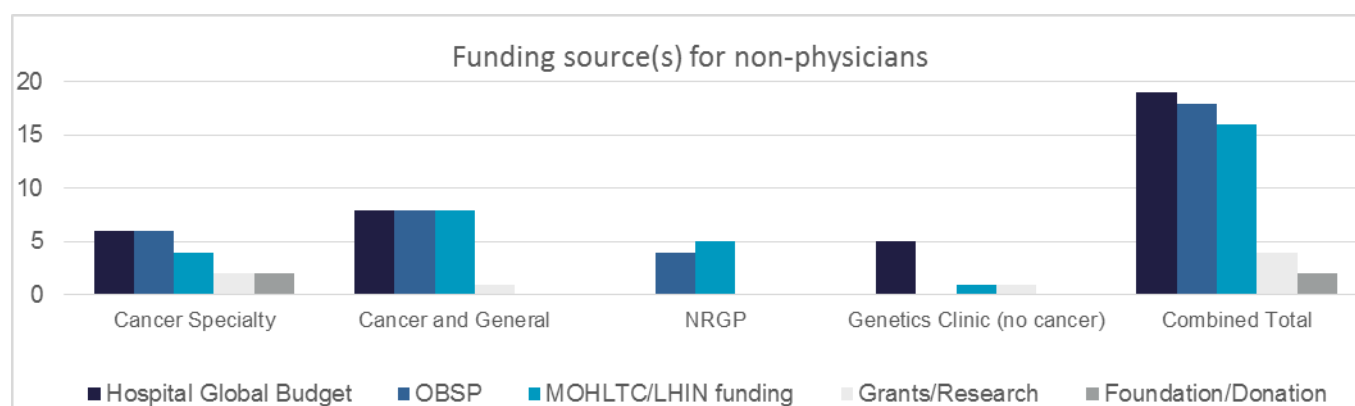
Most clinics have two or fewer clerical staff FTEs at their clinic. Three clinics have more than 4 clerical staff FTEs.

Figure 5. Types of physician funding sources reported by genetics clinics



A variety of funding sources are used for funding physician positions within and between genetics clinics. The 5 NRGP sites do not use OHIP billing for physician funding, as they have no onsite geneticists. Instead, the various geneticists working with these clinics are paid a stipend to travel 4-6 times per year from southern, western or eastern Ontario to attend 4-6 patient clinics per site per year (most often these are 2 day clinics). In addition, each of the 5 NRGP sites has one geneticist who is paid a yearly stipend to act as the Clinical Advisor for the site and, in this role, is available to the genetic/nurse counsellors in the genetics clinic throughout the year by phone, email, and/or video conference.

Figure 6. Types of non-physician funding sources reported by genetics clinics



Most clinics that accept cancer referrals rely on base funding (MOHLTC/LHIN, hospital global budget) and OBSP funding to support funding of non-physician positions. Four clinics also utilize funding from grants/research, and two clinics reported funding provided through foundation/donation.

Most respondents (71%, 20 clinics) require, or might require (11%, 3 clinics), additional resources to ensure timely access to services for their current patient population. Needs identified include: Administrative support; Additional clinical staff; Access to specialists/medical geneticists; Information technology; and, Consultation space/location. Five clinics (18%) reported meeting their current resource needs.

Recommendations for Ontario

The following recommendations build on key elements of the Ontario cancer system, including:

- A network of clinical genetics centres and laboratories to coordinate access and delivery of high quality genetic services
- Increased understanding of the role of genetic services in the detection and prevention of cancer
- Advances in technology that allow more genes to be investigated for the same (or lesser) costs as single gene testing
- Increased need for genetic information to be available in the province to support patient treatment decision making over time and across practice settings
- Increased use of molecular tumour testing to identify patients with a possible hereditary cancer syndrome
- The development and refinement of high-risk cancer screening and surveillance guidelines

There is a need for increased coordination, oversight and resourcing to enhance patient access, to ensure the delivery of high quality services, and integration with new and developing cancer programs.

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 - Education of providers and public
- Broad engagement with stakeholders to:
 - Foster and develop strong partnerships to support the development and delivery of comprehensive and coordinated services
 - Move new knowledge, evidence, and translational research to patient care
 - Include a variety of perspectives of those who will impact and be impacted by these services, such as genetic services providers, oncologists, surgeons, primary care providers and patients and family members
- Provide advice on funding mechanisms to support sustainable access to Ontario patients

The demand for genetic services⁶ is increasing, there are long wait times and variability in how services are offered. Oversight is needed to put a system in place to support this service area that has the responsibility and accountability for planning, quality, service delivery, access and funding.

Recommendation 2. Improve patient access to genetic services through strategic planning

Conduct comprehensive strategic planning to assess/address capacity and service gaps in clinical and laboratory cancer genetic services, and develop policies to close those gaps to improve patient access to services.

Strategic planning activities should:

- Utilize system capacity estimates and demand projections for hereditary cancer testing to perform Health Human Resource (HHR) modelling to identify the resources needed to meet growing demand for testing, including laboratory genetic services and corresponding clinical cancer genetic services.
- Investigate alternate models of care that would alleviate wait times and improve patient access and experience, such as:
 - Oncology-based/rapid genetic testing ('mainstreaming' - facilitates cancer patients to access germline testing at one of their routine cancer clinic appointments, eliminating a step in the traditional referral process)
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- Leverage technology to support the referral process and alleviate the administrative workload of genetic counsellors, such as:
 - Electronic Medical Record (EMR)
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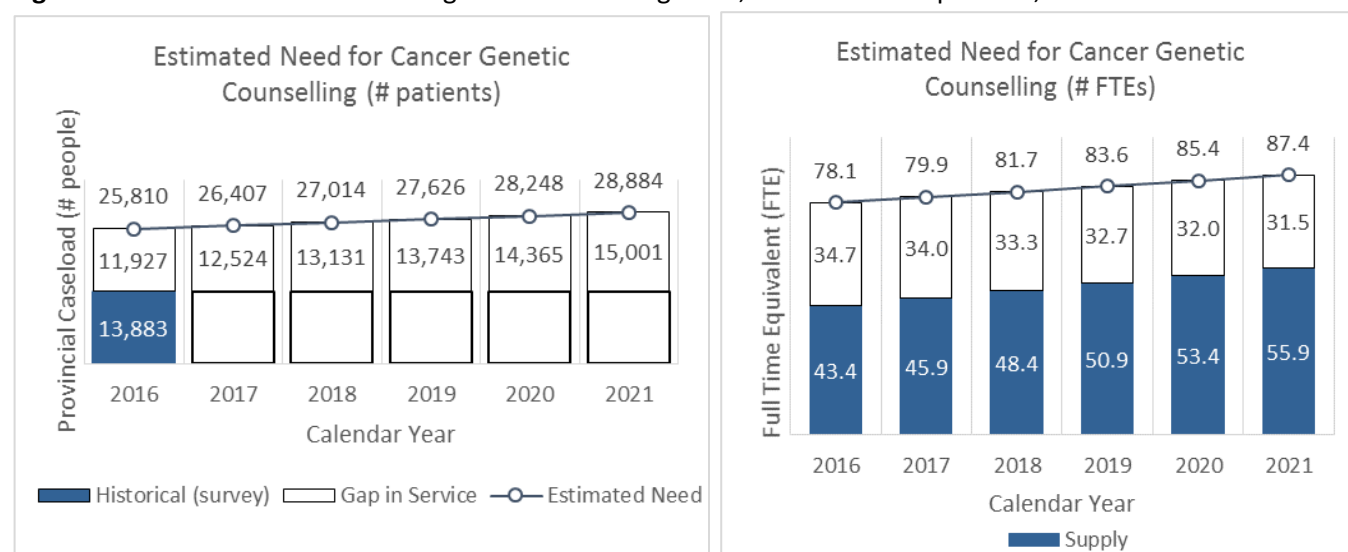
There is a lack of provincial oversight and resourcing for this health service area at a time where there is also increasing demands for service. Utilizing information provided in the baseline survey and coupled with incidence projections and estimated family need for services, health human resource modelling was performed to estimate the need for cancer genetic counselling FTE's, and the estimated number of patients needing cancer genetic counselling (Figure 7). It is estimated that Ontario requires **78.1 FTE's** to meet the need for cancer genetic counselling based on current state. Results from the baseline survey show there are currently **43.4 genetic counsellor FTE's** in the province working in a clinical cancer setting (meeting ~56% of the need), meaning there is

⁶ Includes both genetic counselling (as evidenced by the baseline survey results) and genetic testing (see section 'System Impacts' in the *Hereditary Cancer Testing in Ontario* report)

an estimated unmet need of **34.7 FTE** cancer genetic counsellors. A proportional increase in medical geneticists/medical oncologists would also be required to support the increase in genetic counsellor FTEs, not only to supervise and advise the genetic counsellors, but to also provide direct patient care. Approximately 5.5 additional medical geneticist or oncologist FTEs would be required to maintain the current ratio of genetic counsellors to medical geneticists/oncologists.

The modelling was based on incidence projections and did not include prevalent cases and associated family need. As a result, these estimates likely underrepresent the true FTE deficit. Details about the health human resource modelling can be found in Appendix D.

Figure 7. Estimated need for cancer genetic counselling FTE's, and number of patients, in Ontario for 2016 – 2021.



Note: The estimated need (# patients) is the projected need in the province based on incidence projections and estimated family need. The number referred in 2016 was closer to 18000 (self-reported survey data), so there is also a gap in the number eligible for referral and those that actually get referred

Together, these projections illustrate a gap in service that will lead to further increases in wait times if not addressed systematically.

In Canada, there are five graduate programs for genetic counsellors, which accumulatively graduate approximately 20 - 25 students per year. The University of Toronto has the only program in Ontario and graduates six people per year⁷. Estimating that 50% of graduates will focus on cancer, there is still a large shortfall to overcome. To address this shortfall, clinics are looking for innovative ways to increase their capacity and throughput while maintaining the delivery of high quality services. Examples include group counselling, telephone or video conferencing counselling and oncologist-based/rapid genetic testing (also known as mainstreaming⁸). Clinics are staffed and resourced in multiple ways with many trying to cobble resources together for their clinic.

⁷ <http://www.moleculargenetics.utoronto.ca/genetic-counselling/#msc-genetic-counselling-program>

⁸ A study in the UK has shown mainstreaming to be effective, efficient, and patient centered. See George, A., et al., Implementing rapid, robust, cost-effective, patient-centred, routine genetic testing in ovarian cancer patients. Sci Rep, 2016. 6: p. 29506.

Models of care need to be developed for this health service area. Models of care should support the efficient use of healthcare resources to promote patient centred, effective, and sustainable care delivery by utilizing a best practices approach to organize and integrate services across sectors, professions, and settings. Technology should be leveraged to reduce the administrative burden on clinical resources and to facilitate the collection, storage and transmission of genetic information. Performance measures should also be developed to monitor quality and access at the provincial level.

For survey results related to referral and scheduling processes and supporting technologies please refer to Appendix E.

Recommendation 3. Standardize practice to reduce variation and ensure high quality services for patients across the province

Develop and implement evidence based tools, advice, and clear guidelines (for referral, testing, and care) to standardize practice while ensuring equitable and timely access to genetic services for patients across the province. This may include:

- Developing, maintaining and mandating clear guidelines, or pathways, outlining standardized eligibility criteria for genetic counselling and genetic testing to consistently identify the appropriate referral, test, and/or care for patients
- Endorsing standardized definitions for identifying someone as ‘high risk’ for developing cancer, along with associated surveillance or risk-reducing options, based on current evidence, and developing a mechanism to review and update the clinical guidance
- Establishing standardized definitions for prioritizing referrals (urgent vs. routine), together with consistent provincial wait time targets for each prioritization category
- Evaluating information needs for referrals, streamlining patient information requirements to create a set of standardized provincial referral criteria and associated forms (by referral type)

Create a network for sharing knowledge utilizing multiple methods including communities of practice, continuing education opportunities and the ability to access and share resources.

Eligibility criteria currently available for cancer genetic testing, counselling, and care, are limited to very few disease sites, and are out of date with current evidence. Clinics and laboratories have responded to the advancement of technology and knowledge in hereditary cancer genes on an individual basis (usually based on hospital/clinic specific resources and capacity) leading to significant variability in practices across the province. New, actionable genes of clinical utility continue to be discovered, and laboratory and clinical genetic services must evolve to support and adopt this new knowledge in a coordinated way. These recommendations address the variability that currently exists, and propose an approach to standardizing practices in support of equitable, timely access to high quality care across the province.

Discussion

Nearly a decade ago, Cancer Care Ontario brought together a group of experts to form the Molecular Oncology Task Force (MOTF). MOTF was tasked with developing recommendations for *Ensuring Access to High Quality Molecular Oncology Laboratory Testing and Clinical Genetic Services in Ontario*. This report cautioned us of the explosion of information regarding human genetics and its impact on genetic testing and related clinical genetic services. Today, many of the original recommendations for laboratory services have been implemented and the system has seen significant improvements. The *Hereditary Cancer Testing in Ontario* report builds on the foundation of those improvements to recommend a standardized approach forward for hereditary cancer testing in Ontario. New, actionable genes of clinical utility continue to be discovered at an alarming rate, and the genetic testing landscape for both laboratory and clinical genetic services must continue to evolve. This evolution needs to occur in a standardized, coordinated way across the province to ensure consistency across the province in improving patient access to – and confidence in – Ontario’s genetic services.

Some of the recommendations for clinical genetic services proposed in the 2008 report were not addressed. There have been some adjustments to funding with implementation of the high-risk OBSP. While this has benefitted many Ontarians, it also triggered unintended consequences – causing some clinics to prioritize ‘lower risk’ OBSP funded referrals over ‘higher risk’ non-OBSP patients, creating an inequity in access. Many clinics are concerned with long wait-times for their patients and the variation in practice that exists across Ontario. This is especially true for when family members reside in different parts of the province, and are therefore offered different access to testing, causing Ontario’s cancer genetics system to appear divided and inconsistent. In addition, the demand for genetic counselling continues to increase – referral volumes have nearly tripled over the last 10 years while resources available for counselling these patients have only slightly increased. With the move to panel gene testing, there is an increase in the number of genes being investigated, and an increased need for genetic education and counselling. The baseline survey data reflects these concerns, and the cancer genetic counselling HHR model illustrates a gap in the supply of genetic counselling resources that can only be rectified through change.

Conclusion

The recommendations in this report are a product of the engagement, knowledge and feedback of the genetics field, and propose concrete suggestions for addressing the type of change needed to increase patient access to high quality genetic services anywhere in Ontario.

Ontario has a dedicated and engaged genetics community, including several national and international leaders in the area of cancer genetics. Through the adoption of these recommendations and integration with the cancer care system, Ontario has the potential to position itself as a world leader in the field of Hereditary Cancer Genetics.

Appendix A. Clinical Genetic Services Working Group Members

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Appendix B. Baseline Survey for Clinical Genetic Services – Purpose and Design

Survey Purpose

The purpose of CCO's Clinical Genetic Services Baseline Survey (baseline survey) was to gain a comprehensive understanding of the current state of clinical genetic services in the province in an effort to identify system gaps, and develop recommendations for improvements.

Survey Method and Design

The baseline survey was designed to collect information from genetics clinics across Ontario using eSurveysPro, an electronic online survey program. The content was modelled after the Molecular Oncology Task Force Survey of Clinical Cancer Genetic Services, 2008^{viii}, with updates made to capture additional information requirements. The baseline survey⁹ focused on assessing the current state of clinical genetic services under the following categories:

- Demographics
- Resources and funding
- Patient access to genetic services (wait times)
- Referral and scheduling processes
- Supporting technologies
- Recommendations for improving genetic services in Ontario

Survey Distribution

The survey was sent to 31 Genetics Clinics in Ontario that provide clinical genetic services (excluding privately funded community laboratories or clinics). One Survey Lead (Genetic Counsellor and/or Clinic Manager) was identified¹⁰, assigned, and engaged at each clinic prior to receiving the survey. Survey Leads were asked to complete one questionnaire for their clinic, enlisting the help of team members within the clinic as applicable.

Survey Data

Referral volumes – where possible and appropriate, imputation was used to correct incomplete data based on supplementary data and/or free text data provided in the associated comment fields.


Wait times – Wait time data was collected as an average. Responses that listed a range were converted to a single number by taking the midpoint (e.g. a response of 60-90 days was converted to 75 days).

Assumptions

1. **Enlisting one Survey Lead at each clinic to complete the baseline survey was effective in representing clinic based data and the perspectives of additional team members within the clinic.** Many of the data requests within the survey were facility/clinic level requests – to save time and resources, it was decided that multiple individual requests to the same clinic were unnecessary.
2. **The list of facilities providing clinical genetic services in Ontario is correct and complete (excludes private laboratories and clinics).** For the purposes of this report, the list of genetics clinics was based on the clinic

⁹ A copy of the baseline survey is available upon request via email at: PLMP@cancercare.on.ca

¹⁰ Survey Leads were identified through the help of CCO's Regional Vice Presidents (RVPs), working group members, or direct contact with the clinic to identify the most appropriate person to lead completion of the baseline survey.



listings found on the Canadian Association of Genetic Counsellors website^{ix} – using the Clinic Search page, filtered for Ontario. The final list was vetted through the Clinical Genetic Services Working Group

- 3. The FTE counts collected at the time of the survey (summer 2017) are applicable for the 2016 calendar year.**

Appendix C. Ontario Genetics Clinics Contacted Through the Baseline Survey

Ontario Genetics Clinics		Location
1	Algoma Public Health: Genetics Program	Sault Ste. Marie
2	Children's Hospital of Eastern Ontario: Regional Genetics Program	Ottawa
3	Grand River Regional Hospital/Grand River Regional Cancer Centre: Cancer Genetics	Kitchener
4	Hamilton Health Sciences Centre/Juravinski Cancer Centre: Cancer Risk Assessment Clinic	Hamilton
5	Hamilton Health Sciences: Prenatal Diagnosis Clinic	Hamilton
6	Health Sciences North: Genetic Counselling Services	Sudbury
7	Kingston General Hospital: General and Prenatal Genetics (Kingston)	Kingston
8	Kingston Health Sciences Centre: Familial Oncology Program	Kingston
9	Lakeridge Health: Clinical Genetics	Oshawa
10	London Health Sciences Centre: Regional Genetics Centre of South Western Ontario	London
11	Mackenzie Health: Genetics Clinic	Richmond Hill
12	McMaster University Medical Centre: Clinical Genetics Program	Hamilton
13	McMaster University Medical Centre: Neuromuscular Clinic (Hamilton)	Hamilton
14	Mount Sinai Hospital: Familial Breast Cancer Clinic	Toronto
15	Mount Sinai Hospital: Prenatal Genetics Clinic	Toronto
16	Mount Sinai Hospital: Zane Cohen Centre	Toronto
17	North Bay Parry Sound District Health Unit	North bay
18	North York General Hospital: Genetics Program	Toronto
19	Orillia Soldier's Memorial Hospital: North Simcoe Muskoka Regional Genetics Program	Orillia
20	Peterborough Regional Health Centre: Genetics Program	Peterborough
21	Porcupine Health Unit	Timmins
22	Scarborough and Rouge Hospital, Centenary site: Regional Genetics Clinic	Scarborough
23	Sunnybrook Health Sciences Centre/Odette Cancer Centre: Cancer Genetics & High Risk Programs	Toronto
24	Sunnybrook Health Sciences Centre: Genetics - Women and Babies Clinic	Toronto
25	The Hospital for Sick Children: Clinical Genetics Clinic	Toronto
26	Thunder Bay Regional Health Sciences Centre: Genetics Program	Thunder Bay
27	Trillium Health Partners - Credit Valley Hospital: Clinical Genetics	Mississauga
28	University Health Network/Mount Sinai Hospital: Fred A. Litwin Family Centre in Genetic Medicine	Toronto
29	University Health Network/Princess Margaret Cancer Centre: Familial Breast/Ovarian clinic	Toronto
30	Windsor Regional Hospital: Erie St. Clair Regional Genetics Clinic	Windsor
31	Women's College Hospital: Familial Breast Cancer Research Unit	Toronto

Appendix D. Cancer Genetic Counselling Health Human Resource (HHR) Model

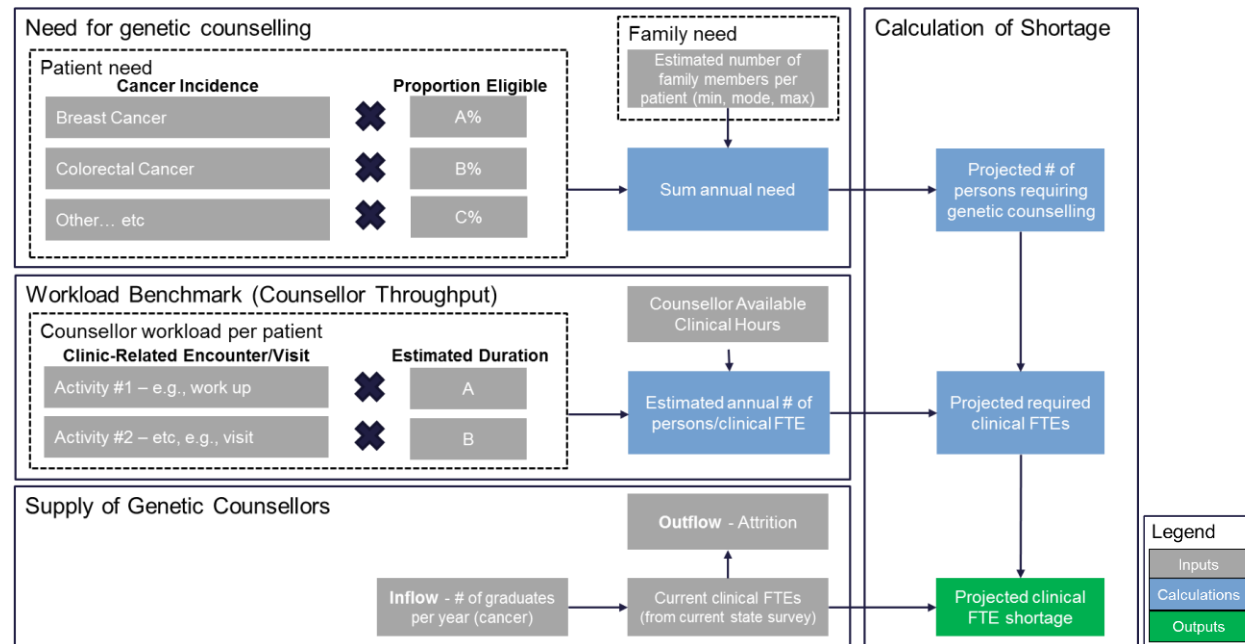
Background and Objectives

Through CCO's engagement channels¹¹, the field communicated concerns regarding long wait times, variation in practice, and inequity in patient access to clinical genetic services across the province. Results from the baseline survey supported these initial claims, and the Cancer Genetic Counselling HHR Model was developed to measure the extent of the issue by addressing five key planning goals:

1. Obtain the **demand** for the program (i.e. how many people currently receive the service?)
2. Estimate the **need** for those programs (i.e. how many people should be receiving the service if there were **no barriers to access**?)
3. Estimate the **capacity** for those programs (i.e. how many people can the current infrastructure service?)
4. Calculate the **unmet need** (i.e. gap in service or the number of people that could potentially benefit from the service that currently are not receiving it or insufficient capacity)
5. Develop **demand forecasts** estimating the year to year growth. This can be influenced by historical volumes, program goals around utilization and reducing gaps in service and changes in the program resulting from clinical developments.

Cancer Genetic Counselling HHR Model Architecture

Figure 8. Cancer Genetic Counselling HHR Model Architecture



¹¹ Initial engagement with CCO Clinical Leads, Provincial Leadership Council, Regional Vice Presidents, and working group members.

Planning Assumptions

Demand Projections

1. **Incidence projections** were developed by the Surveillance group at CCO and are based on actual counts of new cancer cases in Ontario from 1983-2012^x
2. The sarcoma incidence projections are based on the estimates from the provincial sarcoma program within the Specialized Services Oversight group at CCO
3. The **proportions eligible** for genetic counselling are estimated based on Featherstone et al. 2007^{xi} and clinical best judgment where proportions have changed since 2007
4. It is assumed that each patient generates an additional **2.8 people for family need**
5. Assuming 50th percentile of a triangular distribution with a minimum of 1, mode of 2, maximum of 6 additional family members
6. Volumes are **up-adjusted by 10%** to account to expanding indications and other diseases not explicitly modelled

Disease Sites Included	Proportion Eligible
Breast	23%
Ovarian	50%
Colorectal	21%
Endometrium	20%
Pancreas	10%
Skin	2%
Melanoma	5%
Thyroid	5%
Kidney	5%
Sarcoma	2%
Gastric	10%
Brain	2%
Endocrine	5%
Prostate	7%
Other (10% adjustment)	

Workload Benchmark

1. Based on the baseline survey, it was estimated that 1 FTE can see between 3 to 10 new patients per week, with a mode of 8.4
 - a. These values were used to parameterize a triangular distribution
2. Assuming 45 working weeks in a year and 50th percentile of the triangular distribution, it is estimated that 1 FTE can see approximately **331 new patients per year**

Supply Side Modelling

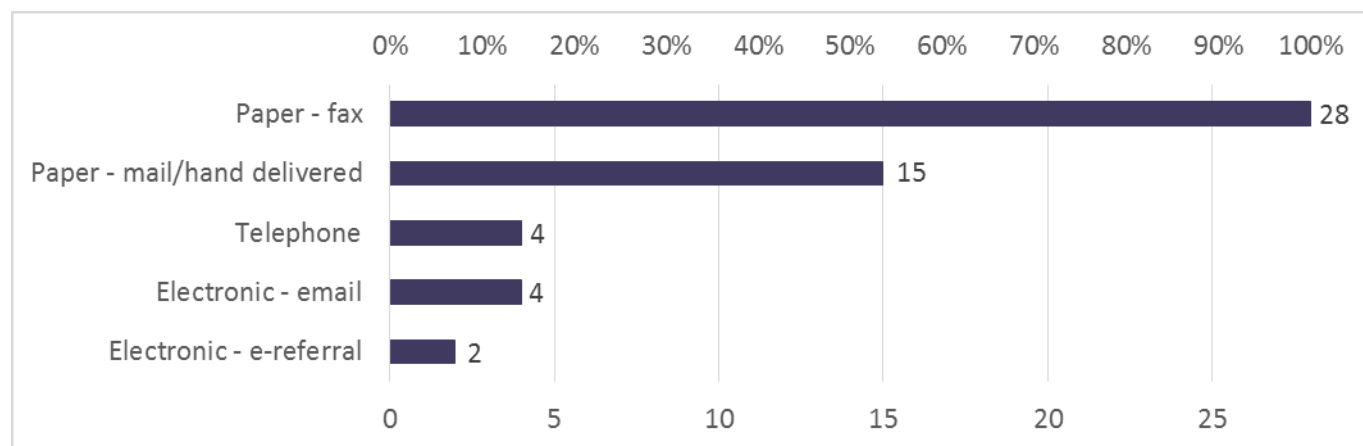
1. Based on the provincial survey, it was estimated that there are **43.4 FTE genetic counsellors** in the province allocated to cancer genetic counselling. This is composed of 41.0 FTE genetic counsellors and 2.4 FTE nurse counsellors.
2. To model the inflow of new supply, it was estimated that the University of Toronto graduates 6 students per year and historically, about 50% of the workload is cancer; this corresponds to **3 new FTE graduates per year**
3. To model the outflow of supply, it was assumed that the **attrition rate** is **0.5 FTE per year**¹².

¹² Further work may be completed to more accurately model the supply side.

Appendix E. Referral and scheduling processes, and supporting technologies

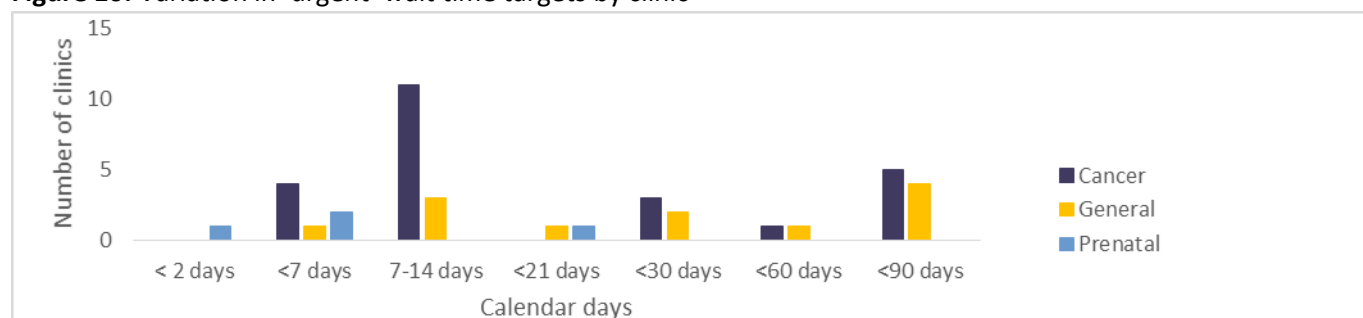
Referral and scheduling processes

Figure 9. Referral methods in use in Ontario genetics clinics



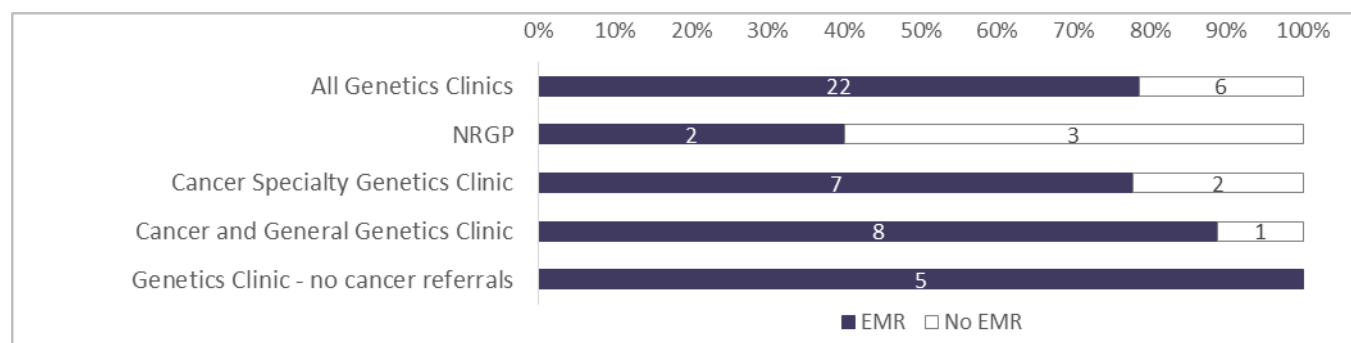
All clinics rely on fax as their primary referral method. Very few clinics in the province have incorporated electronic methods of referral.

Figure 10: Variation in 'urgent' wait time targets by clinic



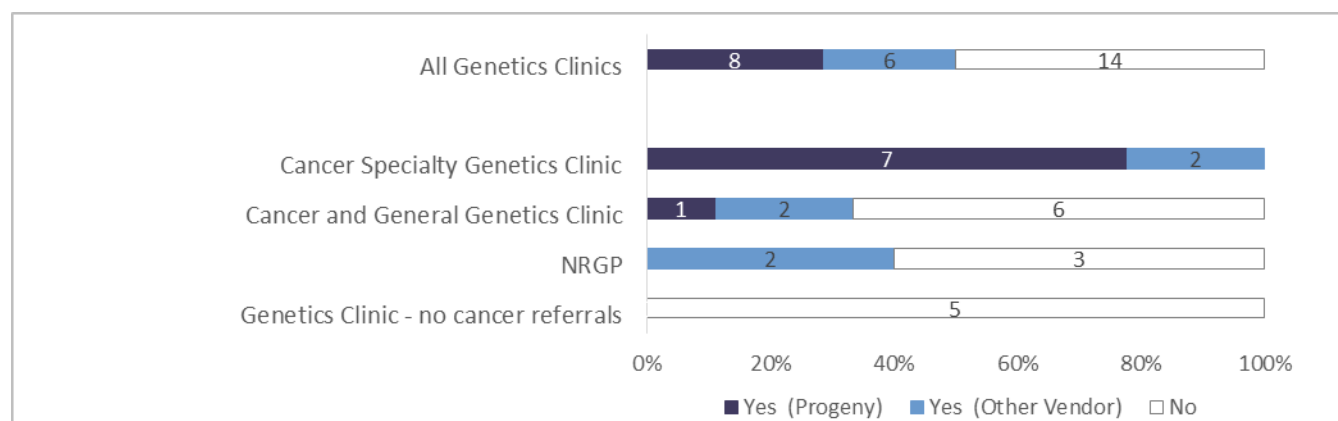
Supporting technologies

Figure 11. Electronic Medical Record (EMR) use by clinical unit



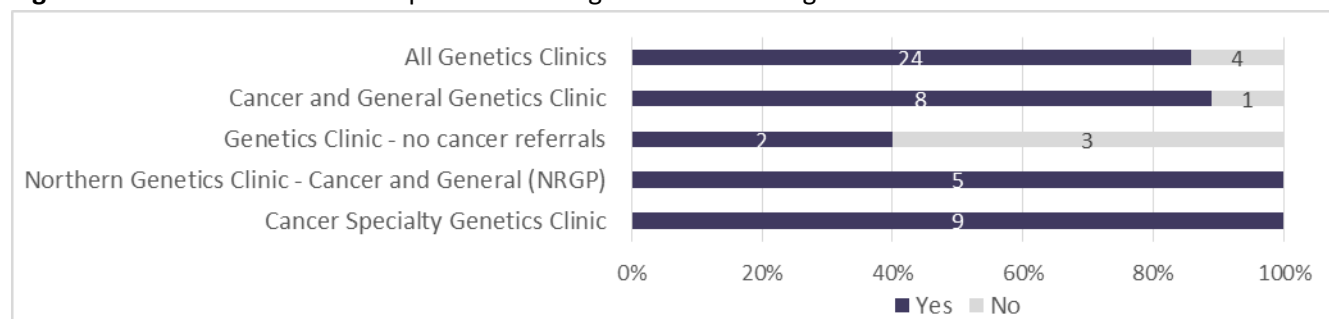
Of the six clinics without an EMR, three are hospital based and three are within public health units.

Figure 12. Electronic pedigree use by clinical unit



Electronic pedigree software is an electronic tool for generating a pedigree, and may include other functionality such as assessing risk, collecting family history data, or ordering and tracking genetic tests. In Ontario, 50% of clinics report having access to this tool.

Figure 13. Number of clinics that provide virtual genetic counselling



The communication products used for virtual counselling sessions include: a combination of telephone plus OTN for 15 clinics (63%); telephone only for 8 clinics (33%); and OTN only for 1 clinic (4%)

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