Mainstreaming Cancer Genetics
Cancer Strategic Clinical Network

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2019/2020 Year End Report

Alberta Health Services
Strategic Clinical Networks™

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June 10, 2020

Table of contents

June 10, 2020

This report has been prepared by Mainstreaming Cancer Genetics Hub Team in partnership with Cancer Strategic Clinical Network™.

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Executive Summary

To integrate cancer genetic testing as part of routine cancer care, deal with the increased demand for genetic testing and address growing wait times, mainstreaming ovarian and breast cancer genetics was implemented as part of a provincial mainstreaming cancer genetics program in 2019/20. The model is based on best practices established in the United Kingdom to bypass the need for separate pre-test genetic counseling in the Hereditary Cancer Clinic (HCC). This model of care enables oncology clinicians to order hereditary cancer genetic testing for appropriate cancer patients. The model relies on supporting a process for oncology clinicians to directly order tests through standardized provider and patient education and measurement and reporting of key access and appropriateness measures.

Provincial implementation of mainstreaming ovarian and breast cancer genetics has resulted in better access to genetics including reduced wait-times from ordering provider appointment to results disclosure overall, and more timely genetic testing for patients whose oncology care depends on these results. Importantly, this initiative strengthened relationships between breast surgeons/oncologists and medical genetics, as well as unified protocols and criteria, and standardized and increased access to patient and clinician educational resources province-wide. Implementation has also resulted in substantial annualized resource release for HCC to see high-risk wait-listed patients and potential treatment cost savings with prevention of secondary cancer through cascade testing. Importantly, patient reported experiences demonstrate a high degree of patient satisfaction with the mainstreaming process and standardized education materials.

The provincial mainstreaming cancer genetics program has also established a platform to spread, scale and sustain the model of care to other relevant cancer types (e.g., pancreatic cancer). This year-end report provides a summary of the provincial mainstreaming cancer genetics accomplishments in 2019/20.

Introduction

Approximately 10-15% of cancer is due to an inherited genetic change, or mutation, in a cancer gene. For breast and ovarian cancer, gene mutations are most commonly found in the BRCA1 or BRCA2 gene. Identifying a gene mutation can impact treatment decisions, indicate risk for other cancers, and inform risks for cancer for family members. As such, access to genetic testing as early in diagnosis as possible is increasingly important.

Genetics mainstreaming is a provincial initiative which allows oncology clinicians to order hereditary cancer genetic testing for appropriate cancer patients, bypassing the need for separate pre-test genetic counselling in the Hereditary Cancer Clinic. This model was piloted with ovarian cancer, and resulted in a time savings, with time of offer of genetic testing to results disclosure of approximately 4 months. The success of mainstreaming for ovarian cancer led to the expansion of the model to breast cancer in August 2019. At the time of expansion to breast cancer, more time savings was introduced by only offering follow-up HCC appointments to patients with (potentially) actionable results, and sending patients with negative test results (about 2/3 of test performed) a templated letter in the mail, with supporting web links to further information about hereditary cancer and a presentation about how to interpret a negative test result (housed on the Cancer Care Alberta website).

Mainstreaming Cancer Genetics Model of Care

Cancer predisposition syndromes are thought to underlie 10-15% of all cancer diagnoses. For people carrying a BRCA1 or BRCA2 mutation, the lifetime risk for certain cancers is substantially increased, including breast and ovarian cancer for women, and prostate cancer for men. (SEER, 2012, Kuchenbaecker, 2017). For example, while the average woman in Canada has an 11% risk of developing breast cancer by age 80 years, the cumulative breast cancer risk to age 80 years is 72% for BRCA1 and 69% for BRCA2 carriers (Balmana, 2011; Kuchenbaecker, 2017). Furthermore, cancer predisposition syndromes diagnoses are crucial to population health. For every individual with an identified cancer predisposing mutation, on average, 50% of their first degree relatives have inherited the same cancer predisposition gene (Flippo-Morton, 2016). This means that relatives of mutation positive patients are eligible for genetic assessment and may also be at increased risk of cancer. Healthy relatives who are found to carry the cancer predisposition gene can be offered increased surveillance for cancer, and/or preventive surgeries.

Identification of an underlying cancer predisposition syndrome not only allows for a better understanding of future cancer risk for a patient and his/her family members, but also has an increasing impact on cancer treatment for patients. It is important for the oncology team to know at the pre-operative / pre-treatment phase of the illness trajectory as most gene mutation carriers will opt to have bilateral mastectomy instead of breast conservation for primary surgical management given a 50% risk of being diagnosed with a new contralateral breast cancer (Flippo-Morton, 2016). Additionally, the presence of a gene mutation may help tailor other treatment decisions including radiation and drug therapies (George, 2016).

Genetic testing for patients has been established as a standard with guidelines in place in Alberta, and across the country. Furthermore, research done by AHS Health Technology Assessment and Innovation has proven the value for money of genetic testing and counselling (Mullie, 2016). This has further been researched in Australia where testing in women with breast cancer was proven to be cost effective and associated with reduced risk of cancer and improved survival (Tuffaha, 2017).

Despite these findings, appropriate access to genetic testing is a challenge. Since 2012, demand for genetic testing for cancer has increased dramatically, which is often referred to as the “Angelina Jolie effect” (Rahman, 2014). Hereditary cancer clinics worldwide have experienced a 2-4 fold increase in referrals following Jolie’s opinion editorial and an increased rate of referrals has been sustained. Further, several

published studies have suggested these increased volumes are for appropriate referrals (Troiano, 2017). Therefore, limited access to genetic testing is a key issue in breast cancer care. Long wait times, and consequently under-referral of patients who are eligible for genetic testing, have become a significant barrier.

To deal with the increased demand for genetic testing and address growing wait times, “Mainstreaming Cancer Genetics” program was developed in the United Kingdom Royal Marsden Hospital in 2013. This initiative has improved access to hereditary cancer genetic testing in breast and ovarian cancer patients by shifting genetic testing from hereditary cancer clinics to oncology clinics, and empowering oncologists to discuss and initiate genetic testing with the patient where appropriate. To support oncology health care providers and patients, their protocol includes healthcare provider and patient education materials, systematic delivery of genetic test results with consistent and appropriate communication to patients, and seamless access to genetics professionals where needed. This approach has proven to be very successful from both a patient and health care provider perspective and has demonstrated cost saving in the context of their health care system. The UK Mainstreaming Cancer Genetics program reported 1157 cancers and 222 deaths prevented per year of testing (George, 2016).

Background on Breast Cancer Genetic Testing in Alberta

Alberta has two hereditary cancer clinic (HCC) genetics programs, located in Edmonton and Calgary, as well as genetic counsellors in regional sites. These programs deliver and evaluate genetic tests, as well as provide patient consultations before and after testing. Patients, after meeting with an oncologist or surgeon, are referred to a genetics program for a pre-counseling appointment. This is followed by an appointment to discuss the offer of genetic testing, and a subsequent appointment for disclosure and review of test results. With demand for testing having increased substantially this decade, there is now a wait list of over 1500 patients, with approximately two thirds of that list being breast cancer patients. Compounding these shifting and increasing needs for hereditary cancer risk assessment are resource constraints – there have been no resources added to the Alberta Hereditary Cancer Clinics since 2012 (Perrier, 2018). Hence, there was an immediate need to look at alternate models of care in Alberta. Alberta's genetics programs have aligned to implement UK's Mainstreaming Cancer Genetics model for ovarian cancer patients and for breast and ovarian cancer in British Columbia (Columbo et al, 2018).

Opportunity

In 2016/17, the Calgary Hereditary Cancer Clinic and Gyne-Oncology Team at the Tom Baker Cancer Centre successfully piloted an early version Mainstreaming Cancer Genetics, called the GO-BRCA project, to remove access barriers to timely genetic testing. Elements of the pilot included patient education resources and competencies for Gyne-Oncologists to provide pre-test genetic testing information. Results included:

- Reduced mean time to communicating genetic test results from 306 (+/- 23) days to 158 (+/- 7) days (approximately 50% reduction).
- 111 pre-test appointments per year released to see other high-risk wait-listed patients.
- High degree of patient satisfaction (100%).

AHS has already conducted a thorough economic analysis that conclusively proved the cost-benefit of genetic testing and counseling for patients. Based on analyses conducted on current state processes at the Calgary Hereditary Cancer Clinic, a Health Technology Assessment and Innovation (HTAI) report concluded that the genetic testing program resulted in cancers prevented that are expected to prevent 46 quality adjusted life years lost and $228,000 (undiscounted) in treatment costs to the system.

This is consistent with published research on the cost-effectiveness of BRCA testing (Tuffaha, 2017; Eccleston, 2017).

The Cancer SCN collaborated with Cancer Genetics programs in both Calgary and Edmonton to implement Mainstreaming for ovarian cancer genetic testing as a provincial standard of care in March 2019. As well, a small breast cancer pilot of Mainstreaming was completed in one breast oncologist clinic each, at Tom Baker and Cross Cancer Institute. The opportunity advanced with the mainstream cancer genetics work in 2019/20 was to spread and scale the ovarian and small breast pilots provincially for breast cancer, and if successful, a broader spread and scale to other types of cancer. The opportunity for spread and scale of the ovarian experience using Mainstreaming was intended to address high demand that has outstripped current resources for breast cancers patients and if successful, could be a viable provincial model for multiple types of cancers.

Implementation of Mainstreaming breast cancer genetics would realize both cost avoidance and cost savings for the system. The model would see shifting of activities conducted by genetic counsellors and incorporate them as part of the routine visit with the oncologist or surgeon, enabling work at the top of scope of practice for the limited pool of genetic counsellors. The model would also result in prevention of secondary cancers in patients as most gene mutation carriers identified at the pre-operative / pre-treatment phase will opt to have bilateral mastectomy as a prevention strategy instead of breast conservation for primary surgical management given a 50% risk of being diagnosed with a new contralateral breast cancer (Flippo-Morton, 2016).

Cost avoidance: Adopting the Mainstreaming criteria would see 700 Albertans with breast cancer eligible for testing under the Mainstreaming annually (Perrier, 2018). Under the current process, these 700 patients would require 1400 appointments with genetic counselors. By adopting the Mainstreaming, the required number of genetic counselor appointments for those patients would be reduced from 1400 to 245 (Perrier 2018), resulting in potential yearly cost avoidance of $281,820 per year. These patient appointment slots in the HCC would be used to address existing backlogs of non-mainstream appropriate patients.

2019/2020 Objectives

The objectives of the mainstreaming cancer genetics work in 2019/2020 were to:

- Implement Mainstreaming breast cancer patients in a provincial manner beginning with the tertiary cancer centres (Tom Baker Cancer Centre and Cross Cancer Institute) and then use a similar approach with the regional centres: Grande Prairie, Red Deer, Lethbridge, and Medicine Hat. Additional spread will be determined by the Steering Committee.
- Implement standardized patient materials to support Mainstreaming and standardized provider education materials for the rollout of Mainstreaming across the province.
- Implement a measurement framework for the Mainstreaming.
- Develop a provincial model for spread and scale of Mainstreaming to other types of cancer.

Summary of Key Accomplishments

- Mainstreaming ovarian cancer genetics process, patient education and provider education was sustained provincially resulting in:
    - Increased number of ovarian cancer patients receiving genetics follow-up in Edmonton from 7 to 42;
    - 50% reduction in average time to results disclosure for ovarian cancer patients in Calgary; and
    - Provincial average time to results disclosure of 4.0 months and lab testing turnaround time of 3.4 months for ovarian cancer patients.

- Mainstreaming breast cancer genetics process, patient education and provider education was implemented provincially resulting in:
    - Increased number of breast cancer patients getting expedited genetics through the HCC by surgeons and oncologists in Edmonton from 5 to 28;
    - Increased number of breast cancer patients getting non-urgent genetics through the HCC by surgeons and oncologists in Edmonton from 1 to 41;
    - Sustained number of breast cancer patients getting expedited genetics through the HCC by surgeons and oncologists in Calgary at just over 30;
    - 44% reduction in average time to results disclosure for breast cancer patients meeting urgent criteria for genetic testing in Calgary;
    - 74% reduction in average time to results disclosure for breast cancer patients meeting non-urgent criteria for genetic testing in Calgary;

  - Sustained average lab testing turnaround time for breast cancer patients meeting urgent criteria for genetic testing in Calgary at 1.2 months; and
  - Provincial average time to results disclosure of 2.7 months and lab testing turnaround time of 2.1 months for breast cancer patients.

- Lab turnaround times for patients undergoing mainstreaming breast and ovarian cancer genetics process were also reduced during implementation phase including:
  - 31% reduction in average lab testing turnaround times in Calgary for ovarian cancer patients; and
  - 42% reduction in average lab testing turnaround time for breast cancer patients meeting non-urgent criteria for genetic testing in Calgary.

- Realization of cost avoidance for HCC and treatment cost savings including:
  - Increased capacity of HCC to see non-mainstreamable ovarian, breast and other cancer patients, by eliminating both pre-test and negative result appointments;
  - Resource release of 0.4 FTE genetic counsellor to accommodate referrals and appointments for this high-risk patient population that would have been wait-listed;
  - Potential $1.5M annualized cost savings with avoidance of treatment due to prevention of cancers through cascade testing; and,
  - Developed economic evaluation framework to assess realization of cost avoidance and cost savings since program inception.

- High degree of patient satisfaction with cancer genetic testing process and standardized education package
  - 91% and 82% of ovarian cancer respondents indicated they were given enough information to make decisions to decide whether or not to have genetic testing and overall expectations were met, respectively; and
  - 100% and 89% of breast cancer respondents indicated they were given enough information to make decisions to decide whether or not to have genetic testing and overall expectations were met, respectively.

- Sustainable program and platform for expanding mainstreaming cancer genetic testing to other types of cancer

- Measurement and reporting system to monitor cancer genetic testing access wait-times and appropriateness of referral metrics;
- Engagement of surgeon and oncology leads for pancreatic cancer North and South; and
- Establishment of an ongoing mainstreaming cancer genetics sustainability program committee.

Mainstreaming Ovarian Cancer Genetics – 2019/2020 Results

Post-implementation, there was an increased number of ovarian cancer patients receiving genetics follow-up in Edmonton (Table 1; 6-fold increase). Since eligibility criteria did not change substantially, this suggests that more patients are getting appropriate genetics follow-up. In Calgary, reduced time to results disclosure and reduced lab turnaround times for ovarian cancer patients were observed after process modification with negative results disclosure letters (Table 2).

Table 1. Mainstreaming ovarian cancer genetics – wait-time metrics – Edmonton

Wait-time Metrics		Ovarian Cancer Edmonton	
		Baseline Feb 2018 – Feb 2019	**Post-implementation Mar 2019 – Mar 2020**
Wait-time from HCC referral/ ordering provider appointment to results disclosure	N Avg Med 87.5th	7 14.9 months 13.5 months 26.3 months	42 5.6 months 6.6 months 8.5 months
Wait-time from MDL sample received/ blood drawn to MDL report	N Avg Med 87.5th	7 7.0 months 6.7 months 9.1 months	46 4.9 months 5.1 months 6.5 months

Notes:

- Baseline:
  - Inclusions: Had Gyne-Oncology-ordered HBOC genetic testing within 1 year preceding Mainstreaming go-live (Feb 25, 2019) and went through full process (i.e., all dates were all available).
  - Process: Patients were only referred to genetics after the results came back, if the Gyne-oncologist thought it was appropriate

    Denominator = 50 cases
    # positives or VUS = 18
    # negatives = 31

    Total exclusions = 43 cases
    No HCC referral date = 35
    No HCC results appointment = 40

    Total Inclusions = 7 cases
    # of positives or VUS = 7
    # of negatives = 0

positives or VUS = 6
of negatives = 31

- Post-implementation: mainstreaming ovarian cancer genetics implemented Feb 25, 2019

  Denominator = 82 HCC notifications
  # of results disclosed = 43
  # of negatives = 32
  # of positives or VUS = 11

Table 2. Mainstreaming ovarian cancer genetics – wait-time metrics – Calgary

Wait-time Metrics		Ovarian Cancer Calgary	
		Baseline Feb 2018 – Feb 2019	Post-implementation Mar 2019 – Mar 2020
Wait-time from HCC referral/ ordering provider appointment to results disclosure	N Avg Med 87.5th	52 5.8 months 5.0 months 9.4 months	76 2.9 months 2.7 months 4.7 months
Wait-time from MDL sample received/ blood drawn to MDL report	N Avg Med 87.5th	52 3.5 months 3.4 months 4.8 months	84 2.4 months 2.3 months 3.8 months

Notes:

- Baseline:
  - Inclusions: Had Gyne-Oncology-ordered HBOC genetic testing within 1 year preceding Mainstreaming go-live (Feb 25, 2019) and went through full process (i.e., all dates were all available).

  - Process: Mainstreaming ovarian cancer genetics process was already implemented through GO-BRCA pilot project

    Denominator = 58 cases
    # positives or VUS = 23
    # negatives = 32

    Total exclusions = 6 cases
    No Gyne-Oncology appointment date = 1
    No MDL sample received date = 2
    # positives or VUS = 1
    # of negatives = 4

- Post-implementation: process was modified for negative results disclosure from GC appointment (baseline) to letter (mainstreaming), implementation Feb 25, 2019

  Denominator = 124 HCC notifications
  # of results disclosed = 81

# of negatives = 30
# of positives or VUS = 51

Mainstreaming Breast Cancer Genetics – 2019/2020 Results

Post-implementation, mainstreaming breast cancer genetics resulted in a substantial increase in number of breast cancer patients in Edmonton getting expedited genetics from Surgery and Medical Oncology (Table 3). Because of the majority of patients in baseline cohort in Edmonton had not completed the genetics follow-up process at the time of this analysis, wait-time comparisons pre and post-implementation for mainstreaming breast cancer genetics were not calculated.

Table 3. Mainstreaming breast cancer genetics – % of patients with results disclosure – Edmonton

Ordering Provider	Breast Cancer Edmonton			
	Baseline Jan 2017- Mar 2019		Post-implementation Apr 2019 – Mar 2020	
	Triage	%, N	Triage	%, N
All	**Red**	80%, 5	**Urgent**	43%, 28
	Other	1%, 95	**Non-urgent**	19%, 42
Surgeon	**Red**	100%, 1	**Urgent**	21%, 14
	Other	0%, 19	**Non-urgent**	0%, 8
Medical Oncologist	**Red**	75%, 4	**Urgent**	64%, 14
	Other	1%, 68	**Non-urgent**	24%, 33
Other	**Red**	NA, 0	**Urgent**	NA, 0
	Other	0%, 8	**Non-urgent**	0%, 1

Notes:

- Baseline:
  - Inclusions: Patients that were referred to HCC for genetics assessment/genetic testing between 2017 and Mainstreaming go-live (March 25, 2019), had the eligible diagnosis, and had only 1 HCC referral date.
  - Process: Patients were receiving testing only after appointment with genetic counsellor

    Denominator = 100 referrals

- Post-implementation: mainstreaming breast cancer genetics process was implemented March 25, 2019

  Denominator = 70 tests
  Results disclosures = 19

- Triage Codes: Red is expedited. Other includes Yellow – book within 12 months and Green – book within 2 years.

In Calgary, mainstreaming breast cancer genetics sustained the levels of expedited genetics from Surgery and Medical Oncology (Table 4) and resulted in reductions in wait-times from HCC referral/ ordering provider appointment to results disclosure (Table 5) and MDL sample received/ blood drawn to MDL report (Table 6) for both expedited and non-expedited groups.

Table 4. Mainstreaming breast cancer genetics – % of patients with results disclosure – Calgary

Ordering Provider	Breast Cancer Calgary			
	Baseline Jan 2017- Mar 2019		Post-implementation Apr 2019 – Mar 2020	
	Triage	%, N	Triage	%, N
All	**Red**	94%, 32	**Urgent**	58%, 31
	Other	95%, 62	**Non-urgent**	36%, 87
Surgeon	**Red**	100%, 15	**Urgent**	60%, 15
	Other	100%, 10	**Non-urgent**	59%, 17
Medical Oncologist	**Red**	88%, 17	**Urgent**	56%, 16
	Other	93%, 45	**Non-urgent**	31%, 68
Other	**Red**	NA, 0	**Urgent**	NA, 0
	Other	100%, 7	**Non-urgent**	0%, 2

Notes:

- Baseline:
  - Inclusions: Patients that were referred to HCC for genetics assessment/genetic testing between 2017 and Mainstreaming go-live (March 25, 2019), had the eligible diagnosis, and had only 1 HCC referral date.
  - Process: Patients were receiving testing only after appointment with genetics counselor

    Denominator = 94 referrals
- Post-implementation: mainstreaming breast cancer genetics process was implemented March 25, 2019

  Denominator = 118 tests
  Results disclosures = 47
- Triage Codes: Red is expedited. Other includes Yellow – book within 12 months and Green – book within 2 years.

Table 5. Mainstreaming breast cancer genetics – time to results disclosure – Calgary					
Wait-time from HCC referral/ ordering provider appointment to results disclosure (in months)		**Breast Cancer Calgary**			
		Baseline Jan 2017- Mar 2019		**Post-implementation Apr 2019 – Mar 2020**	
Triage Status		**Red**	**Other**	**Urgent**	**Non-urgent**
All Ordering Providers	N	26	37	18	31
	Avg	2.7 mo	11.2 mo	1.5 mo	2.9 mo
	Med	1.9 mo	10.2 mo	1.1 mo	3.0 mo
	90th	5.5 mo	17.8 mo	3.3 mo	4.7 mo
Surgeon	N	13	7	9	10
	Avg	2.1 mo	8.9 mo	1.2 mo	2.9 mo
	Med	1.4 mo	7.9 mo	0.9 mo	3.4 mo
	90th	6.5 mo	n too small	3.0 mo	4.4 mo
Medical Oncologist	N	13	25	9	21
	Avg	3.3 mo	11.9 mo	1.8 mo	2.9 mo
	Med	1.9 mo	10.2 mo	1.3 mo	3.0 mo
	90th	11.8 mo	20.7 mo	n too small	5.1 mo
Other	N	0	5	0	0
	Avg	NA	10.8 mo	NA	NA
	Med	NA	11.2 mo	NA	NA
	90th	NA	n too small	NA	NA

Notes:

- Baseline:
  - Inclusions: Patients that were referred to HCC for genetics assessment/genetic testing between 2017 and Mainstreaming go-live (March 25, 2019), had the eligible diagnosis, had only 1 HCC referral date, went through the full process, and had data available for all event dates.
  - Process: Patients were receiving testing only after appointment with genetics counselor

    Denominator = 94 referrals
- Post-implementation: mainstreaming breast cancer genetics process was implemented March 25, 2019

  Denominator = 118 tests
  Results disclosures = 47
- Triage Codes: Red is expedited. Other includes Yellow – book within 12 months and Green – book within 2 years.

Table 6. Mainstreaming breast cancer genetics – lab turnaround time – Calgary					
Wait-time from MDL sample received/ blood drawn to MDL report		**Breast Cancer Calgary**			
		Baseline Jan 2017- Mar 2019		**Post-implementation Apr 2019 – Mar 2020**	
Triage Status		**Red**	**Other**	**Urgent**	**Non-urgent**
All Ordering Providers	N	25	37	19	32
	Avg	1.2 mo	3.6 mo	1.2 mo	2.1 mo
	Med	0.8 mo	3.2 mo	0.8 mo	2.1 mo
	90th	2.5 mo	7.5 mo	2.9 mo	3.4 mo
Surgeon	N	12	7	9	10
	Avg	1.4 mo	3.1 mo	0.9 mo	2.4 mo
	Med	0.7 mo	3.2 mo	0.7 mo	2.5 mo
	90th	5.6 mo	n too small	2.5 mo	3.6 mo
Medical Oncologist	N	13	25	10	22
	Avg	1.0 mo	3.6 mo	1.5 mo	2.0 mo
	Med	0.8 mo	3.0 mo	1.1 mo	1.9 mo
	90th	2.8 mo	7.5 mo	n too small	3.2 mo
Other	N	0	5	0	0
	Avg	NA	4.5 mo	NA	NA
	Med	NA	3.5 mo	NA	NA
	90th	NA	n too small	NA	NA

Notes:

- Baseline:
  - Inclusions: Patients that were referred to HCC for genetics assessment/genetic testing between 2017 and Mainstreaming go-live (March 25, 2019), had the eligible diagnosis, had only 1 HCC referral date, went through the full process, and had data available for all event dates.
  - Process: Patients were receiving testing only after appointment with genetics counselor

    Denominator = 94 referrals
- Post-implementation: mainstreaming breast cancer genetics process was implemented March 25, 2019

  Denominator = 118 tests
  Results disclosures = 47
- Triage Codes: Red is expedited. Other includes Yellow – book within 12 months and Green – book within 2 years.

Zone Comparisons

Though mainstreaming ovarian and breast cancer genetics models of care were implemented provincially, there is still variation in time to results disclosure and lab turnaround times between Zones for both ovarian cancer (Table 7) and breast cancer (Table 8). Target wait-times can be established as the mainstreaming cancer genetics program is sustained based on Zones with lowest access wait-times for results disclosure and lab testing turnaround.

Table 7. Mainstreaming ovarian cancer genetics – access metrics since inception (April 2019 – March 2020)

Zone	Tests Submitted	Results Disclosures	Average wait-time from ordering provider appointment to results disclosure (n)	Average wait-time from MDL sample received to MDL report (n)
Calgary	124	83	2.9 months (76)	2.4 months (84)
Central	27	16	4.4 months (16)	3.9 months (16)
Edmonton	82	43	5.6 months (42)	4.9 months (46)
North	24	10	6.1 months (10)	4.9 months (13)
South	16	8	3.3 months (8)	2.3 months (7)
Other	3	1	N/A (0)	N/A (0)
Total	**276**	**161**	**4.0 months (152)**	**3.4 months (166)**

Table 8. Mainstreaming breast cancer genetics – access metrics since inception (April 2019 – March 2020)

Zone	Tests Submitted	Results Disclosures	Average wait-time from ordering provider appointment to results disclosure (n)	Average wait-time from MDL sample received to MDL report (n)
Calgary	118	49	2.4 months (49)	1.8 months (51)
Central	18	8	2.0 months (8)	1.3 months (8)
Edmonton	70	20	3.8 months (20)	3.2 months (20)
North	21	6	3.1 months (6)	2.9 months (6)
South	10	4	2.3 months (4)	1.9 months (4)
Other	2	2	N/A (0)	N/A (0)
Total	**239**	**89**	**2.7 months (87)**	**2.1 months (89)**

Resource Release

Implementation of mainstreaming ovarian and breast cancer genetics in 2019/20 has realized resource release equivalent to 0.4 FTE genetic counsellor (including pre-test counseling and negative results sessions) through staged roll-out to Medical Oncology, Surgery and Radiation Oncology (Table 9). The annual investment to sustain mainstreaming includes 0.4 FTE Clerical and 0.4 FTE Genetic Counselor. With sustainment for breast and ovarian cancer cases estimated at 700 cases per year with current eligibility criteria, this provincial program forecasts 0.6 FTE genetic counselor capacity created to manage referrals and appointments for this high-risk patient population that would have been waitlisted.

Table 9. Mainstreaming ovarian and breast cancer genetics – HCC resource release

Return on Investment – HCC Resource Release	Realized	Forecasted		
	2019/20	2020/21	2022/23	2023/24
# of mainstreamed breast and ovarian cancer patients	515	721	743	765
# of genetic counselor work hours released for high-risk wait-listed patients	850 hrs	1,190 hrs	1,226 hrs	1,262 hrs

Assumptions:

- Pre-test and post-test genetic counselor appointments are 1hr in length on average
- 1x pre-test GC appointment is avoided for each patient that goes through the mainstreaming process; an additional 1x post-test GC appointment is avoided for all patients that go through the mainstreaming process and receive negative results
- 65% of mainstreamed patients are expected to receive negative results
- Implementation in 2019/20 involved staged roll-out to Medical Oncology, Surgery and Radiation Oncology; sustained pathway for breast and ovarian cancer is estimated at 700 cases per year with current eligibility criteria
- Incidence increase of 3% per annum (Alberta Report on Cancer Statistics – Breast Cancer Incidence Projection 2021)

Treatment Cost Savings

Implementation of mainstreaming ovarian and breast cancer genetics in 2019/20 is estimated to have realized treatment cost savings of $880,212 (Table 9). With sustainment for ovarian and breast cases estimated at 700 per year with current eligibility criteria, this provincial program forecasts $1.5M per year in net cost savings with prevention of secondary breast and ovarian cancer through cascade testing.

Table 9. Mainstreaming ovarian and breast cancer genetics – treatment cost savings

Return on Investment – Treatment Cost Savings	Realized	Forecasted		
	2019/20	2020/21	2022/23	2023/24
# of mainstreamed breast and ovarian cancer patients	436	721	743	765
# of expected positives	153	252	260	268
# of close relatives that are expected to be mutation carriers	46	76	78	80
# of carriers expected to get cancer in the absence of preventive therapy	27	45	47	48
Net cost savings with prevention of secondary breast and ovarian cancers	$880,212	$1,488,185	$1,564,881	$1,650,535
Present value of annual investment to sustain mainstreaming	($456,541)	-	-	-

Return on Investment:

Net present value over 3 years = $4,441,286
Internal rate of return over 3 years = 232%

Assumptions:

- 65% of mainstreamed patients are expected to receive negative results; 15% of positives are expected to have two close relatives who are mutation carriers; ~60% of carriers are expected to get cancer related to carrier status in the absence of preventive therapy
- Net costs savings with prevention of breast and ovarian cancers in patients who produce positive or VUS results are estimated on a per patient basis at $1,297 for genetic counseling and BRCA tests, -$9,459 for preventive therapies, and +$42,801 for treatment.
- Implementation in 2019/20 involved staged roll-out to Medical Oncology, Surgery and Radiation Oncology; sustained pathway for breast and ovarian cancer is estimated at 700 cases per year with current eligibility criteria
- Incidence increase of 3% per annum (Alberta Report on Cancer Statistics)
- Inflation rate of 2.24% per annum; discount rate of 5% per annum
- Annual investment to sustain mainstreaming includes 0.4 FTE Clerical and 0.4 FTE Genetic Counsellor

Patient Reported Experience

Implementation of mainstreaming ovarian and breast cancer genetics in 2019/20 was associated with high degree of patient satisfaction with cancer genetic testing process and standardized education package (Table 10). A process for collecting formalized clinician feedback is in progress, though communication has been ongoing with oncology teams.

Table 10. Mainstreaming ovarian and breast cancer genetics – patient experience

Patient survey result	Breast Cancer Respondents N = 17	Ovarian Cancer Respondents N = 55
Strongly agree or agree that my cancer care doctor or nurse practitioner was the right person to talk with me about genetic testing	94%	95%
Strongly agree or agree that I was given enough information to decide whether or not to have genetic testing	100%	91%
Strongly agree or agree that I am satisfied with the way I got my result	65%	91%
Strongly agree or agree that I got helpful answers to my questions about my genetic testing result	82%	89%
Strongly agree or agree that overall, my expectations were met	82%	89%

Appropriateness of Genetic Testing

To measure changes in appropriateness of breast cancer genetic testing with roll-out of mainstreaming breast cancer genetics, the proportion of breast cancer age ≤ 35 and males with breast cancer referred to HCC pre- and post-mainstreaming was assessed (Table 10). Current results indicate that there is an opportunity to focus on improving appropriateness of breast cancer genetic testing with sustainment of the provincial mainstreaming cancer genetics program.

Table 10. Mainstreaming breast cancer genetics – appropriateness metric

Phase	Time Period	% referred to HCC (N)	
		Breast Cancer Age ≤ 35	Breast Cancer Male
Pre-mainstreaming	**Jan – Dec, 2018**	53% (68)	29% (17)
Implementation phase	**Jul – Dec, 2019**	50% (40)	25% (16)
Post-implementation phase	**Jan – Mar, 2020**	52% (25)	33% (6)
	Apr – Jun, 2020	TBD	TBD

Key Lessons Learned

- Facilitating formalized discussions with stakeholders (oncology, genetics, laboratories, etc.), unit managers, and operational leads during pathway design phase led to consensus on indications for mainstreaming, optimization of processes and helped ensure province-wide adoption of the pathway.

- Resourcing a project team with a dedicated project manager, steering committee, data analyst, and education specialist was critical to the co-design and dissemination coherent and electronically accessible inclusion criteria, process materials, and education materials for patients and clinicians.

- Introduction of the “Hereditary Cancer Clinic Hub” was essential to coordinate day-to-day communication between ordering oncologists, genetics clinicians, and the molecular diagnostic laboratories performing genetic testing. Having dedicated resources to staff the Hub with genetic counsellors and an administrative assistant is essential.

- Conducting continued data collection and analysis will allow continuous assessment and improvement of processes, and allow for scalability and adaptation to other tumour groups.

- Pre-recording clinician education materials and enabling online access will help to train new staff and remove barriers to training for clinicians with limited availability.

- Patient feedback indicates mainstreaming is an appropriate and acceptable approach to hereditary cancer genetic testing.

Exhibit A – References

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Exhibit B – Contributors

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