Genetics **E**ducation **C**anada **K**nowledge **O**rganization

Inter-Society Coordinating Committee for Practitioner Education in Genomics Meeting
January 24, 2017

June C. Carroll MD CCFP FCFP

Sydney G. Frankfort Chair in Family Medicine

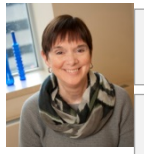
Professor and Clinician Scientist

Department of Family & Community Medicine

Mount Sinai Hospital, Sinai Health System, University of Toronto

GEC•KO — Genetics Education Canada Knowledge Organization

Who

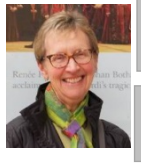


Dr. June C. Carroll

Co-founder and co-director

Professor and Clinician Scientist

Family physician



Dr. Judith E. Allanson

Co-founder and co-director

Professor

Retired clinical geneticist

Ms. Shawna Morrison

Program manager

Certified genetic counsellor

What

To increase genetics literacy in healthcare professionals and thereby enhance quality of genomic care in order to optimize the health and well-being of Canadians.

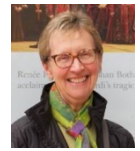
How

Funding

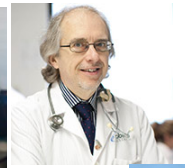
CHEO

Mount Sinai Hospital
Sinai Health System
Joseph & Wolf Lebovic Health Complex

Development







Genomic medicine in primary care: Needs assessment results

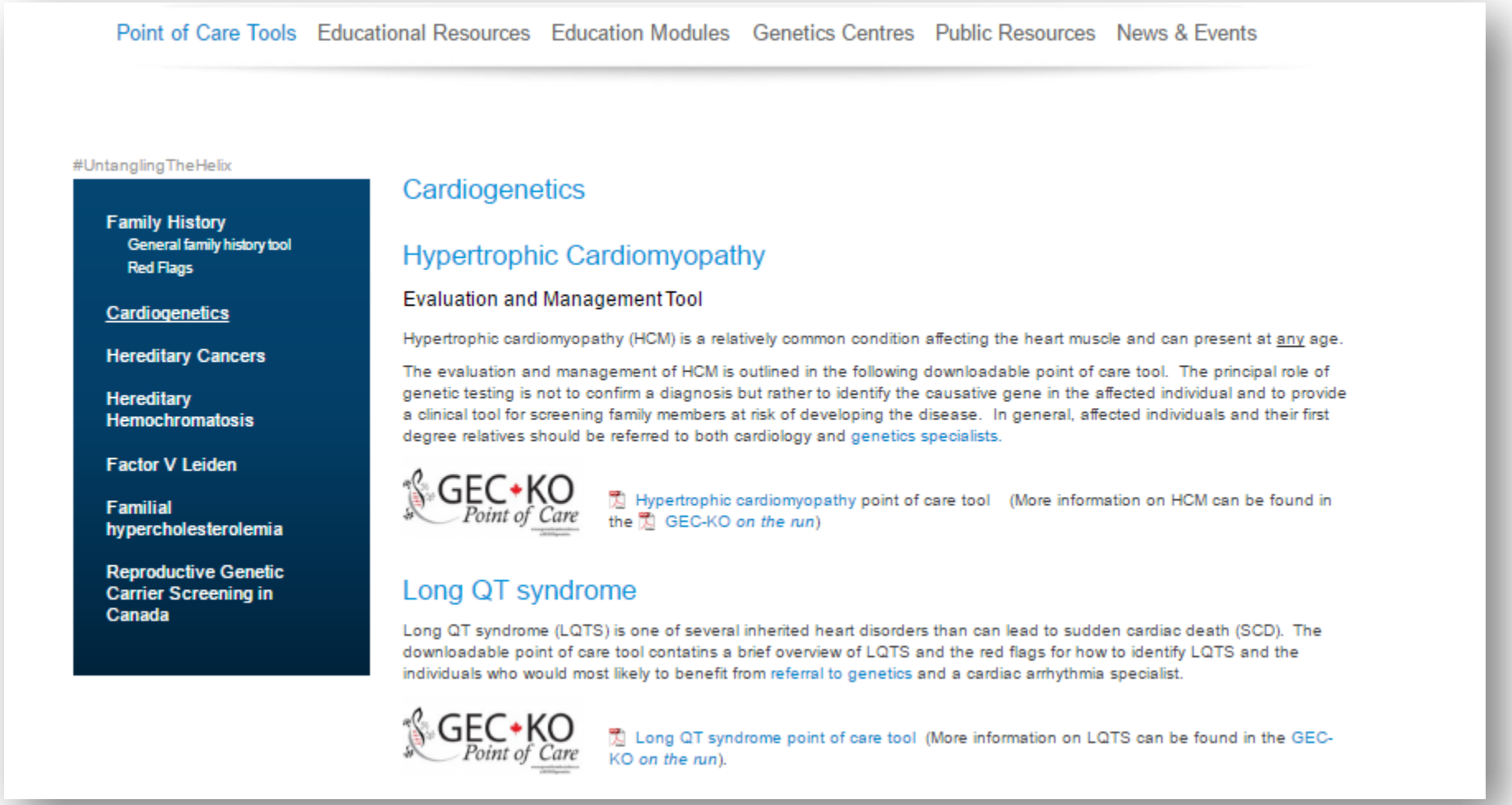
- Brief summary of needs assessments that informed our product development
  - Survey
  - Qualitative

Genomic medicine in primary care:
Needs Assessment: Qualitative results

- Wanted
  - Point of care tools
    - Embedded in EMR with clinical decision support
    - Web based
  - Non biased, up to date
  - Connection with genetics

Types of GEC-KO products:
the website www.geneticseducation.ca

Types of GEC-KO products:
point of care tools www.geneticseducation.ca



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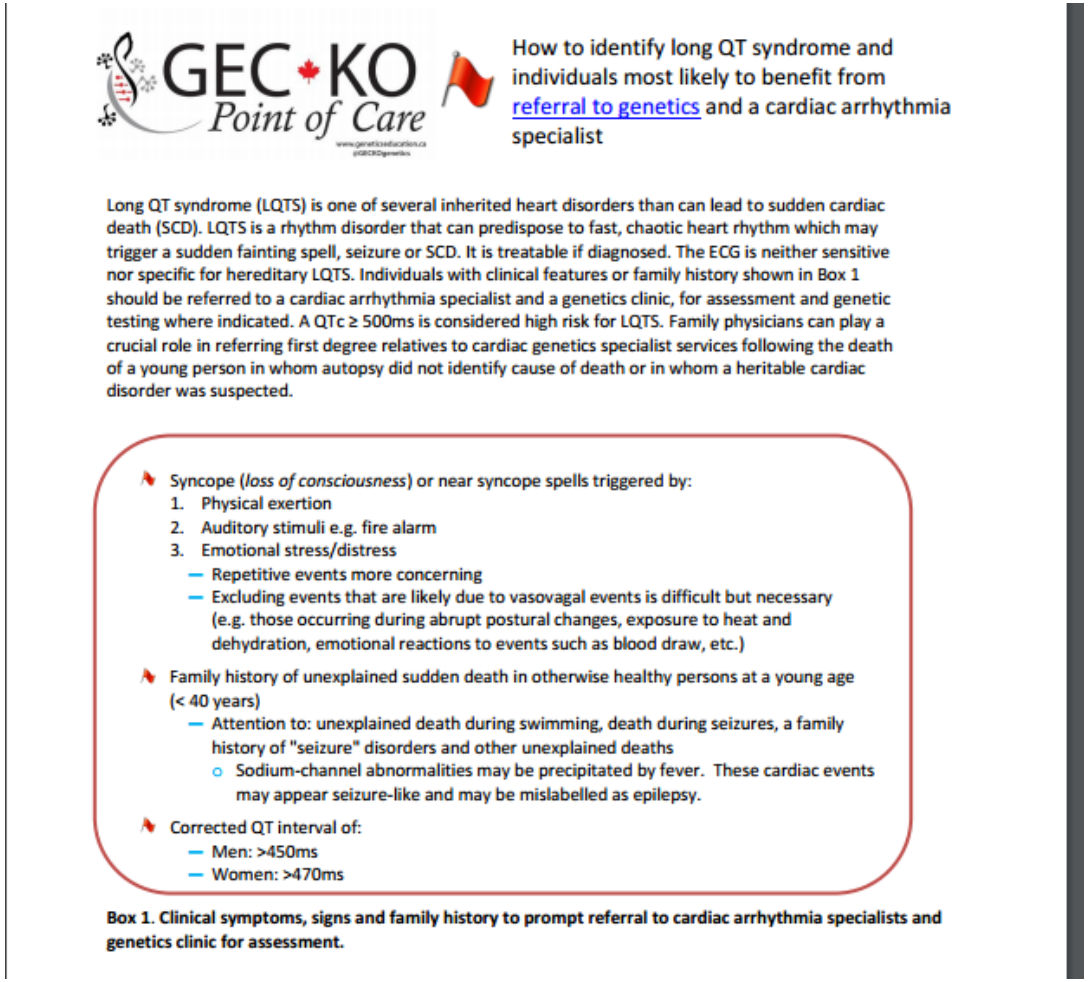


GEC•KO Point of Care

How to identify long QT syndrome and individuals most likely to benefit from referral to genetics and a cardiac arrhythmia specialist

Long QT syndrome (LQTS) is one of several inherited heart disorders than can lead to sudden cardiac death (SCD). LQTS is a rhythm disorder that can predispose to fast, chaotic heart rhythm which may trigger a sudden fainting spell, seizure or SCD. It is treatable if diagnosed. The ECG is neither sensitive nor specific for hereditary LQTS. Individuals with clinical features or family history shown in Box 1 should be referred to a cardiac arrhythmia specialist and a genetics clinic, for assessment and genetic testing where indicated. A QTc ≥ 500ms is considered high risk for LQTS. Family physicians can play a crucial role in referring first degree relatives to cardiac genetics specialist services following the death of a young person in whom autopsy did not identify cause of death or in whom a heritable cardiac disorder was suspected.

- Syncope (*loss of consciousness*) or near syncope spells triggered by:
  1. Physical exertion
  2. Auditory stimuli e.g. fire alarm
  3. Emotional stress/distress
     - Repetitive events more concerning
     - Excluding events that are likely due to vasovagal events is difficult but necessary (e.g. those occurring during abrupt postural changes, exposure to heat and dehydration, emotional reactions to events such as blood draw, etc.)
- Family history of unexplained sudden death in otherwise healthy persons at a young age (< 40 years)
  - Attention to: unexplained death during swimming, death during seizures, a family history of "seizure" disorders and other unexplained deaths
    - Sodium-channel abnormalities may be precipitated by fever. These cardiac events may appear seizure-like and may be mislabelled as epilepsy.
- Corrected QT interval of:
  - Men: >450ms
  - Women: >470ms

Box 1. Clinical symptoms, signs and family history to prompt referral to cardiac arrhythmia specialists and genetics clinic for assessment.

Types of GEC-KO products:
point of care tools www.geneticseducation.ca

GEC KO Point of Care

Part I: Hereditary breast and ovarian cancer referral screening tool to identify patients most likely to benefit from referral to genetics

Part I of this tool is used to predict which individuals should be referred for genetic counselling due to increased risk for a hereditary breast cancer syndrome including but not limited to hereditary breast and ovarian cancer (HBOC) syndrome caused by mutations in *BRCA1* and *BRCA2* genes. Part II of this tool is used to identify individuals who are at high risk to carry a mutation in *BRCA1* or *BRCA2* genes.

1. Did any of your first degree relatives (parent, sibling, child) have breast *or* ovarian cancer?	Yes ☐	No ☐
2. Did any of your relatives have bilateral breast cancer?	Yes ☐	No ☐
3. Did any man in your family have breast cancer?	Yes ☐	No ☐
4. Did any woman in your family have breast *and* ovarian cancer?	Yes ☐	No ☐
5. Did any woman in your family have breast cancer before the age of 50 years?	Yes ☐	No ☐
6. Do you have 2 or more relatives with breast *and/or* ovarian cancer?	Yes ☐	No ☐
7. Do you have 2 or more relatives with breast *and/or* bowel cancer?	Yes ☐	No ☐

Management: **With 1 or more** positive responses, discuss referral to genetics

This POC tool is based on the Family History Screening-7 (FHS-7) (Ashton-Prolla *et al* 2009), which was designed for use in primary care settings and demonstrated an overall sensitivity of 97.0% and a specificity of 53.0% for HBOC syndrome. Overall, **using as cut point one positive answer**, the sensitivity and specificity of the instrument were 87.6% and 56.4%, respectively for hereditary breast cancer syndromes.

Reference: Ashton-Prolla P, Giacomazzi J, Schmidt AV, *et al*. Development and validation of a simple questionnaire for the identification of hereditary breast cancer in primary care. *BMC Cancer* 2009; 9:283

GEC KO Point of Care

Part II: Red Flags to identify patients at **high risk** of hereditary breast and ovarian cancer most likely to benefit from referral to genetics

These are general guidelines to identify patients at **high risk** for hereditary breast and ovarian cancer (HBOC) syndrome. You should consider referring your patient to your local genetics centre or hereditary cancer program for further assessment if s/he has a family or personal history of:

- Breast cancer diagnosis at a young age (<35-45 years) [both invasive and ductal carcinoma *in situ*]
- Ovarian cancer at any age [epithelial]
- Male breast cancer
- Multiple primaries in the same individual e.g. bilateral breast cancer (particularly if the diagnosis was before age 50), breast and ovarian cancer
- Breast cancer diagnosis **AND** a family history of two or more additional HBOC- related cancers, including breast, ovarian, prostate (Gleason ≥7) and pancreatic cancer
- High risk ethnicity (Ashkenazi Jewish, Icelandic) and a personal and/or family history of breast, ovarian or pancreatic cancer
- Triple negative breast cancer diagnosed <age 60

OR if s/he has a personal

- Probability of 10% or higher to carry a *BRCA* mutation

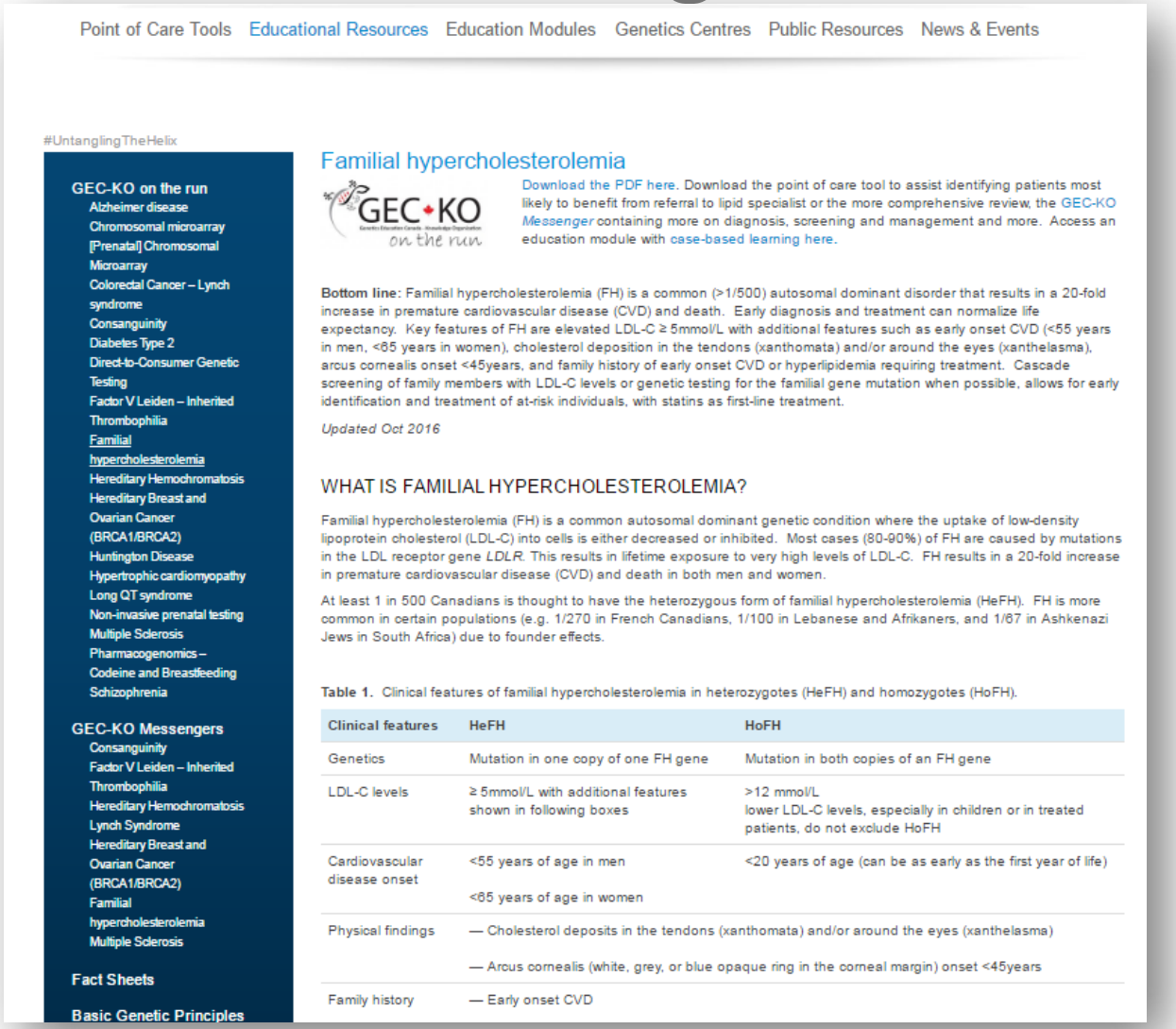
Eligibility criteria for genetic testing vary among organizations. In general, criteria are based on clinical features that increase the likelihood of a hereditary cancer susceptibility syndrome.

If possible, the affected individual in the family at highest risk to carry a mutation is offered testing first in order to maximize the likelihood of detecting a mutation.

Testing an unaffected individual should only be considered if an affected individual is not available for testing. There are significant limitations to interpretation of test results in an unaffected individual. Unaffected individuals can be referred for genetic counselling, risk assessment and information. It is important to note that any individual of Ashkenazi Jewish ethnicity or French Canadian ethnicities can be offered genetic testing for the mutations commonly found in these ethnic groups (e.g. three common mutations in those of Ashkenazi Jewish ethnicity). A negative result in this situation only rules out those ethnic-specific mutations.

Types of GEC-KO products:

GEC-KO *on the run* www.geneticseducation.ca



Point of Care Tools | Educational Resources | Education Modules | Genetics Centres | Public Resources | News & Events

#UntanglingTheHelix

GEC-KO on the run
- Alzheimer disease
- Chromosomal microarray
- [Prenatal] Chromosomal Microarray
- Colorectal Cancer – Lynch syndrome
- Consanguinity
- Diabetes Type 2
- Direct-to-Consumer Genetic Testing
- Factor V Leiden – Inherited Thrombophilia
- Familial hypercholesterolemia
- Hereditary Hemochromatosis
- Hereditary Breast and Ovarian Cancer (BRCA1/BRCA2)
- Huntington Disease
- Hypertrophic cardiomyopathy
- Long QT syndrome
- Non-invasive prenatal testing
- Multiple Sclerosis
- Pharmacogenomics – Codeine and Breastfeeding
- Schizophrenia

GEC-KO Messengers
- Consanguinity
- Factor V Leiden – Inherited Thrombophilia
- Hereditary Hemochromatosis
- Lynch Syndrome
- Hereditary Breast and Ovarian Cancer (BRCA1/BRCA2)
- Familial hypercholesterolemia
- Multiple Sclerosis

Fact Sheets

Basic Genetic Principles

Familial hypercholesterolemia

GEC-KO on the run

Download the PDF here. Download the point of care tool to assist identifying patients most likely to benefit from referral to lipid specialist or the more comprehensive review, the GEC-KO *Messenger* containing more on diagnosis, screening and management and more. Access an education module with case-based learning here.

Bottom line: Familial hypercholesterolemia (FH) is a common (>1/500) autosomal dominant disorder that results in a 20-fold increase in premature cardiovascular disease (CVD) and death. Early diagnosis and treatment can normalize life expectancy. Key features of FH are elevated LDL-C ≥ 5mmol/L with additional features such as early onset CVD (<55 years in men, <65 years in women), cholesterol deposition in the tendons (xanthomata) and/or around the eyes (xanthelasma), arcus cornealis onset <45years, and family history of early onset CVD or hyperlipidemia requiring treatment. Cascade screening of family members with LDL-C levels or genetic testing for the familial gene mutation when possible, allows for early identification and treatment of at-risk individuals, with statins as first-line treatment.

Updated Oct 2016

WHAT IS FAMILIAL HYPERCHOLESTEROLEMIA?

Familial hypercholesterolemia (FH) is a common autosomal dominant genetic condition where the uptake of low-density lipoprotein cholesterol (LDL-C) into cells is either decreased or inhibited. Most cases (80-90%) of FH are caused by mutations in the LDL receptor gene *LDLR*. This results in lifetime exposure to very high levels of LDL-C. FH results in a 20-fold increase in premature cardiovascular disease (CVD) and death in both men and women.

At least 1 in 500 Canadians is thought to have the heterozygous form of familial hypercholesterolemia (HeFH). FH is more common in certain populations (e.g. 1/270 in French Canadians, 1/100 in Lebanese and Afrikaners, and 1/67 in Ashkenazi Jews in South Africa) due to founder effects.

Table 1. Clinical features of familial hypercholesterolemia in heterozygotes (HeFH) and homozygotes (HoFH).

Clinical features	HeFH	HoFH
Genetics	Mutation in one copy of one FH gene	Mutation in both copies of an FH gene
LDL-C levels	≥ 5mmol/L with additional features shown in following boxes	>12 mmol/L lower LDL-C levels, especially in children or in treated patients, do not exclude HoFH
Cardiovascular disease onset	<55 years of age in men <65 years of age in women	<20 years of age (can be as early as the first year of life)
Physical findings	— Cholesterol deposits in the tendons (xanthomata) and/or around the eyes (xanthelasma) — Arcus cornealis (white, grey, or blue opaque ring in the corneal margin) onset <45years	
Family history	— Early onset CVD	

Types of GEC-KO products:

GEC-KO *on the run* www.geneticseducation.ca

Familial Hypercholesterolemia

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Clinical features	HeFH	HoFH
Genetics	Mutation in one copy of one FH gene	Mutation in both copies of an FH gene
LDL-C levels	≥ 5mmol/L with additional features shown in following boxes	>12 mmol/L *lower LDL-C levels, especially in children or in treated patients, do not exclude HoFH*
Cardiovascular disease onset	<55 years of age in men <65 years of age in women	<20 years of age (can be as early as the first year of life)
Physical findings	— Cholesterol deposits in the tendons (xanthomata) and/or around the eyes (xanthelasma) — Arcus cornealis (white, grey, or blue opaque ring in the corneal margin) onset <45years	
Family history	— Early onset CVD — Hyperlipidemia, often requiring treatment	

How is familial hypercholesterolemia diagnosed?

While there are no Canadian-specific FH diagnostic criteria, the Canadian Cardiovascular Society (CCS) recommends using those published by the Dutch Lipid Clinic Network (see the FH Point of Care Tool).

How to recognize individuals with FH:

- An individual (>30years) with hypercholesterolemia (LDL-C ≥5mmol/L)
  - * Exclusion of secondary causes of elevated LDL-C, e.g. obstructive liver disease, hypothyroidism, nephrotic syndrome, anorexia nervosa

AND

- Personal or family history of clinical stigmata of FH

OR

- Personal or family history of premature CVD

OR

- Family history of significant hypercholesterolemia, often requiring treatment

Individuals with LDL-C ≥5mmol/L and at least one of the features above are considered to have a *possible* FH diagnosis. Those with LDL-C ≥ 5mmol/L and 2 additional features are considered to have a *probable* FH diagnosis. Individuals with possible or probable diagnosis should be referred to a lipid specialist for diagnosis and management.

Cascade Screening

The most cost-effective approach for identification of new FH cases is cascade screening of family members of a known index case (the first individual with a confirmed diagnosis). Screening can be by LDL-C measurements, genetic testing for a known familial gene mutation when possible or use of diagnostic criteria (See the FH Point of Care Tool). Some experts recommend referral for specialist consultation beginning at age 2 years for those at high risk for HoFH (individuals where both parents have HeFH).

Where do I refer my patient?

Find a Canadian FH specialist here.

You should refer your patient to your local genetics centre if s/he has had a positive genetic test result and would like genetic counselling to discuss the implications for self and family. Include all relevant information on your referral (e.g. family history, genetic test results, and investigations like LDL-C) to prevent unnecessary delays due to further clarification needed before an appointment can be booked.

Note that genetics clinics vary with regard to the referrals they choose to accept. You may want to contact your local centre for more information.

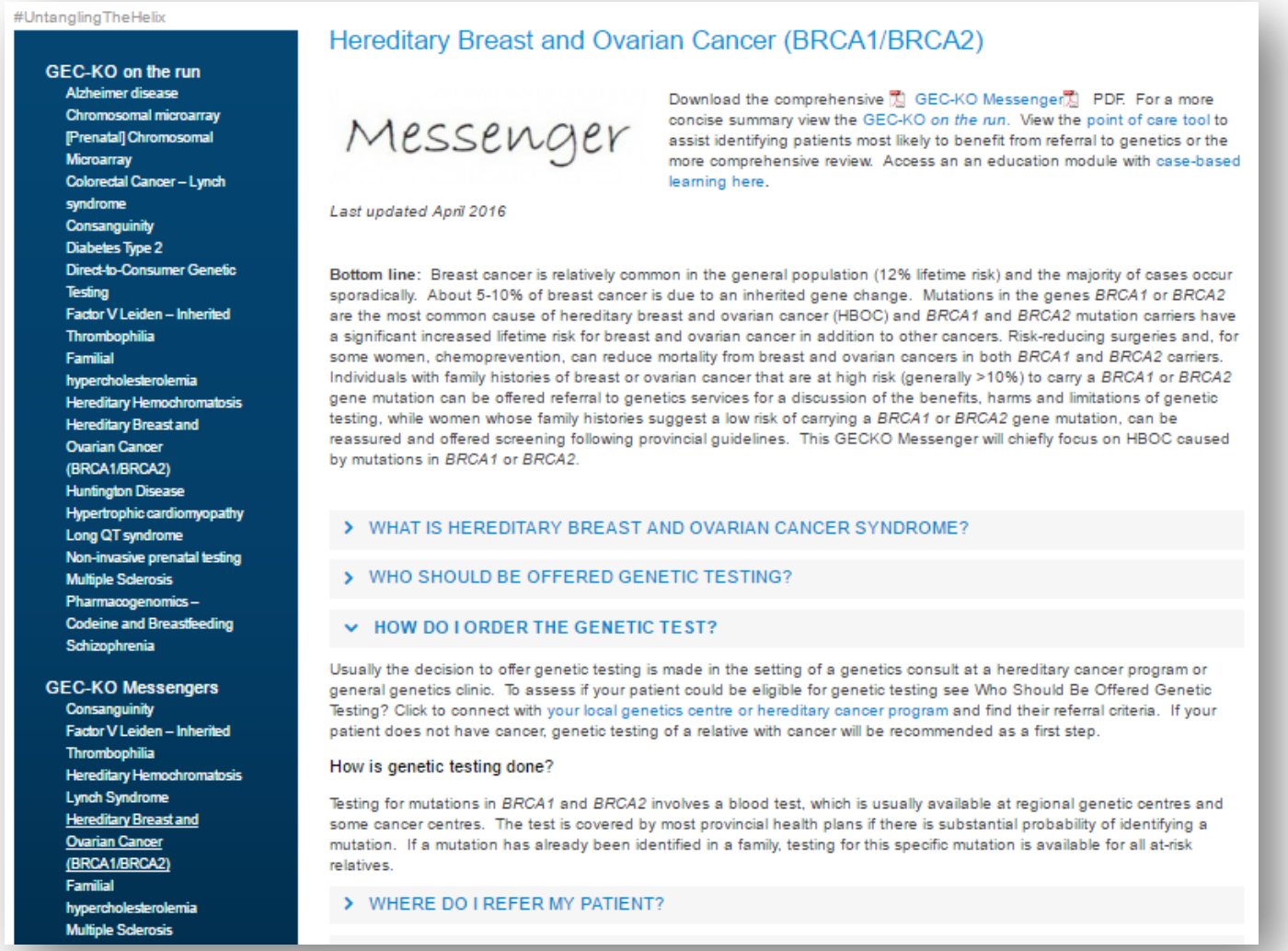
Surveillance and Management

Statins are the drug class of choice for individuals with HeFH. LDL-C should be lowered as fast and as far as possible. **The CCS recommends a >50% reduction of LDL-C from baseline beginning at age 18 as primary prevention with a goal of LDL-C <2.0mmol/L for secondary prevention.** Some individuals with FH will require combination and/or emerging therapy to obtain optimal LDL-C. Families with FH should be counselled about the importance of lifestyle modification such as: smoking cessation and avoidance of passive smoking; diet; exercise; daily activity beginning early in life; maintenance of ideal body weight; and stress reduction.

Children: Lifestyle modifications discussed above remain the cornerstone of CVD prevention in both children and

Types of GEC-KO products:

GEC-KO *Messenger* www.geneticseducation.ca



#UntanglingTheHelix

GEC-KO on the run

- Alzheimer disease
- Chromosomal microarray [Prenatal] Chromosomal Microarray
- Colorectal Cancer – Lynch syndrome
- Consanguinity
- Diabetes Type 2
- Direct-to-Consumer Genetic Testing
- Factor V Leiden – Inherited Thrombophilia
- Familial hypercholesterolemia
- Hereditary Hemochromatosis
- Hereditary Breast and Ovarian Cancer (BRCA1/BRCA2)
- Huntington Disease
- Hypertrophic cardiomyopathy
- Long QT syndrome
- Non-invasive prenatal testing
- Multiple Sclerosis
- Pharmacogenomics – Codeine and Breastfeeding
- Schizophrenia

GEC-KO Messengers

- Consanguinity
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- Hereditary Breast and Ovarian Cancer (BRCA1/BRCA2)
- Familial hypercholesterolemia
- Multiple Sclerosis

Hereditary Breast and Ovarian Cancer (BRCA1/BRCA2)

Messenger

Download the comprehensive GEC-KO Messenger PDF. For a more concise summary view the GEC-KO *on the run*. View the point of care tool to assist identifying patients most likely to benefit from referral to genetics or the more comprehensive review. Access an an education module with case-based learning here.

Last updated April 2016

Bottom line: Breast cancer is relatively common in the general population (12% lifetime risk) and the majority of cases occur sporadically. About 5-10% of breast cancer is due to an inherited gene change. Mutations in the genes *BRCA1* or *BRCA2* are the most common cause of hereditary breast and ovarian cancer (HBOC) and *BRCA1* and *BRCA2* mutation carriers have a significant increased lifetime risk for breast and ovarian cancer in addition to other cancers. Risk-reducing surgeries and, for some women, chemoprevention, can reduce mortality from breast and ovarian cancers in both *BRCA1* and *BRCA2* carriers. Individuals with family histories of breast or ovarian cancer that are at high risk (generally >10%) to carry a *BRCA1* or *BRCA2* gene mutation can be offered referral to genetics services for a discussion of the benefits, harms and limitations of genetic testing, while women whose family histories suggest a low risk of carrying a *BRCA1* or *BRCA2* gene mutation, can be reassured and offered screening following provincial guidelines. This GECKO Messenger will chiefly focus on HBOC caused by mutations in *BRCA1* or *BRCA2*.

> WHAT IS HEREDITARY BREAST AND OVARIAN CANCER SYNDROME?

> WHO SHOULD BE OFFERED GENETIC TESTING?

⌄ HOW DO I ORDER THE GENETIC TEST?

Usually the decision to offer genetic testing is made in the setting of a genetics consult at a hereditary cancer program or general genetics clinic. To assess if your patient could be eligible for genetic testing see Who Should Be Offered Genetic Testing? Click to connect with your local genetics centre or hereditary cancer program and find their referral criteria. If your patient does not have cancer, genetic testing of a relative with cancer will be recommended as a first step.

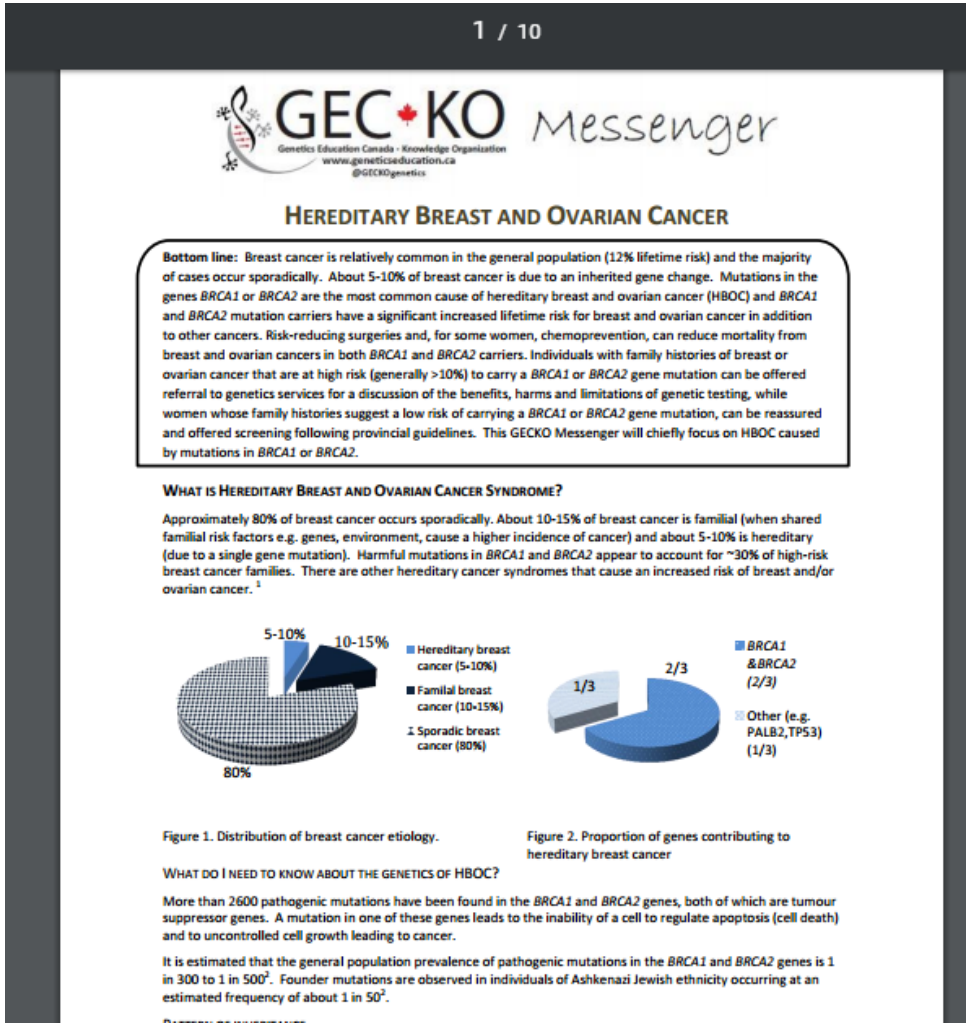
How is genetic testing done?

Testing for mutations in *BRCA1* and *BRCA2* involves a blood test, which is usually available at regional genetic centres and some cancer centres. The test is covered by most provincial health plans if there is substantial probability of identifying a mutation. If a mutation has already been identified in a family, testing for this specific mutation is available for all at-risk relatives.

> WHERE DO I REFER MY PATIENT?

Types of GEC-KO products:

GEC-KO *Messenger* www.geneticseducation.ca



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GEC•KO Messenger

Genetics Education Canada - Knowledge Organization
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HEREDITARY BREAST AND OVARIAN CANCER

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WHAT IS HEREDITARY BREAST AND OVARIAN CANCER SYNDROME?

Approximately 80% of breast cancer occurs sporadically. About 10-15% of breast cancer is familial (when shared familial risk factors e.g. genes, environment, cause a higher incidence of cancer) and about 5-10% is hereditary (due to a single gene mutation). Harmful mutations in *BRCA1* and *BRCA2* appear to account for ~30% of high-risk breast cancer families. There are other hereditary cancer syndromes that cause an increased risk of breast and/or ovarian cancer. [1]

Figure 1. Distribution of breast cancer etiology.

Figure 2. Proportion of genes contributing to hereditary breast cancer

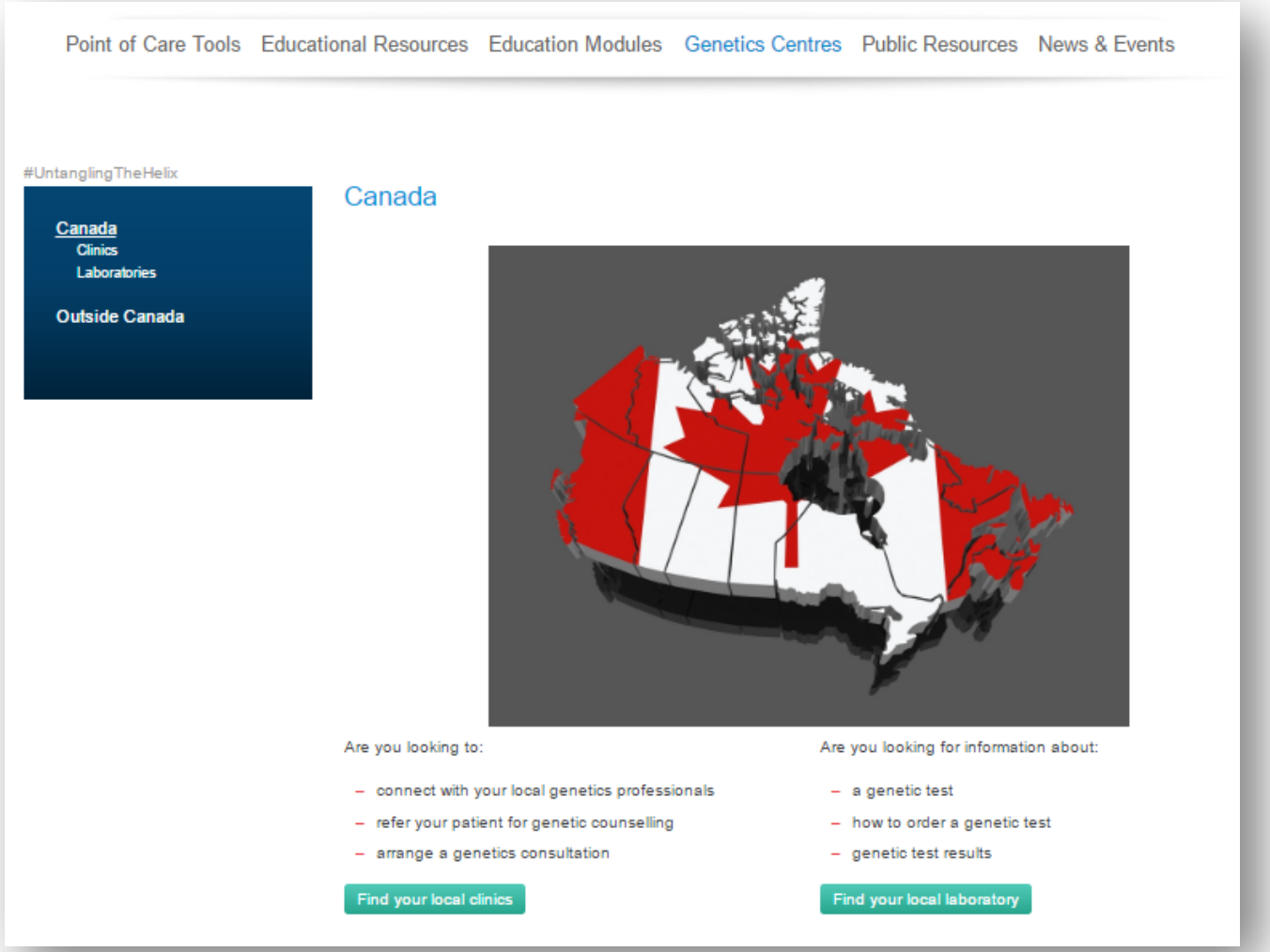
WHAT DO I NEED TO KNOW ABOUT THE GENETICS OF HBOC?

More than 2600 pathogenic mutations have been found in the *BRCA1* and *BRCA2* genes, both of which are tumour suppressor genes. A mutation in one of these genes leads to the inability of a cell to regulate apoptosis (cell death) and to uncontrolled cell growth leading to cancer.

It is estimated that the general population prevalence of pathogenic mutations in the *BRCA1* and *BRCA2* genes is 1 in 300 to 1 in 500[2]. Founder mutations are observed in individuals of Ashkenazi Jewish ethnicity occurring at an estimated frequency of about 1 in 50[2].

Types of GEC-KO products:

Contact to centres www.geneticseducation.ca



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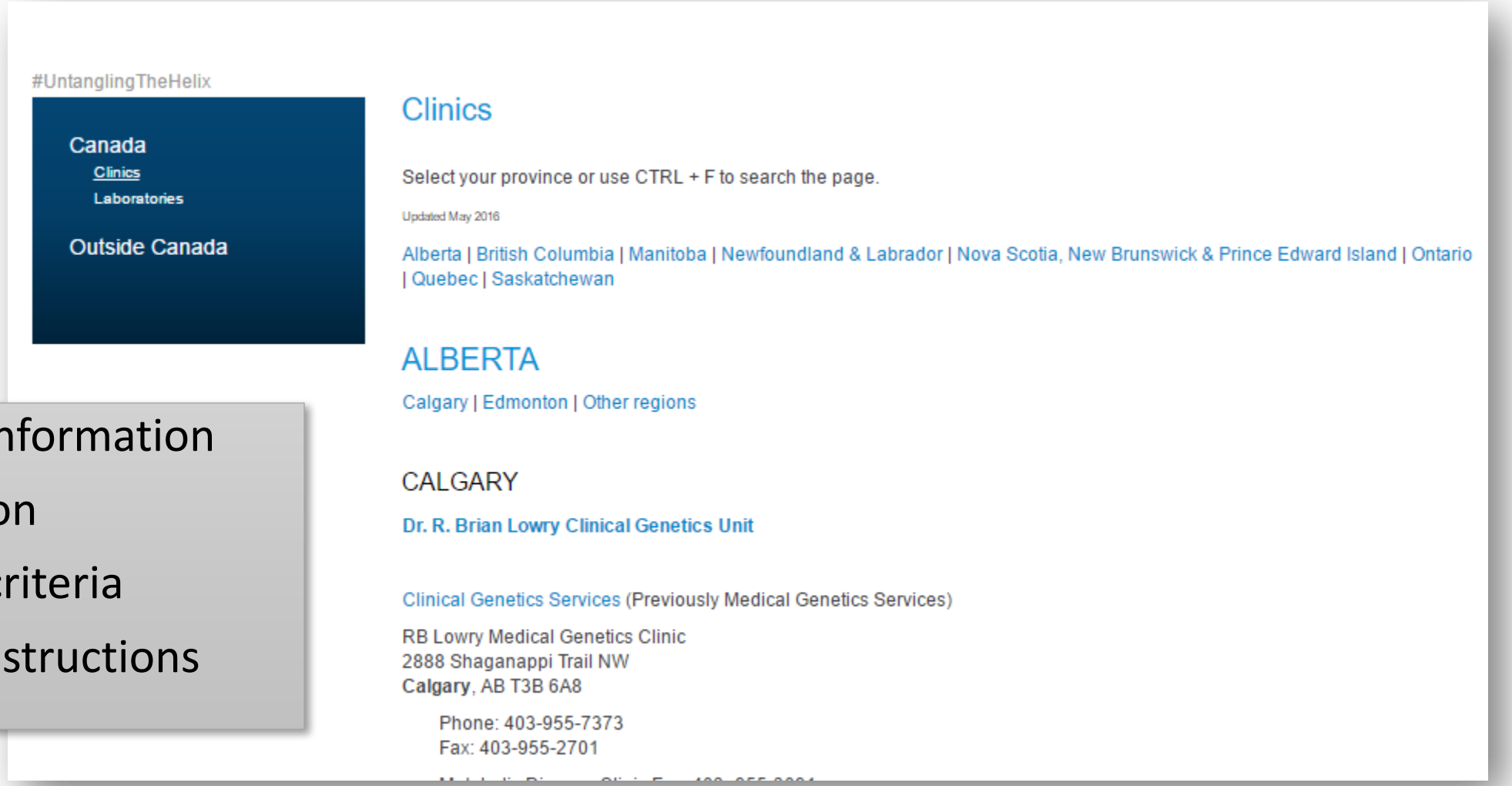
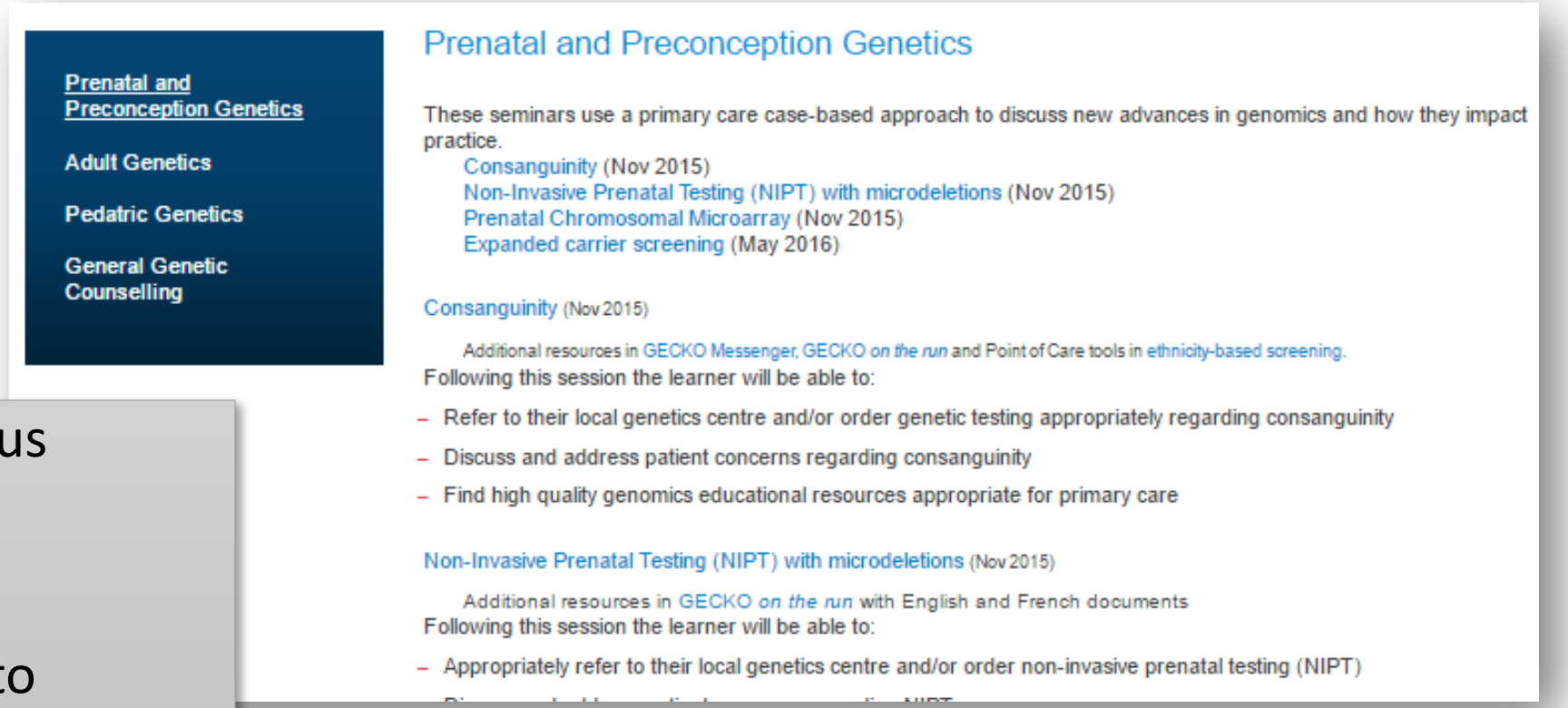


- Contact information
- Requisition
- Referral criteria
- Special instructions

Types of GEC-KO products:
In person seminars www.geneticseducation.ca



- Learning modules on various genomic topics
- Case-based learning
- Can be used by educators to facilitate teaching or by individuals motivated to learn more about genomic topics

Types of GEC-KO products:
In person seminars www.geneticseducation.ca

- General:
  - Familial hypercholesterolemia (**2016**)
  - Hereditary hemochromatosis (2013, 2014, 2015)
  - Alzheimer disease (2014, 2015)
  - Multiple sclerosis (2014, 2015)
  - Factor V Leiden (2014)
  - Autism, developmental delay, intellectual disability and Introduction to chromosomal microarray (2013, 2014)
  - Direct-to-Consumer genetic testing (2013, 2014, 2015, **2016**)
- Cancer:
  - Lynch syndrome (2013, 2014, 2015)
  - Hereditary breast and ovarian cancer syndrome (2015, **2016**)
- Cardiogenetics:
  - Hypertrophic cardiomyopathy (2014)
  - Long QT syndrome (**2016**)
- Prenatal & preconception:
  - Non-invasive prenatal testing (NIPT/cfDNA) (2013, 2014)
  - NIPT with microdeletions (2015)
  - Prenatal chromosomal microarray (2015)
  - Expanded carrier screening (**2016**)
  - Consanguinity (2015)

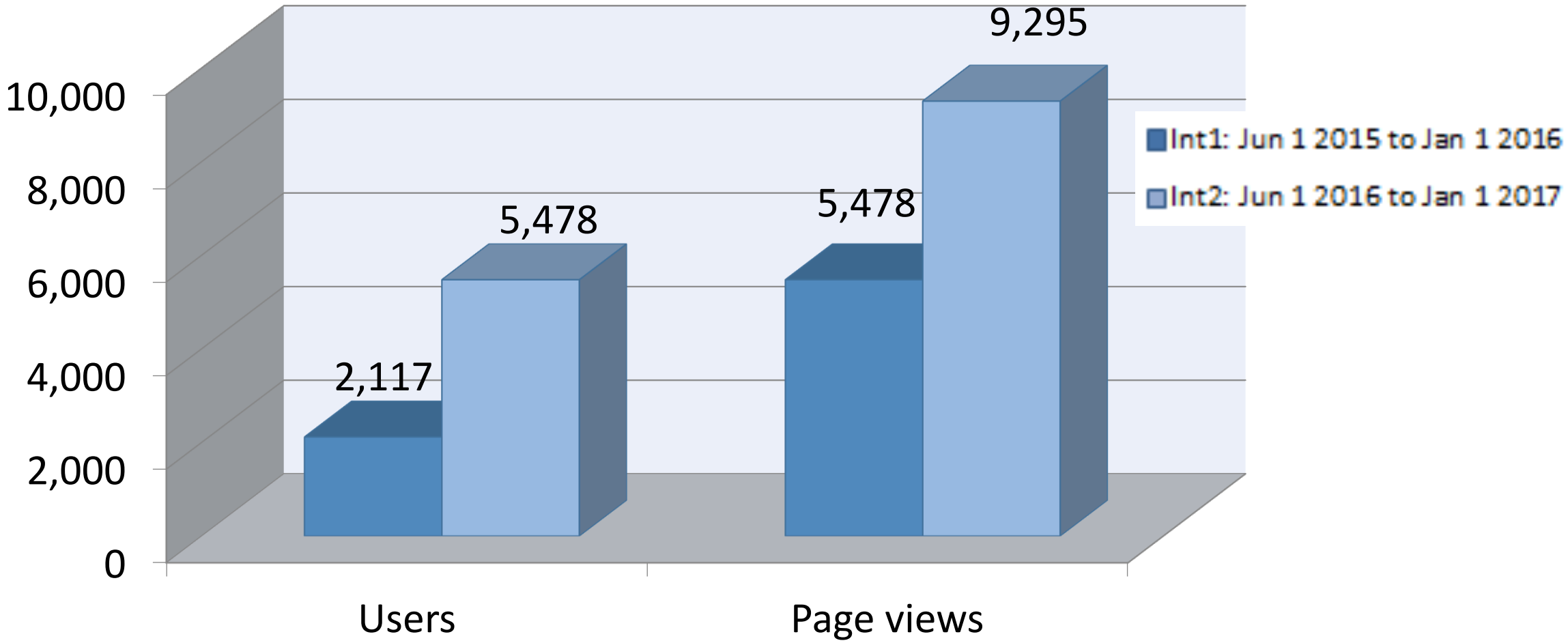
Types of GEC-KO products:
In person seminars www.geneticseducation.ca

- Time:
  - 60-90 minutes
  - ~25% interactive
- Several topics in a session
- Format:
  - Case-based
  - Basic genetics (inheritance, prevalence)
  - Red flags for genetic referral and/or testing
  - Genetic test results (positive, true negative, uninformative, VUS)
  - Screening and surveillance
  - Pearls

Evaluation

- RCT of *GEC-KO Messengers (GM)* showed significant increase in:
  - appropriate referral to genetics
  - self reported confidence in core genetic competencies
    - *Carroll et al Family Practice 2011*
- Email "push" of *GM* to members of the College of Family Physicians of Canada
  - Used Information Assessment Method (cognitive impact, relevance, intended use for a patient, expected health benefits)
  - 73% indicated practice would be improved after reading *GMs*
  - Of those who rated a *GM* relevant, 94% would apply it to at least 1 patient and 70% expected health benefits
    - *Carroll et al JCEHP 2016*
- Seminar evaluation
  - Good
  - Too much content

Evaluation
website analytics www.geneticseducation.ca
Users



Evaluation
website analytics www.geneticseducation.ca
User location

	Int 1	Int 2
Top 5 Countries	**June 1 2015 - Jan 1 2016**	**June 1 2016 - Jan 1 2017**
1	Canada	Canada
2	USA	USA
3	India	UK
4	UK	India
5	France	Australia

Evaluation
website analytics www.geneticseducation.ca
User behaviour

Website section (% of total page views, 9,295)	Most viewed pages from Jun 1 2016 to Jan 1 2017 (Pages Viewed)	
1. Educational Resources (53%, N = 4,943)	GEC KO *on the run (3,738)*	GEC KO *Messenger (463)*
	Non-invasive prenatal testing (NIPT) (2,928)	Consanguinity (194)
	Hereditary breast and ovarian cancer syndrome (210)	Hereditary breast and ovarian cancer syndrome (70)
2. Genetics Centres (10%, N=924)		
3. Point of Care (POC) tools (7%, N=635)	Family history (166)	Hereditary cancer (166)

What works

- Be evidence-based and brief, get to the point quickly
- Keep resources up-to-date and locally relevant
- Limit barriers to information access e.g. no sign in
- Provide resources for point of care
- Integrate into existing education venues
- Use interactive workshop format
- Engage and listen to stakeholders
    - Be flexible, responsive, continuously evolve
    - Meet clinical needs and questions of stakeholders

Challenges

- Engaging with primary care providers
- Implementation into practice
- Evaluation
- New format

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Dr. June Carroll
June.Carroll@sinaihealthsystem.on.ca
Shawna Morrison
morrison@cheo.on.ca