2020 REPORT

LUNG CANCER CANADA

FACES OF LUNG CANCER

SCREENING EARLY DETECTION DIAGNOSIS

THE FACES OF LUNG CANCER REPORT

NOVEMBER 2020

Lung Cancer Canada Volunteers - Diana Szwec, Emily Sellan and Christina Amaral

WHO WE ARE

LUNG CANCER IN CANADA

Lung Cancer Canada is a national charitable organization that serves as a leading resource for lung cancer education, patient support, research and advocacy. We are a member of the Global Lung Cancer Coalition, and the only organization in Canada focused exclusively on lung cancer – a disease that continues to be the leading cause of death in this country.

Lung Cancer Canada's mission is three-fold:

1 **Increase public awareness of lung cancer**

2 **Support and advocate for lung cancer patients and their families**

3 **Provide educational resources to patients, family members, health-care professionals, and the general public.**

We also offer a variety of resources to educate and support patients and their families:

Our website, www.lungcancercanada.ca a trustworthy source of lung cancer information and news

Our newsletter *Lung Cancer Connection*, which explores topics of interest to the entire lung cancer community

Our resource library, which allows patients and their families to access specialized information

Our social media presence

@LungCan

@LungCancer_Can

@lungcancercanada

Discussion forums and patient stories on our website, which offer connection and support with others in the community

Each year, we publish the ***Faces of Lung Cancer Report*** – a report that gives a voice to the issues lung cancer patients and their families face today.

Thank you for taking the time to read, learn and advocate for those with this disease.

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Christina Sit, Dr. Stephanie Snow
& Michele Wright

INTRODUCTION

LUNG CANCER IS THE STORY OF PATIENTS AND THEIR FAMILIES

It's the stories of hope that stay with you.

The story of a mother in Victoria who bravely withstands difficult radiation therapy, so she can celebrate another birthday, witness another milestone, instil another memory. The story of the patient in Halifax who was able to avoid whole brain radiation – because her lab results arrived that morning. Or the story of a father in Calabogie, Ont., whose cancer was caught early enough for the lesions to be removed.

Despite recent scientific and clinical innovation, heartwarming stories like these are not as common as they should be.

Lung cancer – which can affect anyone – is again the leading cause of cancer death in Canada in 2020. The unfortunate truth is that for a Canadian facing this disease, it is of great consequence where he or she lives. A postal code often dictates the level of care that one is able to access and receive. Testing and screening procedures – critical to improved patient outcomes – also vary in their availability and in wait times based on geography.

Science and medicine have evolved, but the reality is these advancements have far outpaced the capacity of our health-care systems. More must be done to increase survivorship, beginning with a commitment to screening, early detection and early diagnosis. Each of these integral issues is explored in our *2020 Faces of Lung Cancer Report*.

In this spirit, we carry hope – because stories can be written differently. In September 2020, B.C. became the first province to publicly fund lung cancer screening, paving the way for more provinces to follow suit. There can be more survivorship. Hope can be realized.

Stories of hope are out there. We must make changes to the management of lung cancer in Canada so we can collectively write more of these stories and reduce the burden of this devastating disease.

LUNG CANCER IN CANADA:

KEY ISSUES

- LACK OF SCREENING PROGRAMS
- ACCESS TO TESTING
- EQUAL ACCESS TO CARE

CURRENT STATE OF LUNG CANCER IN CANADA

Lung cancer is the most commonly diagnosed cancer in Canada and is the leading cause of cancer death. At 19 per cent, the five-year net survival for lung cancer is the highest it has ever been, but remains among the lowest of all types of cancer.[1]

Few diseases wage a more devastating impact on Canadian families than lung cancer. In 2020, the Canadian Cancer Society estimates that over 21,200 adults will pass away from this disease – a number greater than the next three leading causes of cancer deaths (colorectal, pancreatic, breast) *combined*.

From coast to coast to coast, there is a new diagnosis of lung cancer every 17 minutes. Tragically, these diagnoses are usually late, resulting in low survivorship – lower in fact than nearly all chronic diseases. This is a particularly poignant point when 86 per cent of lung cancer cases are preventable.[2]

There are 13 provincial and territorial health systems in Canada, and there is little synergy between them in how efficiently lung cancer patients are diagnosed and managed. Disparities continue to be common depending on where a person lives – both between provinces and territories and within them.

In September, the Canadian Cancer Society released a 2020 special report on lung cancer.[3] Key findings include:

Overall, incidence and mortality rates are decreasing among men and women.

- Both rates among males have been declining for over 20 years
- Incidence rates among females began to decline in 2012 and in 2006 for mortality rates
- Among Canadians younger than 55 years of age, these rates are higher in females than males

Excluding Quebec, lung cancer incidence and mortality rates are generally highest in the territories and Atlantic provinces.

About half of all lung cancers are diagnosed at stage 4, which is generally considered incurable and at which point the survival rate is extremely low.

- An added 20 per cent of cases were diagnosed at stage 3
- A greater percentage of males than females were diagnosed at stage 4, while the reverse was true for stage 1 cases
- The highest rate of stage 4 lung cancers was in Nunavut (57 per 100,000), while the lowest was in Ontario (28 per 100,000)

Lung cancer survival is typically higher among females than males, regardless of age or province at diagnosis.

- One-year and five-year net survival rates are higher among females than among males

Three-year net survival for lung cancer decreases depending on stage, from 71 per cent of those diagnosed at stage 1 surviving, compared to only five per cent of those diagnosed at stage 4.

RECENT PROJECTIONS OF CANCER STATISTICS IN CANADA REVEAL[4]:

1 IN 4

PROPORTION OF ALL CANCER DEATHS ARE CAUSED BY LUNG CANCER

29,800

CANADIANS WILL DEVELOP LUNG CANCER IN 2020

LUNG | BREAST
COLORECTAL | PROSTATE

MOST COMMONLY DIAGNOSED TYPES OF CANCER IN CANADA

1 IN 15

CANADIANS WILL DEVELOP LUNG CANCER IN THEIR LIFETIMES

DAILY RATE

NEW LUNG CANCER DIAGNOSES ACROSS CANADA

LUNG CANCER AS A PERCENTAGE

13%

OF ALL NEW CASES OF CANCER.

Across Canada, projected age-standardized incidence and mortality rates for lung and bronchus cancers in 2020 show*:

2020 Lung Cancer Incidence and Mortality Rates by Gender and Canadian Province

	MEN		WOMEN	
PROVINCE	INCIDENCE	MORTALITY	INCIDENCE	MORTALITY
British Columbia	53.2	41.7	52.7	38.5
Alberta	58.9	44	57.4	40.5
Saskatchewan	66.7	52.4	62.8	44.8
Manitoba	69.2	48.9	62.1	46
Ontario	66.4	46.7	59.6	35.6
Quebec**		69.7		54
New Brunswick	85.2	71.8	70.9	46.8
Nova Scotia	84.8	68.6	75.7	54.4
P.E.I.	89.1	70	66.1	45.9
Newfoundland	77.1	75.2	61.7	44.2

**Estimate rates are per 100,000 people. All estimates are from Canadian Cancer Statistics 2019. Quebec estimates for incidence are not included because a different projection method was used for Quebec than the other provinces, meaning the estimates are not comparable.*

The data show the promise of change is already underway. Nevertheless, there is so much we can do – and must do – to support the rising number of Canadian families impacted by this devastating disease.

There are two key challenges facing lung cancer patients today. First, we must detect a patient's cancer at an earlier stage while curative treatment is still an option. Second, for patients diagnosed with advanced stage cancer (stage 3 or 4), we must improve treatment options so they can live longer and with a better quality of life. As our *2020 Faces of Lung Cancer Report* details, alleviating the burden of this disease and improving outcomes means targeting the key elements of every patient's journey.

PART 1

SCREENING

WHY IS EARLY SCREENING IMPORTANT?

Lung cancer kills more Canadians than any other cancer. Early screening with low-dose CT scans for those at highest risk, can help save up to 13,000 lives per year.[5]

Currently, 7 in 10 lung cancer diagnoses are made at either stage 3 or 4[6], when survival rates decrease significantly. In fact, the three-year net survival rate decreases from 71 per cent among those diagnosed at stage 1, to five per cent among those diagnosed at stage 4. Organized screening programs can change that.

"We know that when patients participate in an early screening program, there is a significant shift of cancer detection from more advanced stage disease to earlier stage disease, which is entirely curable," says Dr. Eric Bédard, thoracic surgeon, University of Alberta. Currently, only 30 per cent of lung cancer is diagnosed at early stages in Canada[7], when curative treatments are an option.

While this has clear positive implications on patient outcomes, it also benefits the system: the cost of treating patients with advanced lung cancer is far higher than its early stages, due to the need for more intensive and often expensive treatments[8].

"Right now, helping our patients who have metastatic disease involves costly systemic therapies," says Dr. Cheryl Ho, medical oncologist, BC Cancer. "Screening is a much smarter approach, as it would give our patients the best chance of a cure and *prevent* metastatic disease, reducing health-care costs overall."

Still, early screening must be done in conjunction with prevention efforts, as reducing the rate of smoking is the single most effective way to prevent lung cancer. However, among those who have already stopped smoking, screening is the only feasible intervention to lower mortality.

"IT'S INCREDIBLE TO WATCH THE JOURNEY PATIENTS GO THROUGH, THE THINGS THEY MUST DEAL WITH, THEIR FAMILIES COMING TOGETHER IN SUPPORT. THEY ACCEPT SUCH HARD CHALLENGES WITH SUCH GRACE. IT'S REMARKABLE."

DR. CHERYL HO,
MEDICAL ONCOLOGIST,
BC CANCER, VANCOUVER

CANADA NEEDS ORGANIZED SCREENING PROGRAMS

In mid-September 2020, the province of B.C. announced that it would commit to an organized lung cancer screening program set to begin in 2022. This laudable move will hopefully swing the pendulum in other provinces as well – because as it stands, this would be the first formal program anywhere in Canada.

The recommended screening technique for lung cancer is low-dose computed tomography (LDCT). Two high-profile trials have shown the world that using LDCT to screen high-risk patients improves outcomes. The Dutch-Belgian NELSON study showed significant reduction in lung cancer deaths after 10 years compared to no screening (25 per cent reduction in men; up to 61 per cent in women).[9] The National Lung Screening Trial tested three annual LDCT screens to chest X-rays in 53,000 people at high risk of lung cancer. Over six years, LDCT led to a 20 per cent reduction in lung cancer mortality.[10]

In a report earlier this year, the Canadian Partnership Against Cancer (CPAC) projected that LDCT could detect up to 17,000 more stage 1 cases of lung cancer over 20 years. This translates into 14,000 fewer stage 4 cases – and as many as 13,000 deaths prevented.

FOR GRAHAM HYMAS, EARLY SCREENING WAS LITERALLY A MATTER OF LIFE AND DEATH. READ HIS STORY ON PAGE 10.

MOVING IN THE RIGHT DIRECTION

Fortunately, change is afoot – led by CPAC and supported by Lung Cancer Canada as well as other groups. CPAC is issuing seed grants and guidelines for pilot screening programs. Before the recent B.C. announcement, there had been a research study underway in that province, as well as another in Alberta – and pilot trials in Ontario and Quebec. According to CPAC, early signs are that they are both feasible and effective in a Canadian context.

Lung cancer screening related strategies in Canada (July 2018)

Image source: Canadian Partnership Against Cancer. Environmental Scan. 2018

WE MUST RETHINK THE ISSUE OF FUNDING

Today, lung cancer screening for at-risk Canadians is not a standard of care outside of B.C., due likely to perceived high startup and infrastructure costs. In its place, opportunistic screening is taking place – unorganized, unevaluated, and not in the best interests of patients.

"An organized lung cancer screening program will provide a structured platform to improve the survival and quality of life of patients with lung cancer through early detection, rapid diagnosis and treatment," says Dr. Stephen Lam, respirologist, BC Cancer.

Similar to the infrastructure in place for breast and colorectal screening, data linkages to various health authorities would need to be implemented in a provincial program. All screening sites would need computer diagnostic tools to screen and report on CT scans in a standardized fashion. Then, a uniform protocol on how to approach patient management would need to be put in place, one that engages all stakeholders, from radiologist to thoracic surgeon to respirologist to oncologist.

"But we don't need to reinvent the wheel," Dr. Lam says. "We can leverage existing colorectal or mammography screening and adopt their information technology systems to fit a lung program. When you perform focused screening on high-risk people, the number of people who may need subsequent tests and procedures is much smaller than screening programs of these other cancers. They can be absorbed into the current system."

What's more is that such programs appear to be cost-effective, at least on par with existing screening programs for breast, cervical and colorectal cancers.

In a 2017 study led by Dr. Lam and Dr. Sonya Cressman, researchers found that focusing on high-risk people could reduce the budgetary impact of these programs by reducing the number of people who need to be screened by 80 per cent. Cancer interventions are often benchmarked at $100,000 per year of life saved – the cost of lung cancer screening was calculated to be less than $21,000[11]. This is backed up by CPAC, which projects lung cancer screening programs to cost $20-$40,000 in this same way, on par with efforts in breast cancer – whose mortality rate is far lower.[12]

LUNG CANCER CANADA BELIEVES

Screening and early detection cannot be separated from prevention, but instead must be part of a holistic program that includes counselling and education toward smoking cessation. It is vital to deploy low-dose CT screening to target high-risk individuals in an accessible fashion to try and reduce the number of Canadians being diagnosed with stage 3 and 4 advanced lung cancer. This effort will require government funding but will, over time, become a far more cost-effective measure than treating patients with advanced stage cancer.

GRAHAM HYMAS

FACES OF LUNG CANCER PATIENT STORY

It all started in 2018, when Graham Hymas and his wife moved to the beautiful ski town of Calabogie, Ont. There, it was a simple question from his new family doctor that changed Graham's life forever.

"How can I help you quit smoking?" Graham had long struggled with the answer to this question. His mother had passed from stage 4 lung cancer after being diagnosed at the age of 82, and with his retirement looming, Graham felt an urgent need to quit.

He joined a smoking cessation support program, where he received both nicotine patches and counselling support. A few months later, Graham was offered a chest X-ray as part of a screening pilot program at the Renfrew Victoria Hospital. He was not prepared for the results of that screening: there was a lesion in the upper left lobe of his lung.

"It was a shock, it was very emotional," Graham says, adding that it took some time to build up the nerve to tell his family. "Being told you've got cancer but not knowing what stage it is, what treatment options you have – it's upsetting." Graham went through additional tests at The Ottawa Hospital, over an hour away from his home. A few weeks later, he got the answers he was waiting for.

Diagnosed with stage 1 lung cancer, Graham was one of the "lucky" patients whose cancer was caught at an early stage, when curative treatment was an option. In fact, only 1 in 5 of all lung cancer patients in Canada are diagnosed at this stage[13].

"The people I've known with lung cancer have generally died, but they didn't get to find out until it was later stages," says Graham. "I felt so thankful for the screening pilot program because they found it early enough where they could do something about it."

After undergoing surgery to remove the lesion, Graham continued to have regular checkups to ensure the cancer hadn't returned. In fact, he recently transitioned from six-month checkups to annual checkups – a hopeful step toward a full return to health.

Today, Graham is thankful he could access early screening, and advocates for other patients by sharing his story.

Graham Hymas

"I was surprised to learn screening programs are not available across the country. Early screening saved my life, so everyone should be able to access it. It's the difference between life and death."

- Graham Hymas

PART 2

DETECTION AND DIAGNOSIS

WHY IS TESTING IMPORTANT?

Many clinicians describe treating lung cancer as a race against the clock, a race that, if successful, can give patients a chance at better outcomes – and more time to create memories with their loved ones. Of all that is taken by lung cancer, time is felt most acutely by families.

Testing is a critical part of any patient's medical journey, and considered a precursor to effective treatment. Molecular testing (biomarker testing) can help "match" the treatment with the signature of a patient's individual tumour.

Just as no two fingerprints are the same, neither are any two tumours. In the emerging age of personalized medicine, biomarkers are like genetic clues that give clinicians the ability to customize a patient's treatment according to the specific characteristics of of his or her cancer. These clues can help identify the type or subtype of cancer, how aggressive it is, what's causing a cancerous growth (e.g. genetic mutation), and what treatment each person will respond to best.

Nova Scotia currently has one of Canada's most robust molecular programs to test for biomarkers. Dr. Zhaolin Xu, professor of pathology, Dalhousie University, led efforts to elevate testing capabilities within the province.

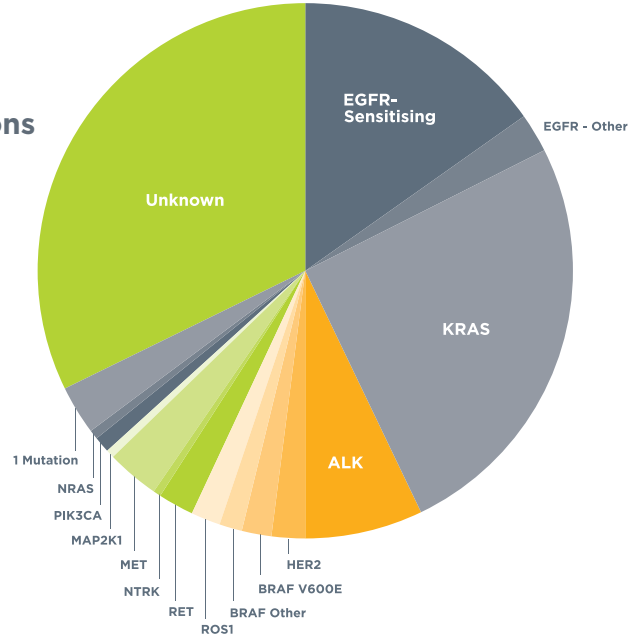
"The discovery of gene mutations in the last 10 to 15 years have led to significant improvements in how we provide care for lung cancer patients," says Dr. Xu. "Molecular testing can lead to better cancer diagnosis and treatments, better patient outcomes and a better quality of life overall." He adds that precision treatments make any treatments used more effective and manageable for an individual patient, while limiting adverse effects.

WHAT TESTING IS AVAILABLE

In Canada, a new 2020 study identified the frequency of six known mutations across a variety of lung cancer subtypes in earlier stages.[14] A total of 799 surgically resected non-small cell lung cancer cases with sufficient molecular data were collected from 2005 to 2016 at the Queen Elizabeth II Health Sciences Centre in Halifax. The study's results differ from previously published data, highlighting new avenues for lung cancer research and indicating the possibility of unique risk factors found in the study population's particular geographical location. The data revealed can also guide future research in personalized medicines that will ultimately improve lung cancer survivorship and quality of life.

Which Mutations Are Most Common in Lung Cancer?

Image source: Hirsch F, st al. New and emerging targeted treatments in advanced non-small-cell lung cancer. Lancet. Vol 388. September 3, 2016



To identify biomarkers, clinicians can test either a sample of the tumour tissue, or of a patient's blood.

Tissue-Based Biomarker Testing

Next-generation sequencing (NGS), immunohistochemistry (IHC), fluorescence in situ hybridization (FISH) and polymerase chain reaction (PCR) are all examples of tissue-based molecular testing.

The first step in most cases is to perform a biopsy on the tumour, and obtain sufficient tissue should multiple tests be needed (preventing the need for a patient to undergo further biopsies). Tissue samples are then ideally sent for multiplex ("panel") testing. NGS, a type of panel testing, hunts for many biomarkers at the same time – which can result in a faster diagnosis, more optimal treatments, and potential financial and workflow efficiencies for a hospital.

It is important to note that not all panels are created equally. For example, some panels test for molecular subtypes called 'gene rearrangements', like ALK and ROS1, while others do not. As a result, rearrangements are often tested for separately and, in some provinces, these samples are sent to laboratories in the United States, adding both time and cost.

Some health-care centres are testing *sequentially* – where one particular gene biomarker is tested first. A negative result means tests are ordered one after another, until the correct biomarker is identified. This style of testing can work against the clock, causing diagnostic delays for the patient.

Blood-Based Biomarker Testing

Though tissue-based testing is most common, blood-based biomarker testing is emerging as an exciting new area. A cancer's genetic material leaks into a person's bloodstream as cancer cells die naturally, allowing for molecular fingerprints to be detected. While it lacks the sensitivity of tissue tests, blood-based tests are nonetheless a valuable avenue for biomarker testing, particularly if a tissue biopsy is too difficult or risky.

Such tests also represent new-found hope for people with advanced lung cancer who may be too ill to undergo a tissue biopsy, or whose tumours are located in an area where a biopsy is not possible. A liquid biopsy affords them the same opportunity as other patients when it comes to testing and precision treatments. Still, it's a new area of science, one that relies on genes being released from cancerous cells and absorbed into the blood – at levels that can be detected. The cost of this method is significantly higher than tissue-based testing.

Of the various tests, next-generation sequencing (NGS) is emerging as one that could be adopted nationally. NGS is best positioned to provide:

- Comprehensive testing capabilities; potential to detect biomarkers across different mutation categories
- Testing using limited tissue (especially important for patients with advanced-stage cancer)
- Quick testing results
- Greater cost efficiency than other forms of panel tests

Testing at a Glance

Single-Gene, Sequential Testing

- Cost savings in the short term (fewer tests potentially ordered)
- Increases risk of insufficient tissue for all tests, leading to a greater potential for multiple biopsies
- Potentially longer wait times for diagnosis

Multiplex (Panel) Testing (i.e. NGS)

- Tests for multiple genes at once
- Long term cost savings but more expensive up front
- More efficient workflow
- Faster patient diagnosis
- Treatment recommendations can be determined quickly
- Reduces the risk of insufficient tissue

Guidelines for Biomarker Testing

In 2018, Lung Cancer Canada initiated a paper in which a committee of thoracic oncology experts explored a national approach to biomarker testing by studying the available literature on the subject.

This committee sought also to ensure biomarkers that had a Health Canada approved drug treatment were included in the recommended standard. They determined that any testing standard must be flexible enough to incorporate novel biomarkers as they become available, because any national guidelines will lag behind technological advances in this area.[15]

These proposed Canadian guidelines are also supported by international guidelines on molecular testing. In 2018, the College of American Pathologists, the International Association for the Study of Lung Cancer and the Association for Molecular Pathology updated their recommendations, which include:

- Multiplexed panels (such as NGS testing) are preferred over multiple single-gene tests
- Biomarker testing for patients with early-stage disease is encouraged
- EGFR and ALK testing for all patients with advanced lung cancer; testing for T790m in patients with EGFR
- Testing for ROS1 mutations for all lung cancer patients
- If NGS is being used for testing, including additional markers such as BRAF, ERBB2 (HER2), MET, RET and KRAS
- To predict a patient's response to immunotherapy, samples should be set aside for future PD-L1 testing – reducing the need for additional biopsies and issues with insufficient tissue if the cancer advances

Molecular Testing Standard of Care

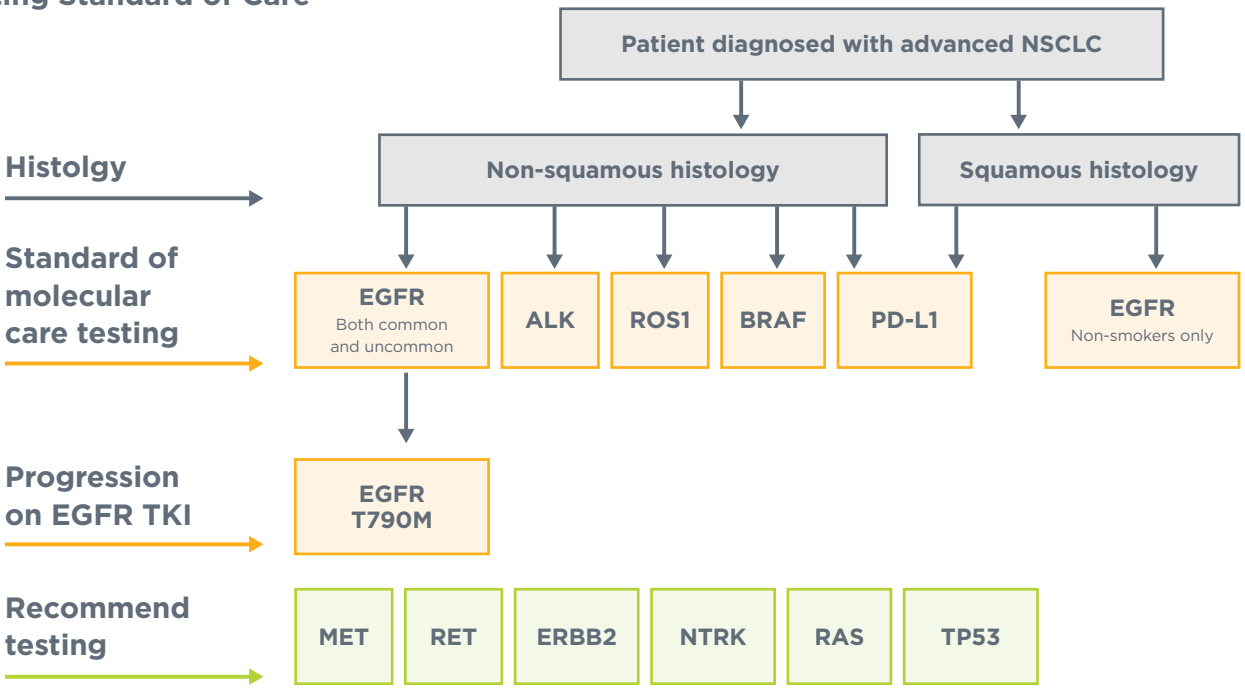


Image source: Standard biomarker testing in Canada, as recommended in "Standardizing biomarker testing for Canadian patients with advanced lung cancer."

LUNG CANCER CANADA BELIEVES

Biomarker testing should be a standard of care for all Canadians. Patients have a right to access personalized treatment that can lead to better outcomes – but access to these treatments is compromised if testing to identify the targetable mutation cannot be done.

In addition, testing for novel biomarkers should become standard as soon as new treatments targeting these markers are approved by Health Canada. It is unethical to prevent patients from accessing approved treatments due to a lack of related testing.

HOW ARE WAIT TIMES BEING REDUCED?

To combat the ticking clock, clinicians, governments and cancer centres across Canada are striving to improve how quickly test results are returned to patients. Having biomarker test results early in a patient's medical workup can mean the difference between starting chemotherapy or being prescribed targeted therapies instead.

One such effort "to beat the clock" relies on reflex testing. In this model, molecular tests begin automatically after a specific threshold is met – such as the first detection of cancer. Reflex testing ensures results are available before a patient's first oncologist consultation, when the physician already has a fuller picture of the patient's status. This model reduces time to treatment for lung cancer patients[16,17] and generates more immediate, informed treatment decisions.

"To me, reflex testing is a defensive strategy – especially when you have a lengthy testing turnaround time," says Dr. Brandon Sheffield, pathologist, William Osler Health System. "When you know it's going to take eight weeks, you try and give your oncologist a three-week head start by testing reflexively."

Reflex testing can also save hospital budgets through such efficiencies as:

- Streamlined pathology-clerical personnel responsibilities
- Reduced overtime costs
- Fewer physician appointments and tests for patients

The value of reflex testing was life-changing for Ann Uloth. Not only did it give her oncologist critical data important for treatment almost 20 days earlier, it also saved Ann from full-brain radiation. Read her story on page 18.

"BEING ABLE TO GAIN ACCESS TO TARGETED THERAPY TREATMENT IN A TIMELY MANNER HAS MEANT THAT MOM HAS BEEN ABLE TO SPEND QUALITY TIME WITH US IN REASONABLE HEALTH. SHE HAS DELAYED THE RIGOURS OF FULL BRAIN RADIATION AND CHEMOTHERAPY. I WILL ALWAYS BE GRATEFUL FOR THIS TIME I HAVE WITH HER."

COLE, SON OF ANN ULOTH, A LUNG CANCER PATIENT. *READ ANN'S STORY ON PAGE 18*

In Nova Scotia, pathologists use true reflex testing in which molecular profiling is done immediately upon diagnosis, regardless of cancer stage. But in some other provinces, reflex testing – if available at all – is reserved for patients with advanced cancer, those who are under a specific age, or those with a certain subtype of lung cancer. Dr. David Dawe, medical oncologist at CancerCare Manitoba, explains this is a result of funding constraints, as well as the immediate usefulness of that information.

"To this point, knowing EGFR, KRAS or BRAF status has not been actionable information in patients with earlier stages of lung cancer," he says. That's because drug treatments – that correspond to the biomarker present – are typically indicated for patients whose cancer has metastasized or advanced whereas curative surgery to remove a cancerous lesion is the most common approach for early-stage cancer patients.

This too, however, is changing. Case in point: new data show that the drug osimertinib (typically used to treat advanced stage cancer patients) significantly improves disease-free survival in patients with early-stage lung cancer who also underwent surgery to remove the tumour.[18] These results are promising and point to the value of molecular testing, even for patients whose cancer is detected at a curative stage.

Another consideration of stage-based versus reflex testing lies in the potential efficiency of true reflex testing.

"With lung cancer staging, multiple tests are performed, such as PET scans, brain imaging and biopsies, often done by different departments," says Dr. Biniam Kidane, a thoracic and foregut surgeon at the Winnipeg Health Sciences Centre. "As you can imagine, it takes a long time to co-ordinate. We've created a triage and assessment process that has compressed that time, but more needs to be done."

In Halifax, Dr. Xu describes another argument for reflex testing.

"If testing only takes place for patients who have advanced lung cancer, you lose the opportunity to potentially treat patients – who are first diagnosed with early-stage cancer – more effectively in the future," he says.

"For patients whose cancer has metastasized or recurred, you end up delaying treatment because testing takes place after the cancer has advanced, versus when it was first detected. Yesterday's patient with a localized lesion may be tomorrow's advanced cancer patient."

ANN ULOTH

FACES OF LUNG CANCER PATIENT STORY

With retirement approaching, Ann Uloth, 62, was excited to leave work behind and spend more time with family and friends. So when she began experiencing chest pains and shortness of breath, the last thing she expected was to receive a diagnosis of stage 4 lung cancer.

“I had this idea in my mind of who I wanted to be at 60 and I was just getting there,” Ann says. “I was at work one day, and the next week I was in palliative care. It was so bizarre I honestly thought the doctors had the wrong chart.”

Her doctors in Antigonish, N.S. ordered more tests, for which she drove two hours to Halifax on the southern coast. A lung biopsy was performed and the samples were sent for NGS testing, reflexively. Ann also underwent a brain scan, which revealed nine tumours in her brain.

Ann was assessed by a radiation oncologist, who explained she had to be treated quickly, given the advanced state of the cancer. They recommended full-brain radiation, which could lead to unpleasant side-effects, but there was little choice.

Meeting her medical oncologist, Dr. Stephanie Snow, Ann felt a degree of hope. “She told me that she would take care of the cancer, that I was to take care of myself. I really appreciated the kindness.”

Without the test results in hand, there was no way of knowing which mutation was fuelling Ann’s cancer – a vital consideration to recommending a more targeted, less harsh treatment.

Fortunately, the hospital’s reflex testing policy meant Ann’s tests were well underway. This proved significant: the morning that Ann was booked to plan her full-brain radiation, the test results came back.

Ann had an EGFR mutation, so Dr. Snow quickly changed course from the intended radiation to osimertinib, a targeted drug treatment.

Had it not been for the hospital’s reflex testing policy, Ann’s results would have been delayed almost 20 days: the time between the lung biopsy and her first meeting with the medical oncologist, who traditionally orders these tests.

Thankfully, this was not the case. Ann’s results arrived quickly, giving her the option to be treated with targeted medication that would generate far fewer long-term side-effects than radiation, and allow her to enjoy a better quality of life.

Ann continues that treatment today, which she says gives her hope to spend more quality time with loved ones, just as she planned for retirement. A follow-up CT scan recently revealed that her cancer has reduced as a result of osimertinib.

“My family took it hard,” Ann says. “We’re going to do the best we can and I’m still doing really well but, in the end, their support means everything.”

Ann Uloth

“Maintaining a good quality of life – that’s what’s important to me. I want to enjoy my friendships and time with my loved ones. I’m hoping for good things with this drug and that I don’t have too many side-effects.”

- Ann Uloth

Where Are Samples Tested?

What testing is conducted, which biomarkers are tested for and where samples are analyzed varies greatly across provinces and between hospitals.

Some hospitals have the infrastructure to conduct molecular testing in-house, while others must send tissue samples to a centralized lab for evaluation.

Centralized testing can ensure equitable distribution of testing paradigms across regions. For hospitals without the budget, space, technology or resources to establish an in-house laboratory, outsourcing testing via third-party sites can offer a degree of quality assurance as well.

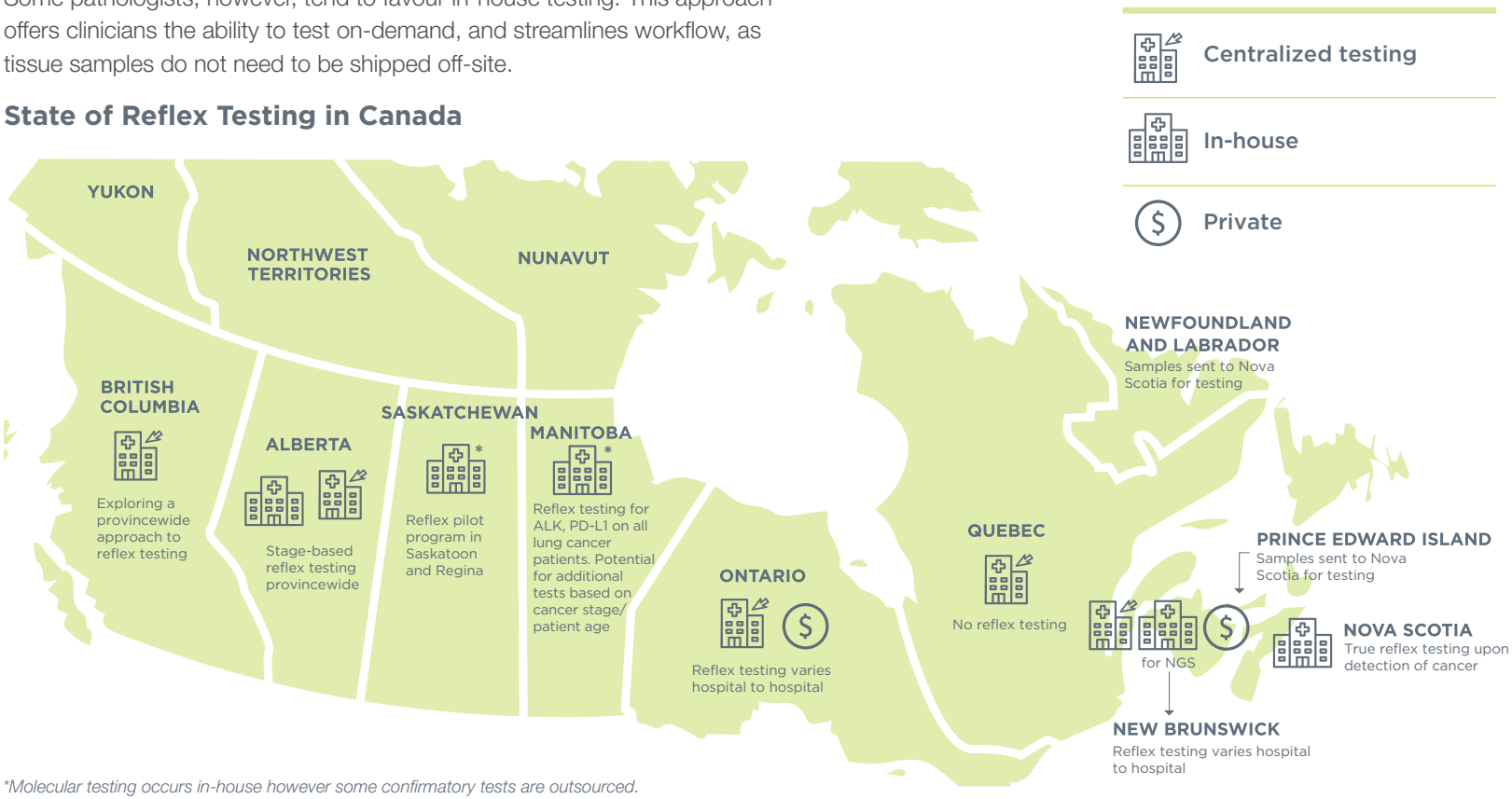
Some pathologists, however, tend to favour in-house testing. This approach offers clinicians the ability to test on-demand, and streamlines workflow, as tissue samples do not need to be shipped off-site.

Each of these models has its own benefits. In either case, samples are "batched" (that is, several samples for various cancers are tested at the same time) in order to reach the necessary critical mass needed to run the samples.

"Optimal batching of testing specimens by referral centres allow for financially viable panels," explains Dr. Diana Ionescu, medical pathologist, BC Cancer. She adds batching is a standard practice in reference laboratories across the country.

A summary of each laboratory system can be found in Appendix A.

State of Reflex Testing in Canada



**Molecular testing occurs in-house however some confirmatory tests are outsourced.*

A CHANGING PICTURE PROVINCE TO PROVINCE

Many individual clinicians and specialty departments are combating wait times within their own centres through a series of formal and informal actions.

Less populous provinces such as Saskatchewan, Manitoba, New Brunswick and Nova Scotia have developed more synergistic workflows. Here, a handful of specialists tend to serve the entire population, which can create more fluid relationships between clinicians in different disciplines, including family medicine.

"In the last year and a half, we've been able to streamline both our processes and resources, such that wait times have decreased significantly," says Dr. Kidane. "We're organizing tests together to reduce repeat visits, which is especially important for people that live in rural and Indigenous communities, who would otherwise experience increased wait and travel times."

HOW CAN WE STRIP AWAY BARRIERS TO IMPROVE DIAGNOSTIC WAIT TIMES?

We examined best practices across the country and identified the following opportunities:

- **Increase funding for biomaker and reflex testing**
- **Establish a consensus for acceptable testing turnaround time**
- **Create a national molecular testing policy and review board**
- **Reduce delays to specialist referrals**
- **Shift to comprehensive NGS panels**
- **Increase pathology funding**

Greater Funding Needed for Biomarker and Reflex Testing

Although experts agree that biomarker and reflex testing should be standard of care for lung cancer, funding hasn't kept pace with available treatments.

We know that relying on industry to pay for testing is not sustainable over the long term, and will lead to more expensive medications. Meanwhile, we also know that testing should be fully accessible rather than its current inconsistency across Canada. We must take an evidence-based approach to determining who is eligible, and ultimately have governments control such eligibility, as well as the costs of testing, through centralized, publicly-funded molecular testing.

LUNG CANCER CANADA BELIEVES

All Canadians have the right to access timely molecular testing. Testing can open new treatment possibilities for patients that can lead to better outcomes. It is unethical for governments to deny patients access to testing on the basis of funding, as provinces have a constitutional mandate to provide effective care. Testing is an important part of this circle of care.

A Consensus Is Needed for Testing Turnaround Times

Regardless of whether testing is outsourced or performed in-house, the international consensus is that test results should be available within two weeks of the sample reaching a lab – and if that lab is external, it should be fewer than three days for a specimen to reach it.[19] Beyond this, rapid testing must be made available for urgent cases.

"Most of Canada is falling well outside of guidelines on molecular testing," says Dr. Sheffield. "If turnaround time exceeds 14 days, the guidelines state that you should consider in-sourcing the testing to your lab. And today, technology exists so that basic lung biomarkers can essentially be done in any medium-sized hospital."

Still, some pathologists recommend taking a hybrid approach: centralizing complicated tests such as NGS, but conducting other tests like IHC in-house.

LUNG CANCER CANADA BELIEVES

Where rapid testing turnaround is not possible, cancer care centres have the responsibility to explore different ways to reduce wait times, including private laboratory options.

Create a National Molecular Testing Policy and Working Group

Canada needs co-ordinated efforts to support patients. The lack of uniformity across the country, coupled with the speed of medical advancements, suggests there is a need for a national body that could recommend evidence-based molecular testing policies, help implement or expand provincewide standards, and facilitate synergies between laboratories across the country. A working group could also determine testing eligibility based on evidence.

That review board can also bridge the gap between system and medical advances by recommending updates to testing standards so patients can benefit from better treatment and outcomes. Co-ordinated efforts can also benefit patients beyond those with lung cancer, because molecular testing is used to inform treatment options for a host of other cancers as well.

Reduce Delays to Specialist Referral

To alleviate any uncertainty about when primary care physicians should or shouldn't issue a referral, employing a system whereby the first abnormal radiography triggers an automatic specialist referral can create a faster-paced pathway. This has potentially widespread implications when we recognize that nearly five million Canadians have no regular family doctor who could be managing the subtleties of their care.[20]

Some hospitals in Alberta, Nova Scotia and New Brunswick have systems like this currently in place.

"We're developing specific language with radiologists that will streamline referrals and ultimately reduce wait times for patients," says Dr. Joseph Ojah, thoracic surgeon, The Moncton Hospital, a part of the Horizon Health Network. "Once radiologists identify specific features on the scan, an automatic referral is made, giving the ordering physician – often primary care doctors – clear direction on next steps."

Canada Needs a Comprehensive NGS Panel

NGS is becoming increasingly adopted but its full potential is far from realized, as many panels don't include biomarker fusions such as ALK, NTRK, and ROS1.

"That means we're currently testing fusions (ALK and ROS1) by immunohistochemistry (IHC) which we run in parallel to other molecular tests," says Dr. Diana Ionescu, a pathologist, BC Cancer. "Running two sets of tests means we issue two different reports at two different times. This adds a layer of complexity for oncologists, but we hope to streamline biomarker reporting in the future."

A more comprehensive NGS panel, especially through the inclusion of fusions, Dr. Ionescu adds, would cut the overall turnaround time in half to just one to two weeks, and provide all but PD-L1 data in one report.

In Search Of: More Pathologists and Lab Technicians

While clinicians can drive more biomarker testing, labs must be ready and equipped to process these samples in a timely fashion.

As the volume and scope of testing increases, pathologists will experience a significant rise in workload. Unfortunately, many provinces have underinvested in pathology. In some provinces, centralized funding structures further complicate the issue.

"The province is responsible for hiring pathologists and lab technicians, and they hire according to certain criteria," says Dr. Donna Maziak, thoracic surgeon, The Ottawa Hospital. "There's no flexibility for hospitals or health-care centres to staff up using their own budget because everything is controlled provincially."

The impact can be far-reaching: without the appropriate number of pathologists to process the growing volume of tests, results will inevitably be delayed.

HOW CAN WE IMPROVE THE PATIENT EXPERIENCE?

Consider a Central Nurse Navigator

Shuffled from one appointment to the next, a patient's journey through the medical system can be daunting. One proven solution is to implement nurse navigators, who would not only help patients traverse the system, but reduce diagnosis delays.

Nurse navigators can, for instance, triage the patient and order additional tests to help paint a broader picture of their cancer status, before the first oncologist meeting even takes place. This is already standard practice in some provinces.

Nova Scotia takes this a step further. Dr. Stephanie Snow, a medical oncologist at the Queen Elizabeth II (QEII) Health Sciences Centre in Halifax, and vice-president of Lung Cancer Canada, says that such a central intake model would improve the patient experience. "We often informally organize things ourselves so patients can get all their tests done in the same day," she says. "But if we could take a multidisciplinary approach to that, it would move things forward, save a lot of money and actively improve outcomes in a significant way."

Consider Socioeconomic Factors

While all Canadians are entitled to the full suite of health care, accessing it is another story. It's long known that those at a lower socioeconomic status tend to have poorer outcomes, led by direct and indirect disparities in care.

Consider the story about a woman in northern Manitoba. After she repeatedly cancelled appointments for a lung biopsy, clinicians looked deeper and learned that she was on a fixed income and couldn't afford the travel costs associated with a hospital visit.

"Every time they come for tests, they have to spend money on gas and parking. Somebody has to take time off work to drive them. It creates these problems where people are unable to engage in their own care," says Dr. Kidane. "The nihilism takes over and they feel they're a burden and that they'll die anyway so what's the point?"

In this case, clinicians eased the woman's burden and co-ordinated all her tests on the same day to minimize travel. "The people that suffer the most are actually people who live in rural areas, who have low socioeconomic status, who may have lower health literacy and who thus can't advocate for themselves," says Dr. Kidane.

Kayla MacWilliam with her son Leighton

KAYLA'S ANGEL FUND

Kayla's Fight Club was established by Kayla MacWilliams's family and friends to provide support through her lung cancer journey, but despite a brave battle, Kayla passed away. As a testament to her spirit, strength and memory, Kayla's Fight Club continues to raise funds to support lung cancer patients.

Kayla's Fight Club and Lung Cancer Canada recently announced the launch of Kayla's Angel Fund. Created to honour Kayla's memory, this fund will help make life easier for lung cancer patients and their families. Beginning locally, the fund will assist with everyday challenges faced, starting by providing parking passes for medical appointments. We hope to expand the program and help more patients and their families.

Consider Digital Pathology

A novel way to diagnose patients is emerging through digital pathology. This technology allows pathologists to analyze and diagnose specimens in a virtual capacity, so they can remotely reach patients no matter where they live. This technique is emerging in step with remote monitoring solutions.

"We're using this technology more often, given COVID-19 restrictions on in-person meetings," says Dr. Darryl Yu, anatomic pathologist, the University of Saskatchewan. "It's going to remove a lot of physical barriers to care. The tests can be read from anywhere so long as you have a microscope, rather than shipping boxes of slides and tissue back and forth."

Other elements such as information technology security, equipment costs, wireless technology and internet infrastructure are factors in successfully adopting digital pathology. Still, the potential here to bridge the access to care issues across Canada is promising, particularly with rapid innovations in virtual care.

Access to timely testing is critical. With innovative thinking and by sharing best practices across the country, there is hope for change.

PART 3

EQUAL ACCESS TO TESTING AND TREATMENT

DOES EVERYONE HAVE ACCESS TO TESTING AND TREATMENT IN CANADA?

Across the country, disparities persist in how Canadians access lung cancer tests and treatments.

Resource Disparities Across Canada

As each province runs its own health-care system, with unique economies, geographies, population demographics and spending priorities, it's no surprise that cancer infrastructure and resources are unequal across Canada.

Where a patient lives continues to be a major factor in what type of care is likely to be ordered. For example:

- PET scanners, critical in the initial diagnosis of lung cancer, are not available in Yukon, P.E.I. and Newfoundland and Labrador (N.L.).
- Stereotactic body radiation therapy (SBRT), which delivers precise doses of radiation to a tumour while preserving nearby healthy tissue, is unavailable in N.L. or any territory.
- Wait times for surgical procedures vary province-to-province and within each province.
- Lung cancer patients in P.E.I. and each territory routinely travel out-of-province for surgical procedures.
- Molecular testing for patients residing in any of the three territories or in P.E.I is conducted via health-care centres in neighbouring provinces. This raises significant financial hardships associated with travel.
- Despite some commonalities as to which biomarkers are tested, some provinces test a broader range of markers than others.

"FROM THE BEGINNING OF MY WIFE'S DIAGNOSIS OUR LIVES TURNED UPSIDE DOWN IN AN INSTANT...

There was no time to consider options, her life was in jeopardy within a matter of a few weeks. Atezolizumab plus chemotherapy saved my wife's life. We are so very lucky that we come from a very small town of truly remarkable people who pulled together to raise the funds to add atezolizumab to her treatment plan. Atezolizumab is approved for use for small cell lung cancer but not approved for funding. Everyone deserves a chance to live. This treatment gives us hope that statistics can be beaten. That extra time my wife has with me and our teen son is a gift that we are forever grateful for."

DARRELL, HUSBAND OF TRACEY DONNELLY, A LUNG CANCER PATIENT. *LEARN ABOUT TRACEY'S JOURNEY ON PAGE 31.*

Lung Cancer Is Not a Postal Code Disease

Resource disparities are also exasperated by the rural versus city divide. Rural Canadians tend to have higher health care needs, but a more difficult time accessing that care. According to the Canadian Partnership Against Cancer, Canadians living in more remote areas have a higher incidence of lung cancer compared to those in and around urban centres. Reasons may include higher smoking rates in rural Canada, as well as reduced access to screening, diagnosis, and treatment services.

"Access to physicians and the availability of different testing modalities are all issues faced by rural Canadians, who must come to city centres," says Dr. Sunil Yadav, clinical associate professor and medical oncologist, Saskatoon Cancer Centre, Saskatoon. "Some have to be flown from their communities, others face challenging winter travelling conditions, and other socioeconomic factors are at play that keep access to care an issue for many people."

Clearly, Canadians would prefer to access medical care in their own communities. This can ease travel and economic hardships, and keep patients plugged into their local support networks. Localized care, however, can inadvertently lead to differences in the level of care received.

In Nova Scotia for example, localized models of care are leading to delays between diagnosis and treatment. "While patients often prefer to be seen by a specialist in their community to avoid travelling, this can lead to delays in care," says Dr. Madelaine Plourde, thoracic surgeon, QEII Health Sciences Centre (Halifax). "Prompt referrals to regional centres with expertise in treating cancer patients allows for more timely access to diagnostic and staging investigations necessary prior to treatment."

Other programs, such as community oncology programs (COP) and satellite clinics, play a role in the circle of care. Services differ province to province, but a key commonality is that patients can access some treatments closer to home. Whether it's oral chemotherapy or psychosocial support, these interventions can have a positive outcome on a patient's quality of life.

LUNG CANCER CANADA BELIEVES

Patients have the right to access testing and excellent care close to home. Community clinics and regional programs can bridge the gap between geographical divides, but co-ordinated workflow and referral paths between community sites and centres of excellence need to be established. This is a significant opportunity to ensure patients receive — and have access to — the optimal standard of care.

Services such as chemotherapy infusion sites within smaller communities can help patients be treated closer to home while decreasing wait times. This also fosters stronger working relationships between cancer care centres.

Further, virtual care technologies should be encouraged and adapted, since they allow patients to interact with clinicians remotely. A variety of services including diagnosis, treatment, education, monitoring and support can be provided using these technologies.

Lung Cancer Canada also calls on financial support mechanisms, such as travel and medical grants, to reduce economic hardships for patients. This support is especially needed for those who live in remote and rural geographies, as well those with lower socioeconomic status.

TREATMENT COSTS REMAIN A PROBLEM IN CANADA

The positive news is that new therapeutic options are promising improved outcomes for lung cancer patients. Unfortunately, such targeted treatments are becoming increasingly expensive.

A 2017 Patented Medicines Pricing Review Board (PMPRB) report found that in the preceding 10 years, the 28-day average treatment cost for oncology medicines rose to $7,057 from $3,867 – an 82 per cent jump.[21]

While health-care systems provide Canadians with access to drug therapies, provincial disparities on which drugs are funded, how quickly they're made available, and who qualifies for access leads to an imbalance in lung cancer treatment access across the country.

Further, if a treatment hasn't been approved by Health Canada or receives negative pCODR recommendations (see sidebar), patients – such as Tracey Donnelly – can quickly find themselves under great financial strain to cover treatment costs out-of-pocket.

Health Canada

Once a drug is approved for use in Canada, the Health Technology Assessment (HTA) process begins with the CDR / pCODR / INESSS process.

CDR / pCODR / INESSS

The value of the drug is assessed: how well does it work vs. standard treatment? Does it meet patient values? What do clinicians feel about the new treatment?

Pan-Canadian Pharmaceutical Alliance (pCPA)

Following a positive pCODR or INESSS recommendation, confidential pricing negotiations are conducted between the (pCPA) and manufacturers.

Ministry of Health

Once a price has been agreed upon, the provinces decide how/when to incorporate into provincial budgets.

CDR - Common Drug Review
pCODR - pan-Canadian Oncology Drug Review
INESSS - Institut national d'excellence en santé et en services sociaux

In each province, efforts are made to help patients navigate formulary rules and obtain financial relief to access therapies.

Alberta has one of the most comprehensive drug coverage programs in Canada. Clinicians can access drugs that are Health Canada approved but still undergoing pCODR review. Further, a Director's Privilege program covers treatment costs for drugs that target rare mutations up to three times over a patient's life.

In British Columbia, a drug access navigator system helps clinicians identify which medications are covered by patient assistance programs or private insurance coverage with the goal of prioritizing those treatment options first.

In Manitoba, such a program does not formally exist, but out-of-pocket treatments may be funded above a certain deductible through the provincial pharmacare.

In Quebec, the Patient d'Exception program allows clinicians to access many drug treatments that are not yet funded in other provinces. Yet, access is dependent on the testing to identify a targetable mutation. This in turn is complicated by issues in the province related to resource constraints, a narrow molecular testing scope and lack of funding.

Oral medications are also funded in an unequal fashion depending on one's postal code. The governments in British Columbia, Alberta and Manitoba, for instance, cover prescribed oral medications at 100 per cent. This is not the same for Ontarians and Atlantic Canadians, for whom only cancer treatments administered in hospitals are fully covered – while those taken at home are not.

Sometimes the fine print impacts access to treatments. In Nova Scotia, oral lung cancer drugs are funded, but for patients younger than 65 access is limited to those enrolled in public pharmacare. This program assesses one's previous earning potential and if a patient's income level exceeds preset thresholds – even if they are unable to work now and for the foreseeable future – they would not be eligible for coverage.

Only when we consider the cost for these oral therapies do funding disparities become clear.

"While we are a province where, for example, first-line osimertinib is funded, I'm racing against time trying to get two young patients on the drug, one of whom would otherwise need full brain radiation," says Dr. Snow. "They both have very limited private drug plans that max out at $1,000 per year but I need to put them on a targeted drug that costs up to $9,000 a month. This is a huge issue."

Dr. Snow says there are further situations where inferior IV therapies are used because the best oral drugs are unavailable. "So we often have to find alternatives including opening up industry sponsored trials as a way to access targeted therapies, because our molecular program is so robust. But once a drug is approved, accessing it is not what you would expect under universal health care."

Other avenues for drug coverage include compassionate programs established by the drug manufacturer, to bridge the gap between Health Canada approvals and pCODR decisions – a move lauded by clinicians. Not only do patients benefit from access to treatment, but pharma can submit positive patient impact stories to strengthen their applications.

Shared risk agreements between provinces and pharmaceutical companies are yet another example of industry partnerships. The latter agree to fund a patient's treatment for a predetermined amount of time. If it's effective during that time, the public health-care system will continue to fund the therapy. While no province or territory currently leverages this model, its potential to create a win-win situation for both patients and industry is clear.

"At the end of the day, I'm grateful for the patients and their patience with the system," says Dr. Juergens. "We must champion equal access to treatments for all Canadians. We know hope is out there."

LUNG CANCER CANADA BELIEVES

Stakeholders – including patients, clinicians, manufacturers, and HTA bodies – must collaborate and act to modernize Canada's public health-care system in order to improve access and affordability.

Personalized medicines are a key component to treating lung cancer. As treatments include more targets, lung cancer patients will be grouped into smaller populations.

It is critical that we explore new funding models, such as shared risk models with manufacturers and testing rebate programs. Oral medications must be fully covered across the country. Funding models should be continuously re-evaluated based on added clinical or real-world evidence.

Lung Cancer Canada calls for national pharmacare, with comprehensive, universal and equitable access to drugs across Canada.

"ONE PATIENT'S CANCER RETURNED IN 2010, JUST AS BIOMARKER DISCOVERY WAS TAKING OFF. WITH NEW TARGETED TREATMENT, SHE WAS ABLE TO SURVIVE 10 YEARS. THIS YEAR, SHE WAS ABLE TO WATCH HER GRANDSON WITH AUTISM GRADUATE FROM GRADE EIGHT. SHE WAS SO THANKFUL TO BE ABLE TO SEE THESE 'MIRACLES' IN HER LIFE. WE KNOW WE CAN MAKE A DIFFERENCE IF WE CAN USE THE LATEST SCIENCE TO TEST PATIENTS AND TREAT THEM."

DR. ROSALYN JUERGENS, *MEDICAL ONCOLOGIST, JURAVINSKI CANCER CENTRE, HAMILTON*

TRACEY DONNELLY

Faces of Lung Cancer Patient Story

Tracey Donnelly, a 54-year-old mother and non-smoker in Sioux Lookout, Ont., was diagnosed in May 2020 with extensive small cell lung cancer – a disease that typically strikes older adults with a history of smoking. Her oncologist said that with chemotherapy, Tracey could live up to one year. Without it, six to eight weeks.

"It was like entering a black hole where there is no hope, no light," Tracey says. "I couldn't help then to feel more like a statistic and less like a human, a mother, in need of hope."

Tracey began to see slivers of improvement after starting chemo. It was then that she learned of immunotherapy – a promising treatment that could extend her life by two months, but whose cost was not publicly covered.

Tracey was unable to secure coverage for atezolizumab — the immunotherapy recommended to her and approved by Health Canada – as both the province and private insurance turned her down. She applied to a compassionate care program from OnCare, which subsequently funded 40 per cent of the treatment.

Even with 40 per cent of the treatment covered, immunotherapy still costs the Donnelly's $4,200 out-of-pocket every three weeks. Tracey's friends launched a GoFundMe page to raise $60,000 to help mitigate this burden.

"It was scary, not really knowing where the money would come from," Tracey says. "When you know there is something out there that could help, you want to be able to at least try."

Tracey began three-week cycles each of chemotherapy and immunotherapy. Within a few weeks, a CT scan revealed that the cancerous nodes in her lungs and pelvis had reduced by nearly half. The tumours in her breast and pancreas had cleared. She could breathe better too, the tumour in her lung no longer pressing on a pulmonary artery.

Tracey went from needing a wheelchair before chemotherapy to running nearly five kilometres – after just four treatments. In fact, she even ran the Princess Margaret Journey to Conquer Cancer marathon to raise money for cancer research in October.

"Initially, I felt the immunotherapy wasn't encouraged, perhaps because it wasn't covered here in Ontario," she says. "That if you're not wealthy, accessing it may not be possible. We live, unfortunately, in a system where some are lucky, and some are not."

Despite these challenges, Tracey is determined to defy the odds. "My son is 14, and even adding a few months to my life is worth fighting for as it could mean celebrating a birthday, or Christmas," Tracey says. "I have so much to live for, everybody does."

Tracey Donnelly

"I wish everyone could access the treatment they need regardless of personal finances, or community support. The fact that you have to fight for treatment that makes you better is brutal when you are also fighting the cancer itself."

– Tracey Donnelly

ARE ALL APPROVED TREATMENTS PUBLICLY FUNDED?

Each year, Lung Cancer Canada releases tables that detail access to lung cancer drugs in our country. These document the time that lapses from FDA approval south of the border to Health Canada approval, as well as time from positive funding recommendations from pCODR or INESSS* (in Quebec) to being listed by provinces. (The FDA was chosen as a baseline because it is often the first regulatory body to approve new treatments.)

The 2020 tables reveal that:

- The difference between FDA approval and Health Canada approval is relatively short.
- Most of the lag time is due to Canada's public health-care system, which has processes in place to ensure responsible use of public funds.
- While regulatory authorities need to be fiscally responsible with public money, the data shows the system needs to modernize in order to more quickly provide patients with access to treatments.

"EVERY TIME I SEE A NEW PATIENT, I ALWAYS TELL THEM ABOUT ALL THE ADVANCES THAT HAVE BEEN MADE IN LUNG CANCER CARE. WHAT I CAN OFFER NOW IS COMPLETELY DIFFERENT THAN WHAT I COULD OFFER FIVE YEARS AGO, AND WILL BE COMPLETELY DIFFERENT FROM WHAT I WILL OFFER FIVE YEARS FROM NOW. THIS IS THE HOPE I WANT TO SHARE WITH PATIENTS."

DR. MATHIEU ROUSSEAU, *THORACIC SURGEON, MCGILL UNIVERSITY HEALTH CENTRE, MONTREAL*

Table 1 — Date of FDA Approval to Health Canada Approval

DRUG Generic name (Brand name)	INDICATION	FDA APPROVAL DATE	HEALTH CANADA APPROVAL DATE	pCODR Status	Phase Data Used
alectinib (Alecensaro®) 2nd line	As monotherapy for the treatment of patients with anaplastic lymphoma kinase (ALK) positive, locally advanced (not amenable to curative therapy) or metastatic NSCLC who have progressed on or are intolerant to crizotinib until loss of clinical benefit.	December 11, 2015	**September 29, 2016**	Final Recommendation March 29, 2018: Recommended pending cost-effectiveness	3
alectinib (Alecensaro®) 1st line	For the first-line treatment of patients with anaplastic lymphoma kinase (ALK) positive, locally advanced or metastatic NSCLC.	November 6, 2017	**June 11, 2018**	Final Recommendation July 25, 2018: Recommended pending cost-effectiveness	3
atezolizumab (Tecentriq®) 1st line	For the first-line treatment of patients with extensive stage small cell lung cancer (ES-SCLC) in combination with a platinum-based chemotherapy and etoposide.	March 18, 2019	**August 8, 2019**	Final Recommendation December 5, 2019 Revised: January 30, 2020 Not recommended	3
atezolizumab (Tecentriq®) 2nd line	For the treatment of patients with locally advanced or metastatic NSCLC who have progressed on or after systemic chemotherapy until loss of clinical benefit.	October 18, 2016	**April 6, 2018**	Final Recommendation June 20, 2018: Recommended pending cost-effectiveness	2 + 3
atezolizumab & bevacizumab (Tecentriq & Avastin)	In combination with platinum based chemotherapy for the treatment of metastatic EGFR and/or ALK positive non-squamous non-small cell lung cancer in patients who have progressed on treatment with targeted therapies.	December 6, 2018	**May 24, 2019**	Final Recommendation: July 3, 2020 Not recommended.	3
bevacizumab (Mvasi)	For treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer, in combination with carboplatin/paclitaxel chemotherapy regimen.	September 14, 2017	**April 30, 2018**	Final Biosimilar Dossier Issued: January 14, 2019	
bevacizumab (Zirabev)	In combination with carboplatin/paclitaxel chemotherapy regimen, is indicated for treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer.	June 27, 2019	**June 14, 2019**	Final Recommendation: Final Biosimilar Dossier not Issued due to CADTH no longer reviewing biosimilars	
brigatinib (Alunbrig®)	For the treatment of adult patients with ALK positive metastatic NSCLC who have progressed on or who were intolerant to an ALK inhibitor (crizotinib).	April 28, 2017	**July 26, 2018**	Final Recommendation August 1, 2019: Not Recommended	2

Continued... **Table 1 — Date of FDA Approval to Health Canada Approval**

DRUG Generic name (Brand name)	INDICATION	FDA APPROVAL DATE	HEALTH CANADA APPROVAL DATE	pCODR Status	Phase Data Used
brigatinib (Alunbrig®)	For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC) previously untreated with an ALK inhibitor.	May 22, 2020	**N/A**	Under review	3
ceritinib (Zykadia®) 2nd line	For treatment as monotherapy in patients with ALK positive locally advanced (not amenable to curative therapy) or metastatic NSCLC who have progressed on or who were intolerant to crizotinib.	April 29, 2014	**March 27, 2015**	Final Recommendation December 3, 2015: Not Recommended	2
ceritinib (Zykadia®) Resubmission 2nd line	For treatment as monotherapy in patients with ALK positive locally advanced (not amenable to curative therapy) or metastatic NSCLC who have progressed on or who were intolerant to crizotinib.	April 29, 2014	**March 27, 2015**	Final Recommendation March 21, 2017: Recommended pending cost-effectiveness	3
crizotinib (Xalkori®) Resubmission 1st line	As monotherapy for use in patients with anaplastic lymphoma kinase (ALK)- positive advanced NSCLC.	August 26, 2011	**April 25, 2012**	Final Recommendation July 21, 2015: Recommended pending cost-effectiveness	3
crizotinib (Xalkori®) ROS1	As a single agent as first-line treatment for patients with ROS1 positive advanced NSCLC.	March 11, 2016	**August 28, 2017**	Final Recommendation May 23, 2019: Recommended pending cost-effectiveness	1 + 2
dabrafenib (Tafinlar®) & trametinib (Mekinist®) 2nd line	In combination for the treatment of patients with metastatic NSCLC with a BRAF V600 mutation.	June 22, 2017	**May 18, 2018 May 16, 2017 (previously treated with chemotherapy)**	Final Recommendation November 2, 2017: Not Recommended (previously treated with chemotherapy)	2

Continued... **Table 1 — Date of FDA Approval to Health Canada Approval**

DRUG Generic name (Brand name)	INDICATION	FDA APPROVAL DATE	HEALTH CANADA APPROVAL DATE	pCODR Status	Phase Data Used
dabrafenib (Tafinlar®) & trametinib (Mekinist®)	For the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600 mutation and who have not received any prior anti-cancer therapy for metastatic disease.	June 22, 2017	**May 16, 2017**	Ongoing review	2
dacomitinib (Vizimpro®)	For the first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR activating mutations.	September 27, 2018	**February 26, 2019**	Final Recommendation May 31, 2019: Conditional Recommendation pending cost-effectiveness	3
durvalumab (IMFINZI®) Stage III unresectable NSCLC	For the treatment of patients with locally advanced, unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy (CRT), for follow-up to a maximum of 12 months.	February 16, 2018	**May 4, 2018 NOC/c August 23, 2019 NOC**	Final Recommendation May 3, 2019: Recommended pending cost-effectiveness	3
entrectinib (Rozlytrek®)	For the first-line treatment of adult patients with ROS1-positive locally advanced or metastatic non-small cell lung cancer.	August 15, 2019	**May 5, 2020**	Under review	1 + 2
entrectinib (Rozlytrek®)	For the treatment of NTRK fusion-positive, locally advanced or metastatic solid tumors in adult and pediatric patients.	August 15, 2019	**February 10, 2020**	Withdrawn	1 + 2
larotrectinib (Vitrakvi®)	For the treatment of adult and pediatric patients with solid tumours that have an Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory treatment options.	November 26, 2018	**July 10, 2019**	Final Recommendation October 31, 2019:	1 + 2
lorlatinib (Lorbrena®)	For the treatment of adult patients with ALK positive metastatic NSCLC who have progressed on crizotinib and at least one other ALK inhibitor, or patients who have progressed on ceritinib or alectinib.	November 2, 2018	**February 22, 2019**	Final Recommendation January 30, 2020: Not Recommended	2
nivolumab (Opdivo®)	For the treatment of patients with advanced or metastatic NSCLC who progressed on or after chemotherapy.	March 4, 2015	**February 26, 2016**	Final Recommendation June 3, 2016	3

Continued... Table 1 — Date of FDA Approval to Health Canada Approval

DRUG Generic name (Brand name)	INDICATION	FDA APPROVAL DATE	HEALTH CANADA APPROVAL DATE	pCODR Status	Phase Data Used
nivolumab in combination with ipilimumab (Opdivo in combination with Yervoy)	Nivolumab, in combination with ipilimumab and two cycles of platinum-based chemotherapy for the first-line treatment of patients with metastatic or recurrent NSCLC with no EGFR or ALK genomic tumor aberrations.	May 26, 2020	**August 6, 2020**	Under Review	3
osimertinib (Tagrisso®) 2nd line	For the treatment of patients with locally advanced or metastatic EGFR T790M mutation positive NSCLC who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.	November 13, 2015	**July 5, 2016**	Final Recommendation May 4, 2017: Recommended pending cost-effectiveness	3
osimertinib (Tagrisso®) 1st line	For the first-line treatment of patients with locally advanced or metastatic NSCLC whose tumours have EGFR mutations.	April 18, 2018	**July 10, 2018**	Final Recommendation January 4, 2019: Recommended pending cost-effectiveness	3
pembrolizumab (Keytruda®) 2nd line	For the treatment of patients with metastatic NSCLC whose tumours express programmed death-ligand 1 (PD-L1) (as determined by a validated test) and who have disease progression on or after platinum-containing chemotherapy.	September 4, 2014	**April 15, 2016**	Final Recommendation November 3, 2016: Conditional Recommendation based on cost-effectiveness	2/3
ramucirumab (Cyramza®) 2nd line	For the treatment of patients with advanced or metastatic NSCLC who progressed on or after platinum-based chemotherapy in combination with docetaxel.	April 21, 2014	**July 16, 2015**	Closed, not submitted	3

ALK = anaplastic lymphoma kinase CNS = central nervous system EGFR = epidermal growth factor receptor NSCLC = non-small cell lung cancer TKI = tyrosine kinase inhibitor

As of October 20, 2020

Table 2 — Date of Provincial Coverage

Drug Name	BC	AB	SK	MB	ON	QC	NS	NB	NL	PEI
alectinib (1st and 2nd line)	May 1, 2019	March 1, 2019	February 11, 2019	May 31, 2019	April 17, 2019	February 1, 2019	Oct 3, 2019	May 16, 2019	September 27, 2019	Not Funded
atezolizimuab	November 1, 2019	October 7, 2019	February 11, 2019	February 13, 2019	December 6, 2019	February 1, 2019	Not Funded	October 30, 2019	Not Funded	Not Funded
ceritinib	September 1, 2018	October 30, 2018	August 15, 2018	July 19, 2018	October 11, 2018	July 4, 2019	October 3, 2019	November 30, 2018	Not Funded	Not Funded
crizotinib (1st line)	December 1, 2015	December 18, 2015	December 28, 2015	January 18, 2016	December 4, 2015	February 8, 2016	May 2, 2016	April 12, 2016	February 1, 2016	August 1, 2018
crizotinib (ROS1)	Not Funded	Not Funded	August 1,2020	Not Funded	Not Funded	May 20, 2020	Not Funded	July 16, 2020	May 1, 2020	Not Funded
durvalumab	February 1, 2020	April 10, 2020	January 1, 2020	December 16, 2019	January 22, 2020	October 2, 2019	February 1, 2020	March 20, 2020	June 1, 2020	Not Funded
nivolumab	March 1, 2017	April 3, 2017	March 23, 2017	March 13, 2017	March 21, 2017	March 22, 2017	April 1, 2017	May 2, 2017	August 3, 2017	August 1, 2018
osimertinib (1st line)	January 1, 2020	April 10, 2020	March 1, 2020	April 2, 2020	January 10, 2020	December 12, 2019	May 1, 2020	March 19, 2020	February 20, 2020	Not Funded
osimertinib (2nd line)	October 1, 2018	November 20, 2018	November 1, 2018	October 18, 2018	October 3, 2018	November 8, 2018	November, 1, 2019	February 27, 2019	February 20, 2020	April 1, 2020
pembrolizumab (1st and 2nd line)	February 1, 2018	February 16, 2018	December 7, 2017	December 15, 2017	January 17, 2018	November 15, 2017	May 24, 2018	May 2, 2018	May 30, 2018	August 1, 2019

As of October 20, 2020

Table 3 — Number of Days from Date of FDA Approval to Date of Provincial Coverage

DRUG Generic name	FDA APPROVAL DATE	BC	AB	SK	MB	ON	QC	NS	NB	NL	PEI
alectinib (1st line)	November 6, 2017	541	480	462	571	527	452	696	556	690	Not Funded
alectinib (2nd line)	December 11, 2015	1,237	1,176	1,158	1,267	1,223	1,148	1,392	1,252	1,386	Not Funded
atezolizumab	October 18, 2016	1,109	1,084	846	848	1,144	Not Funded	Not Funded	1,107	Not Funded	Not Funded
ceritinib	April 29, 2014	1,586	1,645	1,569	1,542	1,626	1892	1983	1,676	Not Funded	Not Funded
crizotinib (1st line)	August 26, 2011	1,558	1,575	1,585	1,606	1,561	1,627	1,711	1,691	1,620	2,532
crizotinib (ROS1)	March 11, 2016	Not Funded	Not Funded	1,604	Not Funded	Not Funded	1,531	Not Funded	1,588	1,512	Not Funded
durvalumab	February 16, 2018	715	784	684	668	705	593	715	763	836	928
nivolumab (2nd line)	March 4, 2015	728	761	750	740	748	749	759	790	883	1,246
osimertinib (1st line)	April 18, 2018	623	723	683	715	632	603	744	701	673	Not Funded
osimertinib (2nd line)	November 13, 2015	1,053	1,103	1,084	1,070	1,055	1,091	1449	1,202	1560	1601
pembrolizumab (1st line)	October 24, 2016	465	480	409	417	450	387	577	555	583	1011
pembrolizumab (2nd line)	September 4, 2014	1,246	1,261	1,190	1,198	1,231	1,168	1,358	1,336	1,364	1,792

As of October 20, 2020

CONCLUSION

LUNG CANCER CANADA BELIEVES

To increase overall lung cancer survivorship:

- High-risk screening programs that are accessible to all Canadians is critical. This will help shift lung cancer diagnoses to an early stage, when curative treatments are still an option and when the likelihood of overall survivorship increases.
- Screening and prevention must be part of a holistic program that includes counselling and education toward smoking cessation.
- These efforts require government funding but will, over time, become a far more cost-effective measure than treating patients with advanced stage cancer.

To effectively treat lung cancer patients:

- Testing is an important part of the circle of care. Denying patients access to timely testing on the basis of funding is unethical and does not fulfil provinces' constitutional mandate to provide effective care.
- Biomarker testing should be a standard of care for all Canadians. Access to personalized treatment that can lead to better outcomes is compromised if the testing needed to identify targetable mutations cannot be done.
- All Canadians have the right to access timely testing. If testing turnaround times fall outside of international guidelines, cancer care centres must work to reduce wait times and should explore private laboratory options as needed.
- Testing for novel biomarkers should become standard as soon as new treatments targeting these markers are approved by Health Canada. It is unacceptable to prevent patients from accessing approved treatments due to a lack of related testing.

LUNG CANCER CANADA BELIEVES

To ensure postal codes do not dictate the level of care Canadians receive:

- Patients have the right to access excellent care close to the communities they live in. Co-ordinated workflow and referral paths between community sites and centres of excellence need to be established.
- Virtual care technologies should be encouraged and adapted.
- Financial support mechanisms – such as travel and medical grants – are needed to reduce economic hardships for patients, especially those who live in remote and rural geographies as well as those with lower socioeconomic status.

To bring the current system of care up to pace with medical advancements:

- Canada's public health-care system must be modernized in order to improve access and affordability. Stakeholders – including patents, clinicians, manufacturers, and HTA bodies – must collaborate and act to achieve this.
- A national pharmacare program, with comprehensive, universal and equitable access to drugs across Canada is needed.
- New funding models, such as shared risk models and testing rebate programs, are also critical.
- Funding models should be continuously re-evaluated based on additional clinical or real-world evidence.
- Oral medications need to be fully covered across the country.

A YEAR-IN-REVIEW

2020 marked a year hit with a pandemic that was not only unexpected but challenged the health-care system in an unprecedented manner, affecting all Canadians including those impacted by lung cancer. 2020 also marks yet another year where lung cancer remains the leading killer of all cancers in this country, with 29,800 Canadians expected to be diagnosed with this disease.

The 2020 report looks at screening, early detection and diagnosis in lung cancer from the lens of the different specialists across the provinces, noting what works, what doesn't and how to address the challenges and disparities, while determining how provision of care can be equitable.

Screening

Lung cancer screening saves lives. The earlier lung cancer is diagnosed, the better the chance for curative treatment. With 75 per cent of cases diagnosed at stage 3 or 4, the importance cannot be overemphasized. While costs to implement screening programs may be daunting, these programs not only save lives but also lessen the significant burden on the health-care system. British Columbia recently took the first step and committed to a provincewide screening program, and it is hoped other provinces will follow suit.

Detection and Diagnosis

For many physicians treating lung cancer, it is a race against the clock. A race to ensure early access to testing that can hopefully give patients a chance at better outcomes. Lung cancer treatment has evolved in the last few years with the emergence of personalized medicine, allowing targetable mutations to be matched with targeted treatments. Matching the right treatment is key and is performed through molecular testing (biomarker testing). With different types of testing carried out across the country, next-generation sequencing (NGS), which has comprehensive testing capabilities, is emerging as one that could be adopted nationally. We encourage such testing be batched for a critical mass and carried out reflexively to promote cost-effectiveness and reduce wait times.

Access to Treatment

Navigating drug coverage remains an issue in Canada. From the expense of new treatments to the time it takes for approved treatments to get funded, to subsequent availability across the provinces, there is an imbalance in this country. We believe national pharmacare, with comprehensive, universal and equitable access to drugs across Canada, can help address this.

Incremental progress has been made over the last few years in the management of lung cancer, but more still needs to be done.

For us, the physicians, it is all about the patients, to help them spend more time with loved ones, achieve new milestones and see new miracles in their lives. This what we aspire to achieve. And there is hope: to find, test and appropriately treat lung cancer in a timely manner. Hope to make a difference in the lives of lung cancer patients.

Join us.

Signed,

Lung Cancer Canada, Medical Advisory Committee and Supporters

APPENDIX A: WHERE IS MOLECULAR TESTING EVALUATED?

	In-House Testing	Centralized Testing	Private Lab
What it is	Patient tissue samples are sent for analysis to a laboratory located within the hospital.	Centralized testing facilities receive tissue samples from multiple hospitals or cancer centres. Samples are "batched" (i.e. several samples for various cancers are sent for testing at the same time) in order to test larger volumes of tissues quickly.	For-profit laboratories, primarily based in the U.S., offer molecular testing services. FoundationOne and Guardant360 are two of the most trusted service providers today.
Advantages	• Faster results; no lost time transporting samples off-site • Samples can be quickly retrieved, re-tested if required • Ability for clinicians to order on-demand testing • Testing can be rushed in urgent cases	• Equitable distribution of testing paradigms • Higher volumes of samples enable quick testing turnaround times • Reduces testing costs for hospitals • Ability to maintain high quality of testing	• Samples tested immediately; private labs are incentivized to provide results quickly • Cost for tests may be on-par or only slightly higher than in-house or centralized testing costs • On-demand tests
Disadvantages	• High startup costs • Needs highly trained staff	• Lose time – samples must be transported off-site • Potential backlogs if labs can't handle the large sample volume	• Provincial health care • System could not absorb large-scale private tests

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Dr. Brandon Sheffield
Pathologist
William Osler Health System

Dr. Richard Bigsby
Thoracic Surgeon
St Paul's Hospital

Dr. Darryl Yu
Anatomic Pathologist
St Paul's Hospital

Dr. Biniam Kidane
Thoracic Surgeon
Health Sciences Centre
Winnipeg

Dr. Gefei Qing
Pathologist
University of Manitoba

Dr. Madelaine Plourde
Thoracic surgeon
Queen Elizabeth II
Health Sciences Centre

Dr. Cheryl Mather
Pathologist
University of Alberta

Dr. Eric Bédard
Thoracic Surgeon
University of Alberta

Dr. Kevin Jao
Medical Oncologist
Hôpital du Sacré-Cœur de Montréal

Dr. Mathieu Rousseau
Thoracic Surgeon
McGill University

Dr. Hangjun Wang
Pathologist
Jewish General Hospital

Dr. Nicholas Finn
Medical Oncologist
Vitalité Health Network

Dr. Jaime Snowdon
Pathologist
Horizon Health Network

Dr. Joseph Ojah
Thoracic Surgeon
Horizon Health Network

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133 Richmond St W, Suite 208
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