Gynecologic
Cancer Initiative

Gynecologic Cancer Initiative (GCI)

accelerating research in women's reproproductive cancers to save lives

STRATEGIC PLAN

"Together, we will save women's lives"

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Gynecologic Cancer Initiative
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gci_cluster

MISSION

The Gynecologic Cancer Initiative will accelerate transformative research on prevention, detection, treatment and survivorship of reproductive cancers. Through synergistic partnering of research institutions, scientists, clinicians and the women of BC we will reduce the incidence and mortality of women’s gynecologic cancers by 50% in the next 15 years.

WHAT IS THE GYNECOLOGIC CANCER INITIATIVE?

British Columbia is a recognized world leader in the field of gynecologic cancer research; the Gynecologic Cancer Initiative (GCI) aims to promote synergies and facilitate the integration between research scientists and clinicians, with the goal of accelerating the pace of change in improving patient outcomes. The group recognizes that the determination, talent and passion brought by each individual on the team and the incredible resources and rich research environment in BC, creates an unprecedented opportunity to 'turn the page on the burden of gynecologic cancers' and change the metrics around the prevention, detection, treatment and survivorship of gynecologic cancers in women in this province.

The vision of the Gynecologic Cancer Initiative is to reduce the incidence, death and suffering from these cancers by 50% by 2034. The goal is to raise $100M to support and enable this initiative over the next 5 years.

Funding will be dedicated to recruiting world class talent, state of the art technologies, laboratory and support infrastructure, and leading-edge and innovative research that will have an impact on women's lives.

VGH UBC hospital foundation

UBC FACULTY OF MEDICINE

OVCARE BC'S OVARIAN CANCER RESEARCH TEAM

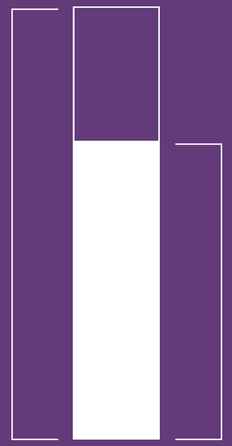
BC CANCER FOUNDATION

WOMEN'S HEALTH RESEARCH INSTITUTE AT BC WOMEN'S

BC WOMEN'S HEALTH FOUNDATION

This year alone,

1,309,165
women around the globe will face a diagnosis of gynecologic cancer



901,517
women will die from their disease

In 15 years

33% increase
in deaths if there are no dramatic improvements in treatment and care

Problem

There has been a significant disparity in funding to support gynecologic cancer research as compared to other cancer sites.

Our Approach.

The GCI aims to build a framework to aggregate the exceptional talent and incredible assets in British Columbia in a shared provincial vision: Research with tangible benefits for women at risk for, diagnosed with, and survivors of gynecologic cancers. The GCI will align with the five priorities identified in the refreshed Canadian Strategy for Cancer Control (2019-2029): decrease risk, improve diagnosis, delivery of high-quality care, eliminate barriers to access, and improve support. This builds upon the global model of cancer control that is used to include prevention, early detection, treatment and supportive care. The regional diversity of patient populations in the province make BC an ideal “living laboratory” to study women’s gynecologic cancer health and address health disparities. The GCI will engage with the Provincial Gynecologic Cancer Tumour Group to continue to promote excellence in research and in care.

The GCI will build on the longstanding history of excellence in gynecologic cancer research and care in the province by fostering new collaborations with scientists whose primary focus is outside of gynecologic cancer. Through partnering with researchers across disciplines, the GCI aims to conduct research that is innovative and transcends traditional areas of research. Finally, the GCI is committed to equity, diversity, and inclusion in both its membership and research to improve outcomes for all women regardless of geography, gender identity, ethnic or socio-economic status.

The tenacity and commitment of this specialized and dedicated group of scientists and clinicians underpins the Gynecologic Cancer Initiative. With support and investment from institutional stakeholders and the community, collectively WE will change the story for thousands of women diagnosed with gynecologic cancer and their families each year.

Cervical Cancer

Success Measurement

- Reduction in the incidence and mortality of cervical cancer
- Increase in number of girls and women in BC receiving the HPV vaccine
- A better understanding of the presence to progression of the HPV virus to cervical cancer
- Economic benefits to BC by measuring the direct cost of HPV infections, cost of Pap test vs HPV testing
- Worldwide uptake of Pap to HPV testing and reduced dosing process

Cervical Cancer

Strategic Initiative

In Canada, 4-5 million pap tests are done per year in order to achieve a low rate of this invasive disease (1550 cases and 400 deaths) by catching the presence of abnormal cells early and treating them.

Canada is prepared to step up to the World Health Organization call to action to eliminate cervical cancer, and we believe that the Canadian opportunity is to demonstrate the capability of elimination. This is largely due to the discovery that a common Human papillomavirus (HPV) is linked to the development of cervical cancer.

HPV vaccination provides safe, effective and lasting protection against the HPV infections that most commonly cause cancer. However, despite great advances having been made in primary prevention with the HPV vaccine, secondary prevention and early treatment of pre-cancer remains vital to achieving the global goal.

Cervical cancer doesn't have to be a death sentence, in fact cervical cancer doesn't have to exist at all.

The Solution - “Pap” test

HPV is the most common sexually transmitted infection and three out of four women who are sexually active are at risk of contracting the virus. In most women, it clears on its own, while for others it becomes a persistent infection which leads to precancerous lesions. A vaccine can eliminate the acquisition of HPV altogether (which shows up in 99.7% of cervical cancer cases) or a Pap smear or an HPV screening test can catch these lesions before they become cervical cancer. BC Women’s Hospital + Health Centre, in conjunction with UBC Faculty of Medicine and BC Cancer are dedicated to the elimination of cervical cancer for women in British Columbia.

British Columbia’s Pioneering Track Record

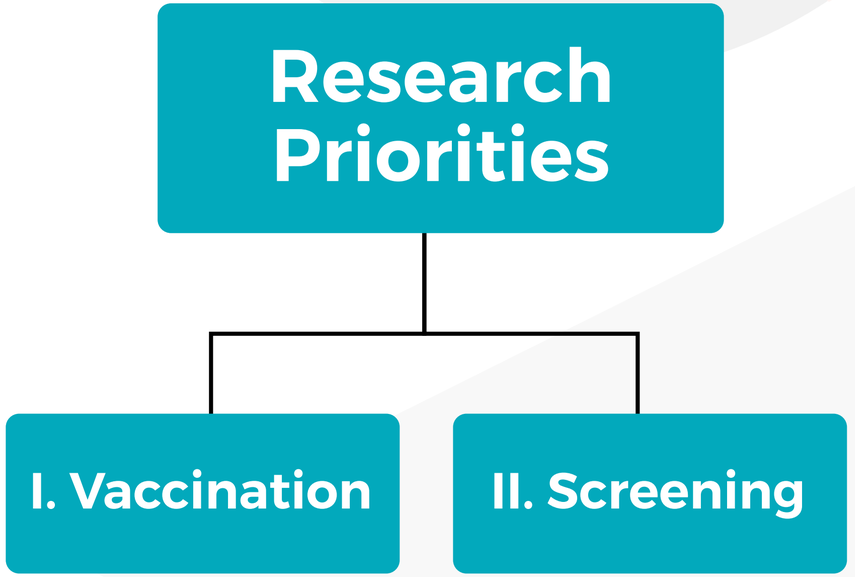
In 1949, BC became the first jurisdiction in the world to introduce a publicly-funded cervical cancer screening program using the Papanikolaou smear or “Pap” test. This effort has led to a decline in deaths from cervical cancer in BC of over 70%.

BC is still leading the conversation on cervical cancer. BC Women's Hospital and BC Cancer scientists have written national guidelines, informed international policies on prevention by increasing the vaccination uptake and creating innovative, cost effective screening to save women's lives, including:

Identifying 2 doses of the HPV vaccine is as effective as the original 3 doses, which changed the World Health Organization policy, the European Union Medicine Association policies and the Pan-American Health Association policies.

Identifying that the HPV test is superior to the Pap test for identifying when precancerous cells are present (HPV test is 99% sensitive compared to 50-60% for Pap tests). This research concluded that an HPV-based screening program (which tests for the infection rather than the resulting abnormalities) has a higher detection rate, and a more conclusive negative, than the traditional Pap smear.

The tools are available to eliminate cervical cancer now, going forward this has to be translated into awareness and change of protocol and practice.



Today, the GCI has an ambitious target to meet. It aims to eliminate cervical cancer in this province and across Canada, aligning directly with the World Health Organization's call to action. With the unique datasets here in BC and the global expertise of the team, the GCI is uniquely positioned to undertake this ground-breaking initiative. The GCI's cervical cancer specialists have identified key knowledge gaps which have informed the strategic priorities outlined below.

I. Vaccination

Impactful research, developed in British Columbia, has already informed practice and policy worldwide, reducing the HPV vaccination process from 3 to 2 doses; this sets the stage for their ongoing research in this area. Today, our BC scientists and clinicians are examining if 1 dose is as or more effective for Canadian girls. By following this group of Canadian girls prospectively, the team will determine if booster vaccinations are required. Currently, only 65% of girls eligible to receive the vaccine do so.

This initiative of the GCI will not only assess the impact of the team's past discoveries on HPV vaccination on cervical cancer incidence and outcomes but will also strive to increase advocacy, education and awareness and innovate new tools to overcome any barriers that currently exist. Through education and better access, the goal is to improve the coverage of the vaccine to 90%.

II. Screening

The factors of access, financial resources, geographic obstacles, or culturally safe care inhibit women from going to be screened for cervical cancer. Creating innovative and cost-effective tools to reduce the access challenges is one of the key priorities identified by the GCI. The research team, working with colleagues across the country is looking to study how to implement the process of self-collection in BC and the rest of Canada. This will also help improve the availability of gynecological healthcare of rural, Indigenous and immigrant populations.

Cervical cancer screening currently lacks the ability to fully define a woman’s risk for the presence of the HPV progression to cervical cancer. By evaluating the bacterial and viral populations that live in the vagina we will be able to group women into high and low risk of developing cervical cancer. The research team is poised to use and advance our knowledge of the normal bacteria that naturally live in the vagina (the vaginal microbiome) to tailor diagnosis, treatment, and knowledge sharing in women's reproductive health. As a result of the HPV FOCAL clinical trial, BC researchers have stored samples collected and individualized patient outcomes for ~6-10 years after diagnosis, which presents an unprecedented opportunity to determine associations between microbial populations, the cervicovaginal proteome and progression to cancer. This will reduce the number of inappropriate and stressful investigations and will set the stage for personalized screening and diagnostic approaches, moving us further towards the goal of elimination of cervical cancer.

In advancing these initiatives the GCI is inviting new expertise, approaches, and infrastructure to forge a leading-edge, cross disciplinary team. The overall goal is to use precision medicine approaches to tailor screening diagnostics, treatment, and knowledge translation for women's gynecologic health. Positive outcomes are expected by creating and fostering expertise, synergies, data-sharing, and knowledge translation not only in BC but worldwide.

Clinical Trials

Success Measurement

- Increasing the number of clinical trial participants across the province
- Increasing the percentage of total patients participating in a clinical trial
- Advancing the changes in clinical policy and practice that the clinical trials initiate
- Measure the accurate parameter of outcomes
- Measure the economic impact of ripple effect of the change in outcomes (provincial, national, international)
- Improvement of baseline reporting from the initiation of GCI Clinical Trials Group over the next 5 years

Clinical Trials

Strategic Initiative

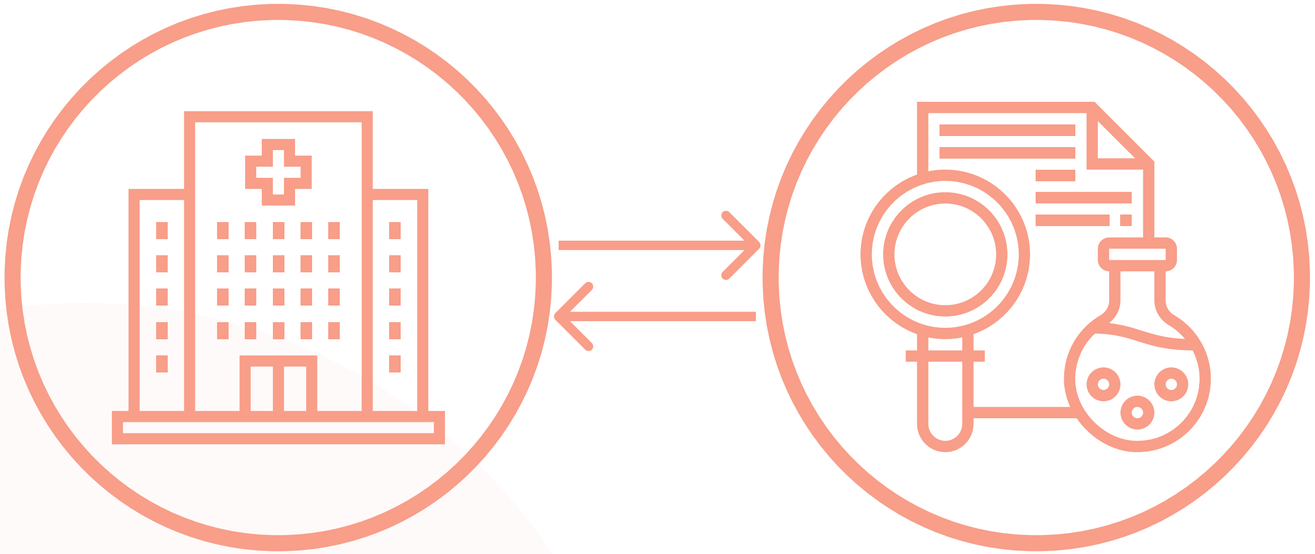
Clinical trials are essential for the study of new methods of cancer prevention, detection and diagnosis, and treatment. While cancer drug trials are often most publicized, clinical trials have few limits in their scope and can be used to assess many different types of interventions, for example:

- The impact of different surgical practices
- The role of physical therapy
- The role of cognitive therapy
- The impact of supportive services (counselling, nurse specialists)
- Strategies to improve treatment tolerance and reduce side effects
- The impact of new predictive and prognostic factors on patient outcomes
- The value of new biomarkers in patient treatment
- The impact of changes in practices and processes in treating gynecologic cancers

The planning and conduct of contemporary clinical trials must include patients as partners and not just as subjects. It is expected that patients will now participate in the design, conduct and evaluation of successful clinical trials. This past year, the GCI established a Gynecologic Cancer Patient & Family Advisory Council to ensure that the patient voice is a part of all studies.

Clinical trials engaging women affected by or at risk for gynecologic cancer in BC are done across multiple sites including the largest at BC Cancer and at BC Women’s Hospital + Health Centre, the Vancouver General Hospital and in cooperation with the UBC Faculty of Medicine.

There is also the need to develop capacity to conduct trials in the regional centres across the Province including Abbotsford, Kelowna, Prince George, Surrey, Vancouver and Victoria.
A strong clinical trials program is fundamental in cancer research and care. Clinical trials are the essential final step for testing important scientific advances and for improving the standard of care for patients.



Clinical Trials in the regional centres across the Province

Research Centres

- Robert H.N. Ho Research Centre, Vancouver
- BC Cancer Research Centre, Vancouver
- Deeley Research Centre, Victoria

Hospital and Lab Partners

- Vancouver
- Victoria
- Surrey
- Abbotsford
- Prince George
- Kelowna
- VGH/UBC Hospital
- Life Labs
- Valley Medical Laboratories
- Diamond Health Care Centre

Research Priorities

I. Strengthening the Environment for Clinical Trials in BC

II. Personalized Care and Treatment

III. Establishing a Rare Gynecological Cancers Program

The GCI Clinical Trials Group will serve as a hub from which innovative new ideas and studies will be carried out throughout BC by clinicians and researchers in the laboratory and in partnership with the patients. To ensure equitable access to clinical studies and to promote collaboration across the province, the trials and studies may be pan-provincial, across multiple health authorities and institutions, diverse in the populations to be studied and ethical in their execution. Given the substantial strength in molecular biology and translational research in gynecologic cancers amongst our group, priority will be given to trials that leverage this basic understanding to improve patient outcomes, including:

- Translational studies with strong emphasis on personalized patient care
- Drug development and testing of novel therapies
- Screening and prevention trials
- Survivorship studies
- Assessment of imaging modalities
- Assessment of radiation therapy techniques
- Patient oriented research surveys
- Patient reported outcome measures

I. Strengthening the Environment for Clinical Trials in BC

To advance the key priority of clinical research, the GCI sees the recruitment of additional talent to spearhead new gynecologic cancer trials as the next crucial step that must be taken to build a comprehensive gynecological cancer research program and achieve global impact to improve outcomes for women with gynecologic cancers. The additional people resources will further develop a coordinated, fully collaborative clinical research agenda and create new opportunities in collaboration with the clinical and research team.

Technology driven research will play a key role in the GCI's success. There is an urgent need for a mass spectrometer and the operating costs and talent to sustain it. The current shared use of this precision equipment for clinical trials requires a lead time of over a year, which is precious time to a newly-diagnosed patient. The dedicated equipment will increase capacity and will enable its use as an adjunct for enrolling gynecologic cancer patients in clinical trials. Once proven in clinical testing, this approach can then be tested prospectively as a decision tool to guide patient care.

Clinical trials are an expensive process as they require protocol development and review, Health Canada approval, contracting between organizations, access to Medidata Rave (an FDA compliant, state-of-the art, web-based electronic data capture system), trial coordination, auditing and data input and reporting (e.g. toxicity), data safety monitoring (e.g. severe adverse events), centralized biobanking, expert pathology review, diagnostic assays and imaging, and any additional tests (e.g. cardiac scan) and biopsies for patients enrolled in the gynecologic clinical trials. For this reason, it is important that the GCI works closely with the resources through Clinical Trials BC in order to optimize our environment for high quality trials (https://www.clinicaltrialsbc.ca/).

BC has a history of successful clinical trials in gynecologic cancers. This advanced program schedule for future trials will only solidify BC's position as a centre of excellence in gynecologic cancer research worldwide.

II. Personalized Care and Treatment

Treatment of gynecologic cancers is still largely generic without consideration of specific molecular features that contribute to disease progression and treatment response. The co-development of biomarkers and treatment research will be fostered through the GCI to ensure that the development and validation of predictive markers are carried through to the clinical setting by enabling access to clinical trials. We believe that translation of precision therapeutics requires tight integration between biomarker development and classification and clinical trials. This is a critical moment for the research team in BC as their genomic research requires further study in patients to see if the important findings can influence treatment selection and patient outcomes.

III. Establishing a Rare Gynecological Cancers Program

As 40% of women's reproductive cancer types are rare (i.e. incidence of <15/100,000/year, as defined by the National Cancer Institute), one of the strategic priorities will be to develop pan-Canadian Rare Reproductive Cancers Program. This Program will support Canadian research in rare reproductive cancers to expedite translation. With leading Genomics Centre expertise located in Vancouver, Toronto and Montreal, the GCI will facilitate genomic profiling for women enrolled in this program, allowing molecular features to be considered in selection of treatments. The pan-Canadian reach of this program will maximize enrollment into rare cancer trials, an important consideration as no single centre has enough cases.

Molecular features and diagnostic information will be used to connect patients to existing clinical trials being conducted across BC and Canada and development of new trial opportunities, including basket trials to group multiple tumour types with similar molecular features to compensate for the small numbers of women affected by these cancers.

Ovarian Cancer

Success Measurement

- Decrease in the incidence of ovarian cancer in British Columbia as a result of prevention strategies put in place by the team
- Development of new prevention strategies for ovarian cancer
- Identification of biomarkers which predict risk of ovarian cancer
- Increase in number of biomarkers for diagnosis of ovarian cancer
- Identification of novel therapeutic targets for testing
- Development of new in vitro and in vivo models of ovarian cancer
- Increase in number of ovarian cancer clinical trials in BC

Ovarian Cancer

Strategic Initiative

Ovarian cancer, of all gynecologic cancers, claims more lives largely because there is no screening test and over 70% of women are diagnosed at advanced stages.

Ovarian Cancer research presents an opportunity to change the metrics on the outcomes of this disease. Investment in ovarian cancer research lags well behind that of other cancers, many of whichhave a much lower 5-year mortality rate 2. As an example,breast cancer has a 5-year mortality rate of 12%, prostate cancer's 5-year mortality rate is 7%, while ovarian cancer is at 55%

In the year 2000 OVCARE was established as a research partnership between Vancouver General Hospital and BC Cancer5. The goal was to advance basic and clinical research that could immediately be translated to the front lines on the prevention, diagnosis and treatment of ovarian cancer. Today, this diverse, dynamic team, with a shared vision, is recognized as in the top 3 ovarian cancer research groups globally, measured in terms of research and clinical impact.

Each year, an estimated

3000

Canadian women are diagnosed with ovarian cancer

1900

will die from the effects of this disease

British Columbia’s Pioneering Track Record

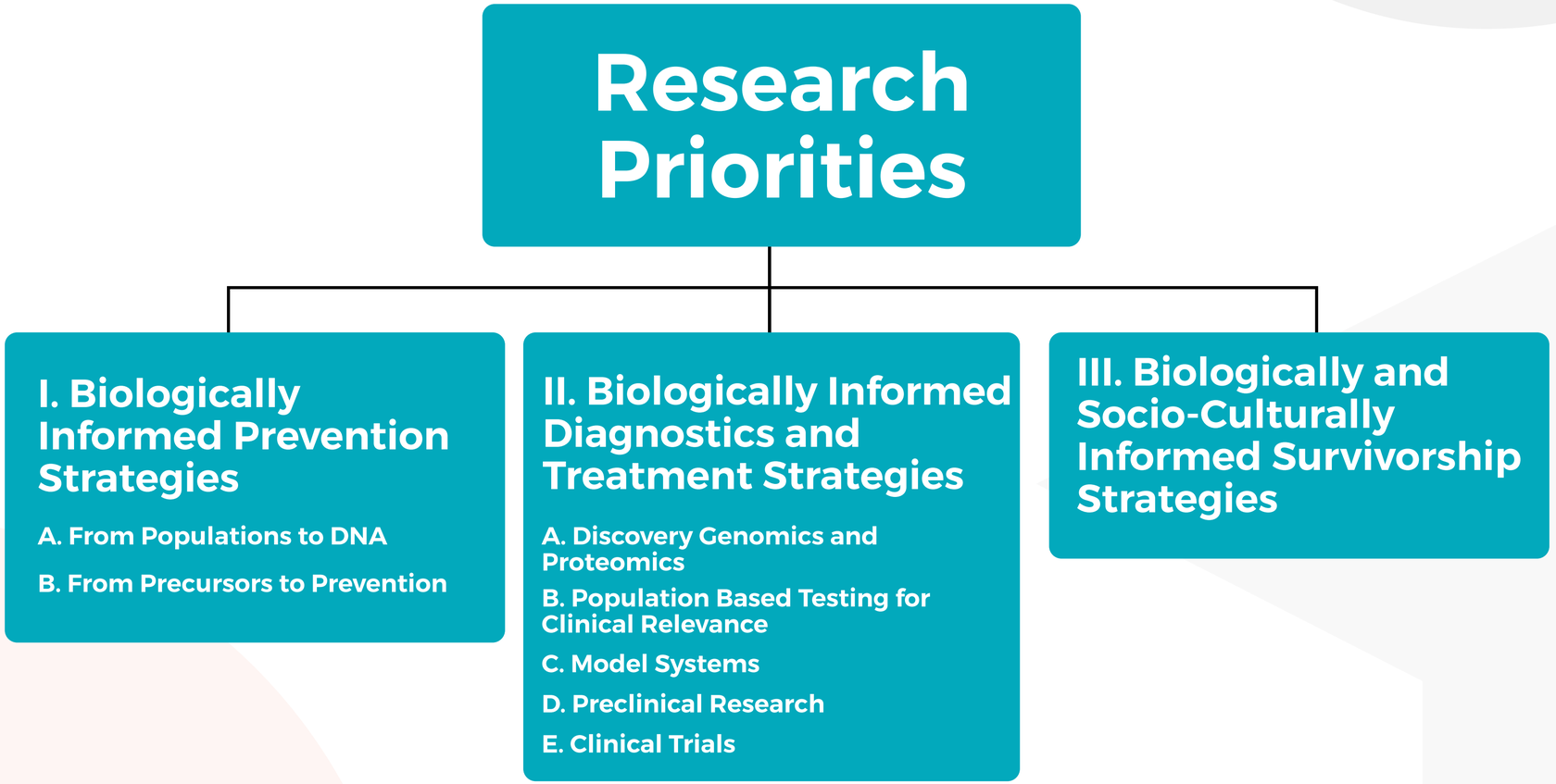
The output from this group has changed worldwide healthcare guidelines and practice impacting the care and treatment of women with ovarian cancer.

- OVCARE proved that ovarian cancer is not a single disease, but multiple distinct disease types and then developed and promulgated today’s subtype specific care and research strategy.
- The OVCARE team identified the key mutations in several types of ovarian and gynecologic cancers which have led to improved diagnostics and international efforts to develop new treatments.
- BC became the first jurisdiction in the world to launch an educational and prevention strategy promoting the removal of fallopian tubes at the time of a hysterectomy or tubal ligation with the goal of reducing the incidence of ovarian cancer in the province of BC by up to 40%.

These are just a few examples of the successes and there are currently studies in clinical trials that will continue to influence the prevention, diagnosis and treatment protocols to save lives of women at risk of or diagnosed with ovarian cancer.

British Columbia also has another unique resource, that of the OVCARE Tissue Bank which is housed within the Vancouver General Hospital Department of Pathology and BC Cancer. This bank contains 56,000 tumour samples from over 6,100 patients5. The tissue samples in the bank are collected from consenting patients following surgical excision and stored in a variety of forms, enabling the extraction of genetic material for analysis. These tissues are used for cell culture, DNA sequencing, RNA sequencing, proteomics, patient derived xenografts (tissue graft) and imaging4. In addition to providing research material for OVCARE researchers, the OVCARE Tumour Bank is shared with national and international research collaborators and has already contributed to over 60 national and international research projects. Over the past two years, OVCARE has invested in reshaping this core research platform by integrating the tissue bank dataset with that of the clinical outcomes unit and linking them to all available research datasets (e.g. molecular, imaging, and pathology). This has created a comprehensive and valuable resource for gynecologic cancer research and leverages the significant wealth of data we have captured over the years fueling future research opportunities.

OVCARE continues to advance ovarian cancer research currently with the advanced technology of artificial intelligence, precision medicine, biologically driven therapeutics, and drug and immunotherapies.



OVCARE'S research includes world leading efforts to develop and test biologically informed prevention strategies and novel diagnostic and treatment approaches. We are building capacity in and developing a program that will address the biologic, social and cultural needs of survivors and their families. All research undertaken by OVCARE is shaped by knowledge gaps, patient need and the unique competitive advantages our provincially funded health care system and single medical school provide.

I. Biologically Informed Prevention Strategies

A. From Populations to DNA

Using BC as a living laboratory, we are determining how prevention strategies developed by our team (e.g. opportunistic salpingectomy – removal of the fallopian tube at the time of hysterectomy or in lieu of tubal ligation for permanent contraception) or known factors that influence risk (e.g. oral contraceptive pills) work to improve the impact of these opportunities to prevent cancer. This is achieved through our unique capacity to connect BC health care administrative datasets with our molecular pathology and genomic expertise. Through these studies we will determine the impact of opportunistic salpingectomy on the incidence of ovarian cancer in BC and other provinces in Canada. As an added benefit, we will also learn more about the cancers that are not prevented by this program. Further study will help determine the impact of the exposure to common medicines such as oral contraceptive pills or ACE inhibitors (commonly prescribed to treat high blood pressure) impact the development of ovarian cancers and shape their behavior.

B. From Precursors to Prevention

Through the direct genomic analysis of precursor lesions (cells that give rise to cancer) for ovarian and uterine cancers we are understanding how endometriosis sometimes transforms into ovarian cancers. Endometriosis, a common condition affecting 10% of reproductive aged women, occurs when epithelial cells in the lining of the uterus grow outside of the uterus such as on the ovaries. While endometriosis is considered a benign condition, some women with a history of endometriosis are at an increased risk of developing clear cell and endometrioid ovarian cancers, the 2nd and 3rd most common types of ovarian cancer. Our studies will shed light on potential markers that may predict a woman's risk of developing endometriosis-associated ovarian cancers and map out the relationship between ovarian cancers and cancers that occur in the uterus.

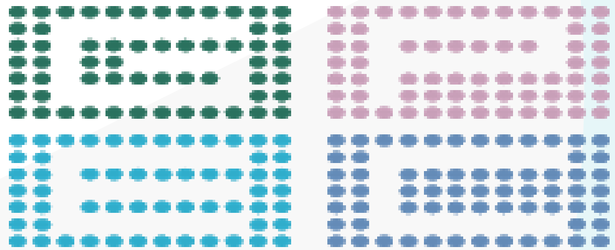
II. Biologically Informed Diagnostics and Treatment Strategies

A. Discovery Genomics and Proteomics

Our team is continuing to lead efforts to determine the molecular features of several poorly understood ovarian cancers. Through a collaboration with Memorial Sloan Kettering Cancer Centre, we are mapping out how the most common ovarian cancer – high grade serous ovarian cancer – is shaped by the immune system to improve immunotherapeutic approaches. For these studies, we are using state-of-the-art single cell sequencing and proteomic approaches. Our research team has also recently completed the largest study on the proteome of clear cell ovarian cancer, the features discovered will be tested as diagnostics and developed as therapeutic targets.

B. Population Based Testing for Clinical Relevance

Once a potential diagnostic feature is discovered through our genomic or proteomic research, we will validate these results using large collections of ovarian cancer cases that we have built as a research resource through our leadership of national (TFRI COEUR) and international (OTTA; Ovarian Tumor Tissue Analysis) consortia. These resources enable us to produce definitive studies on biomarkers to determine their clinical value as prognosticators or diagnostics. This work will take place in our recently rebuilt molecular pathology research centre (GPEC; Genetic Pathology Evaluation Centre) at the VGH.



Genetic Pathology Evaluation Centre

C. Model Systems

Having made the discovery of key mutations in several types of gynecologic cancer and used this information to improve diagnostics, our next major task is to determine how these discoveries can improve treatment. Through our tissue bank, we have established cell line models of different ovarian cancer histotypes (tissue types that arise during the growth of a tumour) which can be used for the study of subtype specific treatment approaches for ovarian cancer. OVCARE is also leading the development of mouse models for rare ovarian cancers which will be shared with the global community for drug development research. For common ovarian and uterine cancers, we have developed a novel approach to study the cancers “from the ground up” using organoids (normal cells from uterus, fallopian tube and ovary grown in a specific fashion to approximate the tissue these cancers arise from). This research will enable us to tease out how the specific cells of origins for these cancers along with the mutations that drive them and the tissue environment in which the cancers occur shape the development of the cancers and their response to known and novel treatments. This model system will also be used to better understand the key steps in the development of ovarian and uterine cancers and then to develop and test prevention strategies.

D. Preclinical Research

Using the research models developed as described in section II.C, we will test the response rates of cancer types to novel or repurposed drugs. This work will be performed in vitro (cell lines and organoids) and when leads are promising in vivo (mouse models).

E. Clinical Trials

Ultimately, treatment approaches need to be tested in rigorous clinical studies before they can be implemented as standard of care in the clinic. OVCARE is working to bolster its clinical trials capacity through strategic recruitment, investment in clinical trials infrastructure and pilot project funding. This effort is being developed in concert with the $10M federal funding committed for clinical trials in ovarian cancer nationally.

Survivorship

Success Measurement

- Results of a self-guided versus navigated Mindfulness App for reducing stress, improving sexual health and quality of living within stratified cohorts
- A tool to identify those at greatest risk of psychosocial distress
- Determining predictors of who will most likely benefit from a mindfulness intervention
- Determining the most cost effective strategy of introducing a Mindfulness program to all Canadian cancer centers
- Establishment of an innovative sexual health team to design and test programs for all pelvic cancers, to support evidence-based clinical care for all groups, and facilitate Canada-wide implementation through its pooling and creation of resources and mentorship
- Development and evaluation of a clinical care model with anticipated sub-group strategies for sexual functioning, alleviate distress, improved quality of life and relationship satisfaction for national uptake
- Reduction in the number of patients suffering from post-diagnosis depression, anxiety and body image disturbance

Survivorship

Strategic Initiative

With continued advances in strategies to detect cancer early and treat it effectively the number of individuals living years beyond a cancer diagnosis is expected to continue to rise. In recent years, there has been a shift in how cancer survivorship is defined. The GCI, consistent with the Canadian Cancer Society, broadly defines survivorship as strategies to improve care and support from the time a woman receives her gynecologic cancer diagnosis until the time of her death or entry into end-of-life care.

Canadian Cancer Society

The new and evolving paradigm of cancer survivorship research is one that comprehensively explores women's survivorship experiences. Hence, our research priorities will be guided by the following principles:

- seeks to identify, examine, prevent and diminish the adverse sequelae after a cancer diagnosis and treatment;
- manages, treats and prevents comorbidities;
- incorporates health promotion and lifestyle interventions to optimize health after cancer treatment;
- defines and incorporates optimal follow-up care and surveillance for all survivors;
- pays special attention to disparities in survivorship outcomes by age, income, ethnicity, geography, cancer site and sexual orientation; and
- incorporates the partner/family/support network within its rubric.

This paradigm looks beyond treatment, representing a shift away from a medical deficit-dysfunction toward a multi-disciplinary and biopsychosocial approach which stresses the importance of understanding women's experiences and listening to their voices to make more informed decisions

Cancer survivorship involves not only the cancer patient; caregivers and family are considered secondary survivors. Three phases of survival have been identified and these phases of survival are important vis-à-vis; an optimal transition into and management of survivorship. They are:

- Acute - extending from diagnosis to the completion of initial treatment, encompassing issues dominated by treatment and its side effects
- Extended - beginning with the completion of initial treatment for the primary disease, remission of disease, or both; dominated by watchful waiting, regular follow-up examinations and, perhaps, intermittent therapy
- Permanent survival - evolves from extended disease-free survival when the likelihood of recurrence is sufficiently low.

A large and growing community of cancer survivors is one of the major achievements of cancer research over the past three decades, and in part has been catalyzed by active involvement of survivor groups working alongside researchers. Both length and quality of survival are important end points. Many cancer survivors are at risk for and develop physiologic and psychosocial late and long-term effects of cancer treatment that may lead to a reduced quality of life or premature mortality. Unfortunately, to-date, there has been very little research on the issues they face and there is a dire need for strategies to help cancer survivors deal with the challenges. Interventions, both therapeutic and lifestyle changes, carry the potential to treat or ameliorate these effects and must be developed, examined and disseminated if we are to improve outcomes for cancer survivors.

Research Priorities

- I. Develop a Holistic Understanding of the Survivorship Needs of Gynecologic Cancer Patients
- II. Address the Psychosocial Needs of Gynecologic Cancer Survivors
- III. Biopsychosocial Sexual Rehabilitation

I. Biologically Informed Prevention Strategies

This research priority uses a patient-centric approach to explore the short- and long-term sequelae of women following their gynecologic cancer diagnosis and treatment. To ensure that the needs of all Canadian women are met, focus groups in multiple languages (e.g. English, French, Mandarin, Punjabi) will be conducted. The knowledge learned from focus groups will be synthesized and validated quantitatively through patient surveys. Participants will be invited for in-depth interviews to flesh out emerging trends from the quantitative survey.

The goal of this research is to gain a holistic understanding of the biologic, social and cultural survivorship needs of women.

We will also explore how gender characteristics, which can impact the hormonal milieu, influences the survivorship experience. The impact of sociocultural aspects of gender on survivorship are largely unexplored, as have the gynecologic cancer experiences of gender diverse individuals and together these both represent important areas of investigation.

II. Address the Psychosocial Needs of Gynecologic Cancer Survivors

Gynecologic (uterine, ovarian, cervical, vulvar, vaginal) cancer survivors identify distress as a major component of their cancer burden6. Stress, anxiety, mood/depressive symptoms, fatigue, fear of recurrence, and sexual difficulties (sexual dysfunction, low sexual desire and sexual distress) also contribute to their overall poor health. Those who are young, those who live in rural/geographically remote areas or those that have few socioeconomic supports are much less likely to have their distress symptoms addressed. We will embark on two complementary approaches to study how we may prevent or diminish psychosocial distress in gynecologic cancer survivors:

First Approach - Digital App-based support

We will develop Digital App-based support that has the potential to overcome barriers found with in-person program participation. The training programs and education in mindfulness and sexual health concerns delivered through the Digital App is one way of using technology to reach a larger audience by availing patients and families access to information they might not otherwise seek. Another use of technology is to assign a personalized cancer journey navigator as the diagnosed patient is going through her journey, including post treatment support.

Second Approach - A standardized model for follow up care clinics

Our second approach is the development of a standardized model for follow up care clinics. Currently the effectiveness of follow-up care clinics in preventing or ameliorating long-term effects of cancer and its treatment is inconsistent. This project will develop a standardized model of service delivery for cancer related follow-up care for application to be uniform across cancer centers and community oncology practices. The research team will assess the quality, content and optimal frequency of follow-up care for cancer survivors. This will be done in the community setting by oncologists or by primary care providers which will inform changes in practice to improve the burden of cancer.

III. Biopsychosocial Sexual Rehabilitation

Gynecologic cancers and their treatments result in significant and persistent sexual problems and distress among survivors and their partners.5 Given a lack of health care provider training, perceived embarrassment, the relative increased emphasis on survival, and limited access to care, sexual concerns are often left unaddressed in cancer clinics.

Sexual dysfunction, defined as a chronic and distressing disturbance in sexual response, affects an astonishing 75% of pelvic cancer survivors. It is reported by survivors to be the single most distressing post-cancer condition affecting their health-related quality of life. Sexual dysfunction manifests uniquely within each population, but consistently involves biologic, psychological and social elements. Ongoing and untreated sexual dysfunction is directly related to other chronic psychosocial entities such as depression, anxiety, body image disturbance, and poorer self-rated health.

There are also significant gaps in health care provider training. To address these concerns the GCI aims to close this critical gap in knowledge through firstly, identifying the sexual health requirements linked to gynecologic malignancies and secondly, developing personalized sexual rehabilitation programs of care inclusive of partners and sensitive to minorities and marginalized groups (e.g. rural, Indigenous, immigrants, LGBTQ+). The GCI will study how these programs improve sexual function and aim to increase accessibility in order to meet the needs of all cancer survivors.

In order to help facilitate access to care, this project will perform a needs assessment among survivors, their partners, and health care providers to determine barriers and enablers to sexual health care. Prior to testing the programs, the research team will establish resources and modes of care to address our current system's deficits. Strategies such as e-health, digital health technologies, and other online resources will be utilized to ensure access to care is optimized, with particular attention to minorities and rural populations.

While the team will incorporate research-based approaches to data collection and scoping reviews in the early phases of this work, their overall approach will be one of implementation science, so that findings can better inform implementation in clinical settings and promote Canada-wide uptake. Efficient referral and triaging processes will be established to ensure that patients and their partners are captured appropriately during their cancer journey, from their respective cancer clinics.

The GCI's goal is to create the scaffold and infrastructure to facilitate wide-spread adoption of our program among all cancer centers across Canada and enable other leaders in sexual health to efficiently implement our developed sexual rehabilitation programs for all pelvic cancer survivors. The research will be undertaken by cross disciplinary experts from various cancer populations to facilitate the implementation of successful and sustainable programs through Canada-wide mentorship and creation of a standardized toolkit for health care providers.

This research project will develop an infrastructure for future innovation and further research to establish a Canada-wide sexual health survivorship working group inclusive to patients and partners, who will be favorably positioned to advance the field of sexual rehabilitation in cancer survivorship.

IV. Addressing Reproductive Health in Gynecologic Cancer Survivors

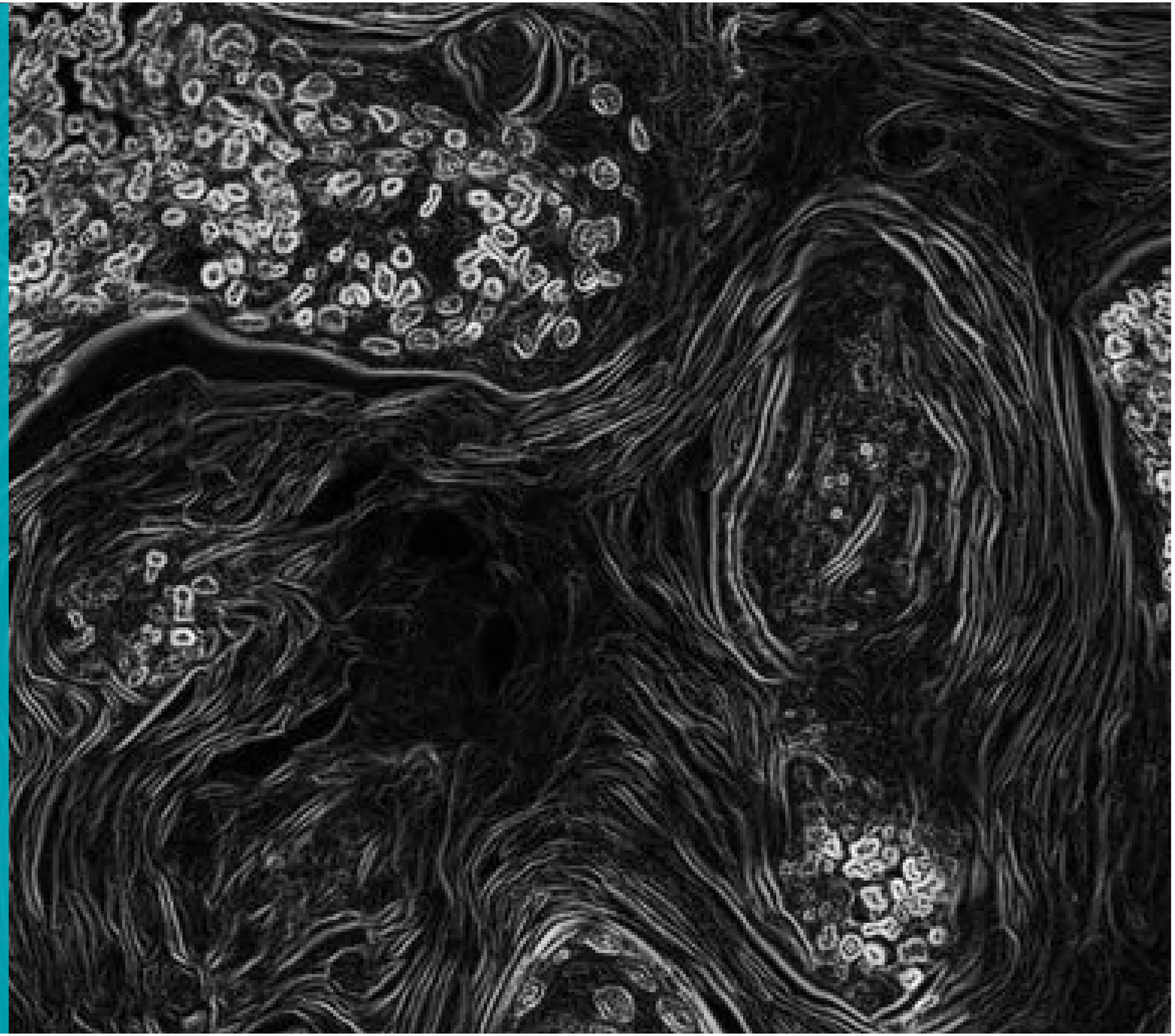
All gynecologic cancers and the subsequent treatments can impact the reproductive health of women, especially those in pre-menopause. The long-term fertility and menopause related side effects post detection and treatment including surgeries, could have both physical and psychosocial implications. This raises important questions regarding patient information needs and treatment decision making.9 Input from cancer patients will be sought on the prospect of infertility, methods of fertility preservation, anatomical changes, induced menopause and sexual disfunction and rehabilitation.

Currently data on cancer survivorship issues is sadly lacking. These studies will help to more clearly define these issues with evidence based consultation, and examine medical psychosocial outcomes of cancer diagnosis and treatment by survivors by filling in the gaps in knowledge and the use of emerging technologies.

Translational Digital Pathology

Success Measurement

- Development of an automated differential diagnostic tool for the major ovarian cancer histotypes that will reduce inter-observer variability in the diagnosis of ovarian cancer histotypes (Pillar 1)
- Identification of molecular subclasses of ovarian cancer through artificial intelligence applied to pathology images (Pillar 2)
- Development of an algorithm which can identify the four prognostic subgroups of endometrial cancer from pathology slides (Pillar 2)
- Identification of new biomarkers for ovarian and endometrial cancer (Pillar 3)

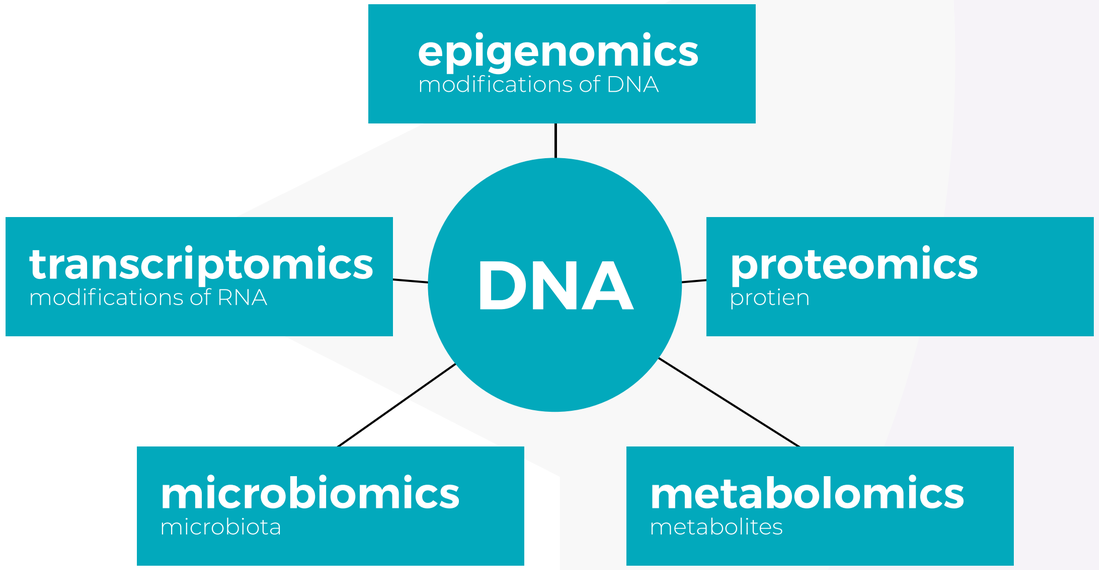


Transitional Digital Pathology

Strategic Initiative

Over the past decade, there has been an explosion of technological capabilities which has revolutionized medical research. In the past, scientists studied one “molecule” at a time providing little knowledge on how these molecules interact with one another and hence little insight on the biological pathways or processes that are disrupted in the development of disease.

Today, researchers are able to undertake a more ‘holistic’ view. Recent advances in innovative omics technologies allow for the comprehensive or global profiling of a set of molecules. Genomics was the first omics discipline; unlike ‘genetics’ where studies involve individual variants or single genes, genomics focuses on the entire genome (DNA). With more cost-efficient and high-throughput technologies now available, omics-based research has become routine. Integration of multiple types of omics data, known as multi-omics, lends the opportunity to elucidate disease mechanism and causality, or identification of potential therapeutic targets.



Expansion of the study from Genomics

In spite of the wealth of omics data available in studies of cancers, the translation of these research findings have been painstakingly slow. An example is the genome-wide studies of cancers; through this work, we know that cancers of the same cell type, origin, and stage have unique molecular features that could impact course of disease and response to treatment. Although these specific molecular features offer great promise for the development of personalized cancer care, the current management of cancers i.e. diagnosis still largely relies upon a patient's tumour cell type assessed through examining the pathology tissue slides under the microscope and the stage of the cancer, without further refinement. Even when distinct diagnostic modalities are used to aid in management, they are done as disconnected parallel activities and without the synergy obtainable through leveraging the vast data available.

Recent advances in artificial intelligence (AI) techniques have shown impressive performances in many challenging applications. In pathology, AI techniques have allowed computers to interpret pathology slide images and infer information from the tumor tissue that is not discernable to the human eye. One study has even been able to correlate histopathology imaging features (currently not appreciated by traditional microscopy) with genetic mutation status in lung adenocarcinomas. As such, these recent advances, fueled by the digitization of the traditional histopathology tissue slides, offers the opportunity to objectively revisit the rich amount of information in pathology slides.

Research Priorities

1. Improvement in Clinical Pathology efficiency through the use of artificial intelligence.

2. Fundamentally change the translational genomics paradigm

3. Generate new insights for precision medicine

This initiative proposes to overcome one of the largest obstacles within the research-to-practice continuum; limited capacity to translate genomic basic science discoveries to the bedside. This obstacle is a direct outcome of shortfalls in clinical resources, translational pathology expertise, facilitating infrastructure, and interdisciplinary informatics expertise.

In BC, we have a unique opportunity to close this gap and build a leading edge centre focused on artificial intelligence (AI) applications in pathology and medicine. The GCI will take advantage of BC's cancer care system (with a single payer system and uniform treatment protocols, together with excellent quality patient outcome data) and leverage the world-class team of clinicians, scientists, and engineers in the province with complementary expertise in pathology, artificial intelligence, genomics, and imaging to accelerate this line of research with the goal of improving the diagnostics and management of women faced with a diagnosis of gynecologic cancer.

This initiative has three pillars of research:

1. Improvement in Clinical Pathology efficiency through the use of artificial intelligence.

The goal is to improve efficiency by pre-screening pathology histological slides prior to review by a pathologist; this will enable triaging of more complex and difficult cases for expert examination and/or additional molecular testing.

2. Fundamentally change the translational genomics paradigm

Artificial intelligence will be utilized to identify features in histological images that can predict genomic subtypes or features. By removing the need to perform genomic tests which may not be readily available in all pathology labs or hospitals, or is costly, this will enable the rapid and accurate stratification of patients into clinically relevant genomic subgroups.

3. Generate new insights for precision medicine

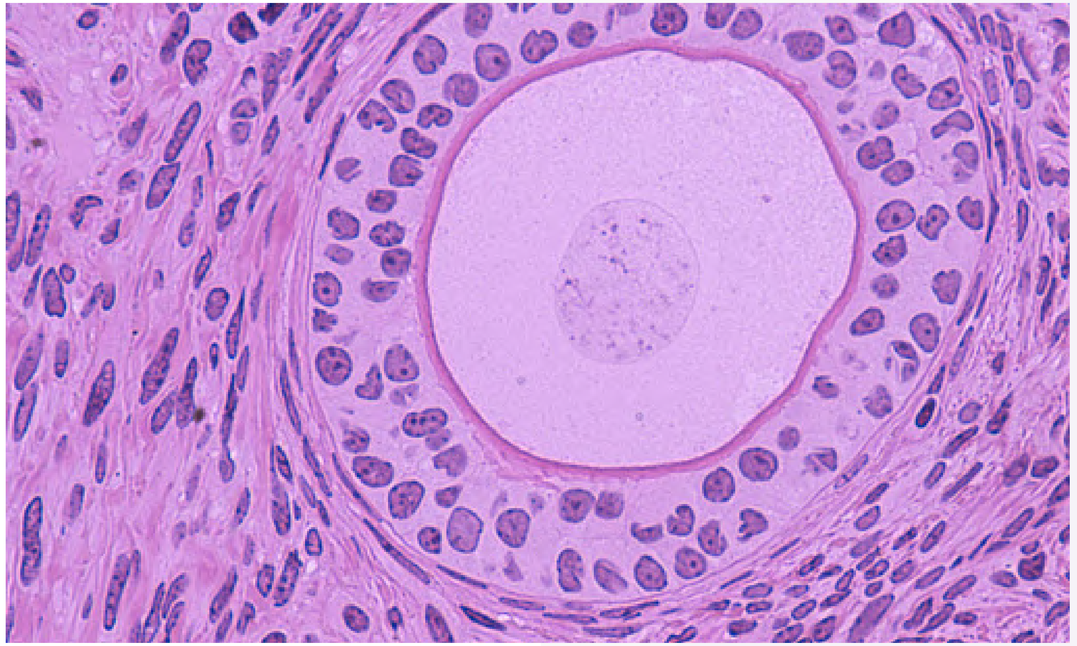
This pillar aims to identify new biomarkers that can improve upon the risk stratification of patients with the goal of improving the current standard of care. We will embrace the unique multi-modal data available which comprises of a combination of genomics, histopathology, and imaging; through a multi-modal approach, there is a greater opportunity to identify novel markers as each data modality provides additional information which is not possible to obtain from individual data sources.

While the current proposal focuses on two gynecologic cancer sites – the ovary and the endometrium, all advanced artificial intelligence techniques developed can be applied to other sites. The key resources we have previously built in these two areas (described below) are critical to the success of this initiative and enables the research proposed.

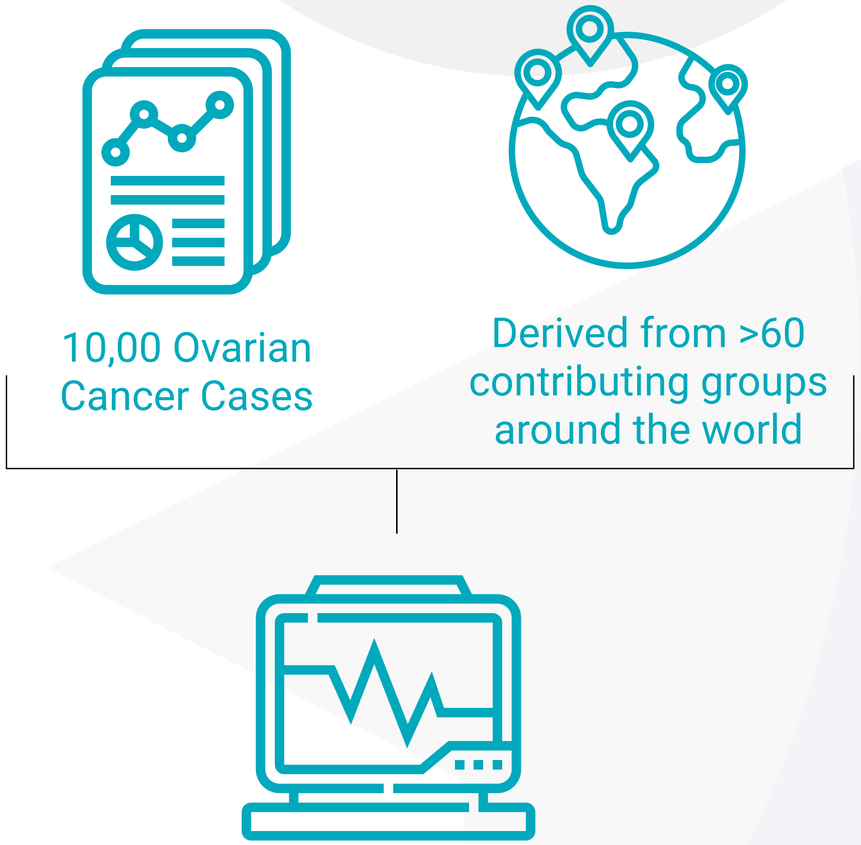
I. Ovarian Cancer

Major ovarian cancer histotypes have distinct cellular morphologies and etiologies, as well as molecular, genetic, and clinical attributes. However, standard clinical management of these histotypes is similar and patient outcomes have not seen any improvements. Recent genomic and molecular sub-classifications of ovarian cancer (including ours published in Nature Genetics3) potentially have important clinical implications, including identification of new therapeutic targets. However, until the discovery of surrogate biomarkers these sub-classifications are based on labor-intensive assays using fresh or snap frozen tumour samples, with long turn-around times, limiting their routine use as treatment must start soon after diagnosis.

Histology has been an important tool in cancer diagnosis and prognostication for more than a century. This phenotypic information reflects the aggregate effect of molecular and genetic alterations on cancer cells and provides a convenient visual readout of disease biology. Histology presents a wealth of information that is not easily accessible through genomics techniques, is inexpensive to acquire, and is the cornerstone for cancer diagnosis and management.



We will leverage our ability to access 10,000 ovarian cancer cases (largest in the world) with histopathology images, clinical outcome and genomic data which are derived from >60 contributing groups around the world. Using this rich resource, we propose to build a platform for characterizing ovarian cancer, based on advanced artificial intelligence techniques, and by combining genetic and histology markers. More specifically, we will build automated differential diagnostic tool for major ovarian cancer subtypes, investigate the relationship between genetic markers, histology and disease outcome, and combine these data for a comprehensive profile of each tumour. New knowledge generated from this project will shed light on the link between histology and genetic markers and identify potential biomarkers that can be rapidly and accurately tested to stratify ovarian cancer for accurate treatment selection.



ENDOMETRIAL CANCER

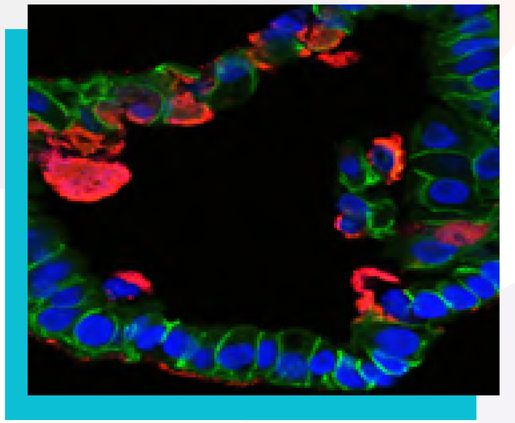
~7,000 Canadian women are diagnosed with Endometrial carcinoma every year.

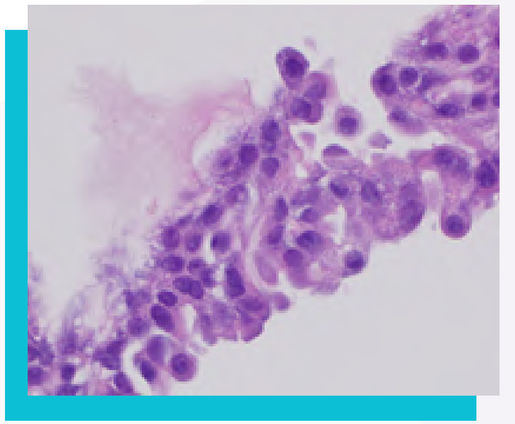
Traditionally histopathology is used to diagnose endometrial cancer; however endometrial cancers are difficult to tell apart under the microscope. Consequently, clinicians struggle to determine ‘the best’ treatment for patients. As a result, many women may be getting unnecessary toxic treatments when surgery alone can cure them and conversely, many women do not receive the aggressive treatments they need that could be tailored to the unique biology of their cancer.

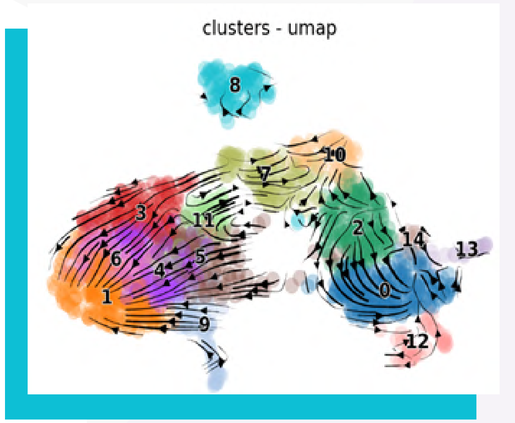
Recent advances in molecular pathology and precision medicine have led to a re-classification of endometrial carcinomas. Now endometrial carcinomas can be genetically profiled and classified into four prognostically distinct groups: ultramutated, hypermutated, copy number low, and copy number high. Unfortunately, this genetic classification is expensive and labour-intensive with long turn-around times. In BC, we have been the first to develop a pragmatic tool (ProMisE) that can reliably distinguish endometrial cancers by molecular features. This tool will soon be tested in a clinical trial setting to determine its utility and ability to change treatment paradigms. This initiative proposes to leverage this extensive dataset with over 2,500 cases assessed according to the molecular classifier with accompanying clinical data.

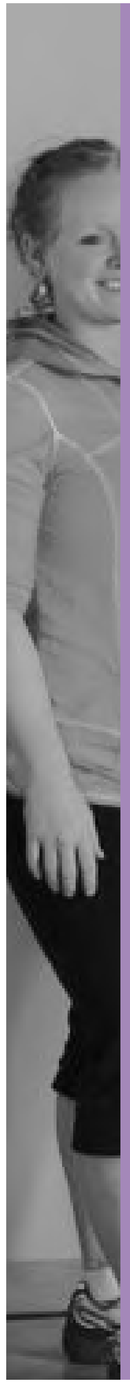
We will apply modern machine learning tools and develop a computer algorithm that is able to predict the four prognostic subgroups (or mutational profile) of endometrial cancer based on histopathology images from the tumour by inferring information from the tumour tissue that is not discernible to the human eye. This algorithm has the potential to be used clinically as a biomarker for prognostic classification5.

As above, the approach we will take will offer the opportunity to identify new biomarkers that is not genomic-based driving discoveries for precision medicine.









Vaginal and Vulvar Cancer

Success Measurement

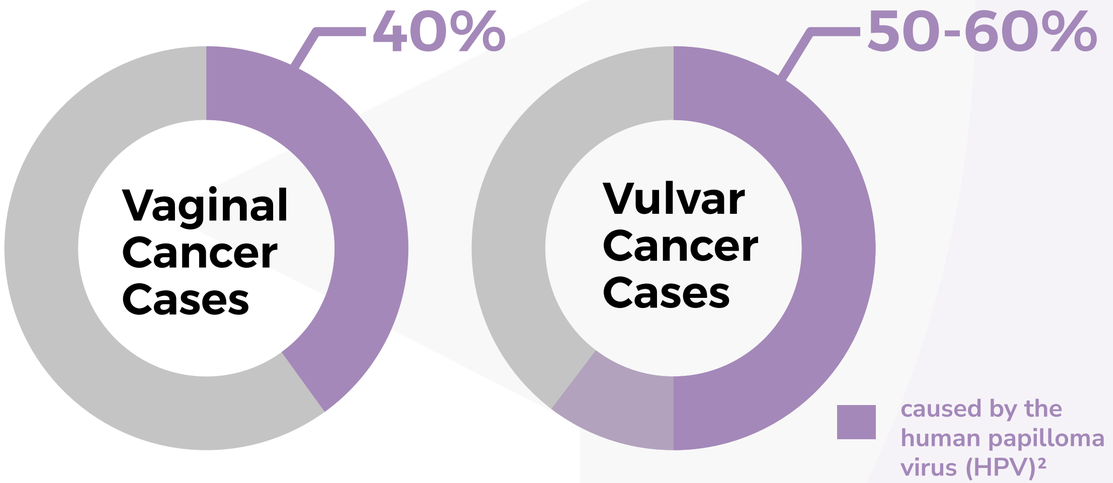
- Increase in the number of vulvar and vaginal cancer molecular research studies
- Increase in the number of vulvar and vaginal cancer survivorship research studies
- Effects of HPV vaccination on primary and secondary prevention
- Increase awareness of vulvar and vaginal cancers
- New biomarkers for the detection of precancerous vulvar lesions
- New biomarkers for the diagnosis of HPV-independent vulvar cancers
- Incorporation of molecular pathology to improved diagnosis and treatments
- Decrease in recurrence rate of HPV-independent vulvar cancers
- Overall improved outcomes for vaginal and vulvar cancers

Vaginal and Vulvar Cancer

Strategic Initiative

Vulvar and vaginal cancers are considered the “forgotten woman’s cancers” and they represent 3-5% of all gynecological cancers. Advances in these two cancer types have lagged behind other cancers, possibly because of the rarity of these diseases. As the main treatment often involves surgery, it can leave a woman feeling as if they have lost their identity as a woman, severely impacting her quality of life.

Vulvar cancer forms on the outer lips of the external genitalia (or vulva). Vaginal cancer originates in the vagina, which is also known as the birth canal, and is approximately four times rarer than vulvar cancer. At both these sites, changes to cells of the vulva or vagina can lead to precancerous conditions. This means that the abnormal cells are not yet cancer, but there is a chance that they may become cancer if they aren’t treated. A cancerous (malignant) tumour is a group of cells that can grow into and destroy nearby tissue.



HPV-related vulvar and vaginal cancer often affect younger women but approximately 70% are over the age of 60. Vulvar cancer shares risk factors with cervical cancer, specifically the number of sexual partners, smoking and being immunocompromised. Non-HPV-associated vulvar cancers mostly affect women with a chronic condition known as vulvar dermatosis. Similarly, with vaginal cancer, in addition to HPV, risk factors include weakened immune system, smoking, if a woman's mother took a medicine called diethylstilbestrol (DES) when she was pregnant between 1940 and 1971 and if radiation therapy had been previously done for cervical, vulva or anal cancer.

Until recently, vulvar cancers were treated as a single disease. New research, done in BC, definitively shows that HPV and non-HPV diseases are distinct conditions as they behave differently and have different treatment needs2,4. Non-HPV lesions are associated with more frequent recurrence and a higher risk of death. The data in BC suggests that aggressive surgery may be more important in HPV-independent lesions; the higher recurrence rate seen in recent years may be secondary to a change in surgical practice where less morbid surgical interventions had been favoured3. In addition, this team has demonstrated that HPV-independent lesions are less sensitive to radiation therapy. These results underpin the importance of disease stratification from the time of first diagnosis so that the correct surgery, adjuvant therapy, and surveillance schedule can be planned; this research provides one step in improving outcomes for women faced with a diagnosis of vulvar cancer.

The GCI recognizes that these two cancers are understudied. There is an opportunity to shift our understanding of vulvar and vaginal cancers by taking what we have learned from other gynecologic cancers and leveraging the technologies and approaches that we have developed to significantly impact outcomes for women with these rare cancer types.

This initiative will build on our preliminary studies of vulvar cancer and leverage the patient cohort we have compiled which is one of the largest cohorts of vulvar cancer patients linked to outcomes and HPV status currently available. Based on our previous work on the molecular stratification of ovarian and endometrial cancer, we propose to use a similar approach to better understand the etiology and pathogenesis of vulvar cancer with the goal of developing management strategies that are biologically-informed.

I. Prevention and Detection

Current screening methods for vulvar cancers include first a thorough clinical examination of the vulva and secondly if concern persists a biopsy is done and the histology (microscopic study) correctly interpreted. In precursor lesions that develop independent of HPV-infection; the histologic features are usually non-descript and they are often misdiagnosed or overlooked. As a result, a patient may be biopsied multiple times, before she is diagnosed as having a precancerous lesion. This is important because the window of opportunity for early surgical intervention and cure is often gone before the precancerous lesion is recognized. As this type of precancerous growth is a biologically aggressive lesion, early intervention is paramount if we are to prevent it from becoming cancerous.

To tackle this problem, we propose to catalogue the molecular features of both HPV-dependent and HPV-independent precancerous vulvar lesions using next generation sequencing technologies, with the hopes of finding a biomarker that could be used to accurately identify the premalignant growths. This would mean that women may be able to have their lesions treated before they turn into vulvar cancer.

The GCI will also play a role in raising awareness and educating both clinicians and women of the risks, preventative measures and symptoms of vulvar and vaginal cancers.

II. Diagnostics and Treatment

While the diagnosis of HPV-related tumours has been perfected over the years and there is little difficulty distinguishing between benign and cancerous forms of the disease, this is unfortunately not the case for HPV-independent cancers which are much more difficult to diagnose4. Also non-HPV related vulvar cancers tend to be more resistant to radiation therapy in comparison to its HPV-related counterparts. Of similar concern is the fact that getting the HPV vaccine will not protect women against non-HPV vulvar or vaginal cancers. With an aging population, the number of cases of non-HPV cancers are likely to climb in coming years.

All these factors combined, there is a clear need to develop better ancillary tests for early detection and diagnosis and more personalized treatment approaches for specific vulvar cancer types based on their unique molecular alterations. Molecular methods now allow scientists and clinicians to go beyond looking at tissue samples under a microscope. This lets patients benefit from heightened vigilance and closer follow-up, to prevent a missed diagnosis or recurrence of the disease. Our research is charting a course for improved diagnostics and treatments. This research could help shape clinical and diagnostic practices, as well as the transfer of knowledge at educational institutions and through medical textbooks. We are still in the discovery phase of this condition, and are working on coming up with uniform terminology and criteria in order to help clinicians and pathologists make more precise diagnoses

Now is the time to develop guidelines for timing, method and aggressiveness of treatment according to clinical and molecular features of vulvar cancer with the goal of decreasing morbidity7. Through international collaboration we are working towards the development of clinical trials that would stratify vulvar carcinomas and precancers by HPV status from first diagnoses; directing surgical interventions, adjuvant therapy and follow-up.

III. Survivorship

The survivor's psychosocial outcomes of diagnosis and treatments of vaginal and vulva cancers can affect their quality of life and may require relationship adjustments8. Nearly 90% of survivors reported supportive care needs and if diagnosed with anxiety or PTSD, results in a four-fold increase in unmet needs. Vaginal and vulvar cancer and its treatments can result in body changes such as scars, skin changes, change in shape and appearance of the vagina and vulva, changes to body functions, and sexual problems.

Comprehensive and extended supportive care services are required to address anxiety and trauma responses and investigate strategies to meet ongoing needs in order to improve long-term psychosocial outcomes8.

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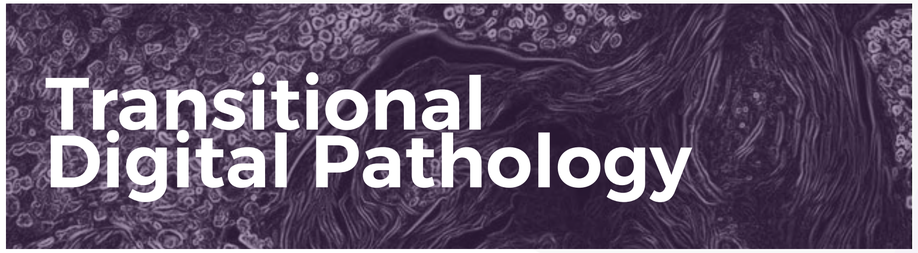

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