

# Pan-Canadian Lung Cancer Screening Initiative Lung Cancer Screening Framework for Canada



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Canadian Partnership Against Cancer 1 University Avenue, Suite 300 Toronto, Ontario, Canada M5J 2P1 Tel: 416.915.9222 Toll-free: 1.877.360.1665 www.partnershipagainstcancer.ca

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## BACKGROUND

## Lung Cancer

# Lung cancer is the leading cause of cancer death in Canada.

It is estimated that 25,500 Canadians were diagnosed with lung cancer in 2013 and that some 20,200 men and women died from the disease in the same year.<sup>i</sup> The five-year relative survival rate for lung cancer is 17 percent.<sup>i</sup>

Lung cancer is the leading cause of death from cancer in Canada and is the second most common cancer in both males and females. Since the mid-1980s the incidence has been declining in men, and while fewer women than men are diagnosed with this type of cancer, the incidence among females has been increasing since 1982. These patterns reflect changes in tobacco use and quit rates: rates of smoking among men started to decline in the mid-1960s whereas declines in smoking rates among females were not observed until the mid-1980s.<sup>i</sup>

Lung cancer is a significant burden to those affected by the disease, their families, and the health care system. The treatment is complex and dependent on a number of factors including stage of diagnosis, tumour pathology, and/or the presence of other medical conditions.

## Lung Cancer Screening

## An international collaborative effort is underway to further our understanding of how lung cancer develops and to devise a framework for earlier detection of the disease through screening.

Cancer screening involves the use of specific tests to detect the presence of disease at an early stage so that treatment can start before the onset of clinical symptoms. The overall goal of screening is to reduce the mortality associated with the disease. With lung cancer screening there exists an important opportunity to also address primary prevention if smoking cessation programs are integrated with screening activities. Advances in low-dose spiral computed tomography (LDCT) have led researchers to assess its efficacy as a potential lung cancer-screening test in high-risk individuals. In the United States, the National Lung Screening Trial (NLST) found that lung cancer deaths fell by 20 percent in current and/or former smokers aged 55-74 (with 30 or more pack-years smoking history) who were screened annually for three consecutive years using LDCT.<sup>ii</sup> The trial also found that all-cause mortality fell by seven percent among this group.

In light of these findings, the International Association for the Study of Lung Cancer (IASLC) Board of Directors struck a CT Screening Task Force to develop an IASLC position statement. This statement concluded that:

- The NLST was the first randomized controlled trial to demonstrate a significant reduction in lung cancer mortality due to LDCT screening in a high-risk population.
- There are both published data and ongoing trials and studies that could help inform the advancement of population-based lung cancer screening.

The Task Force called for the collaboration and active participation of international lung cancer clinicians and researchers to study, assess, evaluate, and refine this proposed screening approach.<sup>iii</sup>

To that end, in 2011, IASLC hosted a CT Screening Workshop to further discuss opportunities for improving and advancing the use of LDCT in lung cancer screening. A number of Strategic CT Screening Advisory Committees were established at this time. Their stated goal was to actively engage lung cancer stakeholders, including professional societies and organizations, to focus on developing guidelines and recommendations in the following areas:

- Identification of high-risk individuals for lung cancer screening programs;
- Development of radiological guidelines for use in developing lung cancer CT screening programs;
- Development of guidelines for the clinical work-up of "indeterminate nodules" resulting from CT screening programmers;
- 4. Guidelines for pathology reporting of nodules from lung cancer CT screening programs;
- Recommendations for surgical and therapeutic interventions of suspicious nodules identified through lung cancer CT programs; and
- 6. Integration of smoking cessation practices into future national lung cancer CT screening programs.<sup>iv</sup>

## A National Approach to Lung Cancer Screening in Canada

# National experts from across Canada collaborated to discuss priorities and issues in lung cancer screening.

To identify priorities for lung cancer screening in Canada, the Canadian Partnership Against Cancer (CPAC) hosted two multi-stakeholder forums (November 22, 2011 and February 29, 2012). It was agreed by forum participants that a national network approach would be useful for both identifying and supporting national priorities.

The Pan-Canadian Lung Cancer Screening Network (PLCSN), hosted by CPAC, was subsequently established with the following mandate: to support initiatives that will inform discussions and decisions around lung cancer screening; to leverage expertise in this area; and to make use of evidence-based recommendations that support policy and best practices in lung cancer screening.

Members of PLCSN include representatives from provincial cancer care organizations, provincial and territorial ministries of health, the Public Health Agency of Canada, and non-government and professional organizations. Individual experts are also invited to participate in PLCSN initiatives depending on the subject matter.

Recognizing that lung cancer screening was a new area of development – both in Canada and internationally – members of PLCSN agreed that developing a Lung Cancer Screening Framework for Canada would be a valuable initial project. As such, this consensus statement-based framework was developed to provide useful guidance to the provinces and territories as they address this important issue in cancer control.

The statements within this framework were developed through an extensive consultation process which took place between April 2013 and April 2014 (a detailed account of the consensus process is included as Appendix A).

## LUNG CANCER SCREENING FRAMEWORK FOR CANADA - CONSENSUS STATEMENTS

## Intent

This consensus statement-based framework has been designed as a tool to support Canadian jurisdictions in their deliberations and/or in planning for lung cancer screening by outlining the key elements for consideration.

The framework is not intended to be prescriptive. It is recognized that lung cancer screening, if it takes place, will evolve differently across the provinces and territories in terms of timing and approaches. In addition, there may be issues and gaps that are not identified and/or resolved in this framework; for that reason, it should be viewed as an iterative process.

Although the development of this framework was facilitated by CPAC, it will be essential to identify the most appropriate group(s) to address the specific aspects of the various statements. In some statements, these groups have been noted.

## Introduction

The vast majority of lung cancers (85-90%) are associated with cigarette smoking.<sup>v</sup> Preventing the onset of smoking and bringing about successful smoking cessation amongst current smokers, particularly by 30-40 years of age, will most effectively achieve primary prevention of lung cancer.<sup>vi, vii</sup> Evidence-based smoking cessation and relapse prevention programs are critical strategies for lung cancer control.

### The role of smoking cessation

This framework is focused on lung cancer screening and not on overall tobacco control or on the broader issues of chronic disease prevention. However, smoking cessation statements have been included as alignment and integration of smoking cessation programs with screening strategies can link effective primary and secondary prevention intervention approaches. Published and ongoing modeling analyses have demonstrated that LDCT lung cancer screening, combined with smoking cessation, appears to be more cost-effective than screening alone.<sup>viii</sup>

One challenge with smoking cessation programs is that long-term smokers who could potentially benefit the most often do not participate. As noted earlier, lung cancer screening presents a new opportunity for cessation programs to access a segment of smokers that have traditionally been difficult to engage.

# How is lung cancer screening different from other kinds of cancer screening?

Lung cancer screening differs from the population-based screening programs that have been implemented for breast, cervical, and colorectal cancers. Whereas the population targeted in those programs are generally at average risk of developing these cancers, lung cancer screening is focused on a defined high-risk population. There is currently no evidence to support routine screening of average-risk individuals for lung cancer. The risks and complications associated with screening lowerrisk cohorts (e.g., false positive findings on LDCT) likely out-weigh any potential benefits.

While the target populations may be different, the principles that guide population-based screening programs can help inform the development of an effective screening strategy for a high-risk target group. In addition, the structure of organized population-based screening provides a useful outline of program components including: an identified targeted population group; a specific screening test; identified screening intervals; policies to guide planning and delivery of screening services; coordination of diagnostic services for individuals with an abnormal screen result; quality standards and monitoring; and evaluation of cancer outcomes.<sup>ix</sup>

#### Who might benefit from lung cancer screening?

In order to define and reach individuals who could benefit from lung cancer screening, there needs to be welldefined risk criteria which are incorporated into tools/models for use in planning and individual risk assessment. While the evidence for some key risk factors is more clearly defined, there is a need for continued work to further develop and confirm the role of known risk factors for lung cancer, including how they might be incorporated (or not) as screening eligibility criteria in the future.

#### Who would be eligible for lung cancer screening?

Setting criteria for eligibility to participate in screening requires consideration of multiple factors, aside from risk exposure factors. Age eligibility is an example of such a factor, and should ideally be standardized across the country, as it is for colorectal cancer screening.

It can be challenging to recruit a high-risk target population for screening as there are no centralized databases that contain risk information beyond age and sex. Therefore, it will be important to find systematic ways to reach eligible individuals and invite them to take part in screening. Development of appropriate patient education and awareness programs may help make these connections.

# Developing guidelines for LDCT use in lung cancer screening

There is a clear need for guidelines pertaining to the use of the LDCT scan as the screening test for lung cancer among the high risk population. Guidelines including start and stop ages for screening and recommended interval between screenings will be essential for the implementation of lung screening in Canada – whether it is carried out in a programmatic fashion or as ad hoc, opportunistic screening. Guidelines for screening and follow-up algorithms are also needed, and these should be based on current evidence and best practices (where the evidence is not definitive). It is likely that one clearly defined clinical pathway will not apply to all cases and circumstances and therefore options will likely vary across the country. Some of this variation will stem from differences in local expertise, resources, and services across regional jurisdictions.

In the area of pathology, much work has been done at the national level in the United States and in Canada on reporting standards. Taking this work to the next level would include the development of synoptic reporting methods for small lung biopsy specimens to facilitate quality and monitoring and evaluation.

### **Evaluating our efforts**

As lung cancer screening is addressed in Canada, it will be important to develop performance measures to evaluate outcomes and quality control. Such measures might include, but are not limited to:

- What proportion of the target population was identified, contacted and enrolled;
- What proportion of the target population who are current smokers were offered and took advantage of the opportunity to quit smoking during or after their screening visit;
- Lung cancer mortality rates in the screened vs. unscreened target populations;
- Stage-at-diagnosis shifts observed in those lung cancers detected by screening vs. those occurring in unscreened individuals.

The statements presented in the next section of this report cover a broad scope. They include the development of screening and clinical pathways; the use of multidisciplinary approaches in patient assessment and evaluation; and setting quality standards for screening, diagnosis, and treatment. As conversations about lung cancer screening take place in regional or provincial jurisdictions, it is intended that this framework will provide a starting point to set the stage for the development of specific clinical practice guidelines and algorithms.

As articulated through the consensus process (detailed in Appendix A), each of the statements have relevancy at national and provincial/territorial levels.

## Lung Cancer Screening Consensus Statements

#### **Smoking Cessation in Lung Cancer Screening**

- Where evidence-based smoking cessation and relapse prevention programs exist and are well organized within a jurisdiction, these services (e.g., quit line promotion, physician referral, or a cessation program embedded in a screening program) should be aligned with existing or developing lung cancer screening programs.
- Periodically updated jurisdictional inventories of smoking cessation and relapse prevention programs need to be completed in order to identify existing and emerging alignment opportunities with lung cancer screening program activities.
- 3. Where evidence-based smoking cessation services and relapse prevention programs do not exist or where their reach is very limited, filling these gaps with evidence-based approaches should occur prior to or in conjunction with initiating a lung cancer screening program.
- In all lung cancer screening programs, whether smoking cessation is offered in-house or by referral, smoking status should be monitored annually as a lung cancer screening program quality indicator.

#### **Recruitment and Eligibility for Lung Cancer Screening**

- Come to consensus, across jurisdictions, on which risk assessment models might be most suitable for use in Canada.
- 6. Risk assessment models evaluated for use for lung cancer screening selection should consider both incidence and mortality as outcomes.
- Identify at what level of individual risk people should be screened. Consider the applicability, in the Canadian context, of various risk prediction equations and algorithms.
- Other risk factors (e.g., second hand smoke, air pollution, asbestos, etc.), in addition to the standard smoking exposure measures should be considered when possible in order to determine an individual's true overall risk.
- Define eligibility criteria for lung cancer screening that includes consideration of existing guidelines, cost-effectiveness, and validated risk-prediction models.
- Age is an important parameter when developing eligibility criteria for lung cancer screening; serious consideration should be given to standardizing upper and lower age limits across the country.
- 11. Define or describe criteria for ineligibility of lung cancer screening.
- 12. Determine ways to capture self reported data from potential screen-eligible persons to confirm their eligibility or ineligibility for lung cancer screening, and to support ongoing research into optimizing determination of eligibility.

#### **Radiological Testing in Lung Cancer Screening**

- Create a standardized definition across Canada for an abnormal lung cancer screen, including identifying which abnormal results require definitive clinical work-up.
- 14. Develop Canadian lung cancer screening algorithms including radiologic management of abnormal findings through assessing the various protocols from randomized controlled trials, prospective studies, and existing guidelines.
- 15. Develop guidelines for technical parameters and dosage levels of low dose computed tomography.
- Develop guidelines for measurement techniques and standardized reporting of low dose computed tomography, including reporting guidelines and scoring systems (e.g., LU-RADS).
- 17. Recommend the development and implementation of an accreditation program for lung cancer screening centres by the Canadian Association of Radiologists; where the radiologists, technologists, equipment, and quality assurance program will be assessed on quality control, image quality, radiation dose, and the use of standardized reports for lung cancer screening and diagnostic follow-up occurring in each centre.
- Create a continuing medical education program for the radiological aspects of lung cancer screening services and programs with support from appropriate professional organizations.

## Diagnostic Follow-up and Treatment after Lung Cancer Screening

 Recommend the development and/or implementation and measurement of quality standards for clinicians treating patients (e.g., radiologists, thoracic surgeons, respirologists, medical and radiation oncologists).

- 20. Define the indications for, and key elements of timely multidisciplinary clinical review processes (e.g., tumour board or tumour conference) throughout the diagnostic and treatment pathways.
- 21. Develop algorithms for the clinical work-up of individuals with abnormal screening results, including additional imaging, biopsy, and surgical resection.
- 22. Based on key clinical factors, identify recommended methods of performing non-surgical and surgical biopsies.
- 23. When feasible, the diagnosis of lung cancer and tumour stage should be confirmed prior to treatment.
- 24. Outline criteria, including involvement of respirologists and thoracic surgeons, for patient assessment to determine resectablity and operability.
- 25. Lung cancer screening strategies/programs should link to the treatment pathways for patients.
- 26. Develop a minimum standard for treatment services. An analysis of current practice could help to inform the standard.
- 27. Monitor all interventions including results and complications.

### Pathology Quality and Reporting in Lung Cancer Screening

- Pathology findings should be reported using the College of American Pathologists synoptic reporting standard, which is endorsed by the Canadian Association of Pathologists.
- 29. Develop synoptic reporting for lung biopsy specimens.
- 30. Develop recommendations for tissue submission and handling.
- 31. Develop recommendations related to defining parameters of an adequate specimen per procedure.
- 32. Cell block preparation for all lung cytology specimens is recommended.
- Pathology reports should indicate the optimal tumour block(s) for future testing.
- Cytology and pathology results should be correlated if possible.

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## **NEXT STEPS**

It is very likely that different approaches will be considered and implemented across the country for lung cancer screening, as has been seen with the development of other existing provincial/territorial cancer screening programs. With lung cancer screening at such an early stage, provinces/territories have an opportunity to coordinate their planning and decision making. This framework will help facilitate the collection of data and best practices to optimize organized approaches to lung cancer screening. PLCSN and additional working group members will determine the priority areas of this framework and discuss which items are most relevant to advance on a pan-Canadian level.

As new guidelines or other information becomes available, the need for revisions to this framework will be considered.

## **APPENDIX A: LUNG CANCER SCREENING FRAMEWORK FOR CANADA - DEVELOPMENT**

## **The Process**

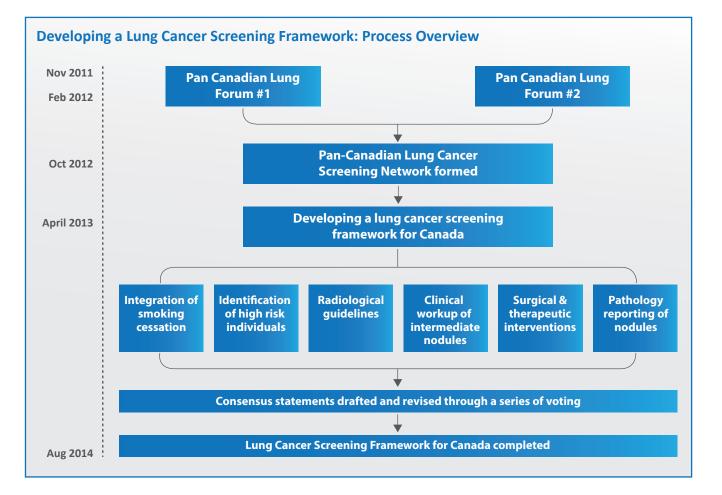
Key areas of consideration for lung cancer screening were identified through an extensive consultation process.

The first priority initiative identified by members of the PLCSN was the development of a Lung Cancer Screening Framework for Canada to provide useful guidance to the provinces and territories as they address this important issue in cancer control.

To begin discussions, pan-Canadian working groups – with chairs and co-chairs – were formed with nominated PLCSN

members and other expert volunteers. Using the IASLC recommendation areas as a guide, <sup>iv</sup> these groups were tasked with developing consensus statements in one of the following priority areas:

- Smoking cessation and lung cancer screening;
- Identification of high-risk individuals and lung cancer screening eligibility;
- Development of radiological guidelines;
- Clinical work-up of indeterminate;
- Recommendations for surgical and therapeutic interventions of suspicious nodules; and
- Pathology reporting of nodules.



Individual working groups produced the first draft of statements during an in-person PLCSN meeting on April 25, 2013. Following this meeting, working group chairs conducted literature reviews and linked relevant evidence to the corresponding statements via an online consensus platform.<sup>x</sup>

The online platform, which used a systematic approach incorporating a modified Delphi technique, allowed the working groups to provide feedback and indicate their level of agreement (vote) for each statement using the following scale:

- Disagree strongly;
- Disagree with major reservation;
- Disagree with minor reservation;
- Agree with major reservation;
- Agree with minor reservation; or
- Agree strongly.

A first round of voting occurred during the summer of 2013. Working group members voted and provided feedback only on those statements that were within their working group area of focus.

In the fall of 2013, following the second revision of the statements, working group members were invited to vote and provide feedback on the entire set of statements after which subsequent revisions took place. A final round of voting occurred during an in-person meeting held on October 2-3, 2013 in Halifax, Nova Scotia. Close to 50 participants, including members of PLCSN, additional working group members, and provincial and territorial cancer screening leads were in attendance.

The process of voting at this meeting began with the chairs and co-chairs of each of the working groups presenting their group's most recent draft statements to highlight key elements and evidence. Each presentation was followed by a facilitated discussion, and minor revisions were made to the statements. Then voting took place, statement by statement. Votes were weighted such that working group members' votes were worth three times more than non-working group members. This weighting was implemented to reflect working group members' expertise with the subject matter.

In addition, attendees were asked to assess whether the focus of each statement was relevant at a pan-Canadian or provincial/territorial level, neither, or both.

To offer an opportunity for further reflection and input after the in-person meeting, the set of revised statements was re-circulated to all attendees for comment. This input was reviewed by working group chairs/co-chairs and incorporated into the statements.

At this point, a draft framework document including the most recent statements and a detailed account of the development process was circulated in December 2013 for feedback. A revised and more complete framework document was circulated in April 2014 for a last round of feedback. This final framework was completed in May 2014.

## **APPENDIX B: PLCSN MEMBERS, EXPERT VOLUNTEERS ON WORKING GROUPS, AND OTHER PARTICIPANTS**

#### **Heather Bryant**

Chair, Pan-Canadian Lung Cancer Screening Network Vice-President Cancer Control Canadian Partnership Against Cancer

#### Maureen Baikie

Deputy Chief Medical Officer of Health, Department of Health and Social Services Government of Nunavut

#### **Gillian Bromfield**

Director, Cancer Control Policy Canadian Cancer Society

Donna Bush Team Lead, Provincial Health Services Authority Ministry of Health, British Columbia

Theresa Callaghan Provincial Director

Diagnostic Imaging Services Health PEI

#### Katherine Canil

Chief of Surgery, Department of Health and Social Services Nunavut, Qikiqtaaluk/Baffin Region

#### Dafna Carr

Director Policy, KTE and Primary Care Prevention and Cancer Control Cancer Care Ontario

#### André Corriveau

Chief Public Health Officer Department of Health and Social Services Government of the Northwest Territories

Connie Côté Senior Director Canadian Lung Association

Dan Coulombe Director of Operations New Brunswick Cancer Network

#### Marla Delaney

Colorectal Cancer Screening Coordinator, Chronic Disease Prevention & Management Unit Health PEI

#### Greg Doyle

Chair, National Committee Canadian Breast Cancer Screening Initiative Eastern Health

Ford Elms Staff Pathologist Health Sciences Centre, Eastern Health

Richard Finley Thoracic Surgeon Vancouver General Hospital

#### **Bill Flanagan**

Chief of Microsimulation Health Analysis Division Statistics Canada

#### **Colin Foley**

Staff Radiologist Health PEI- Queen Elizabeth Hospital

Claire Marie Fortin

Senior Manager, Policy and Guidelines Cancer Care Ontario

#### Jason Garay

Director, Evaluation and Reporting Cancer Screening, Prevention and Cancer Control Cancer Care Ontario

#### Gary Gelfand

Clinical Assistant Professor Departments of Surgery/ Oncology University of Calgary

#### John Granton

Associate Professor of Medicine University of Toronto Director, Pulmonary Hypertension programme, Toronto General Research Institute, University Health Network

#### Jonathan Greenland

Divisional Chief, Radiation Oncology, Eastern Health Clinical Assistant Professor of Medicine, Memorial University of Newfoundland

#### Anne-Marie Grenier

Specialist in Public Health and Preventive Medicine, Screening Medical Advisor Quebec Ministry of Heath

### Karen Grimsrud

Senior Medical Advisor and Director, Prevention Guidelines Division, Public Health Agency of Canada

Marion Harrison Director, Screening Programs CancerCare Manitoba

Amy Henderson Manager, Health Communications The Lung Association

#### **Chris Hergott**

Associate Professor, Respirology and Interventional Pulmonary Medicine, University of Saskatchewan Royal University Hospital

#### Pam Hoeschle

Leadership Development Committee, Canadian Association of Medical Radiation Technologists

#### Meaghan Horgan

Senior Policy Lead, Policy and Guidelines Cancer Care Ontario

#### Diana Ionescu

Clinical Associate Professor University of British Columbia, Staff Pathologist BC Cancer Agency

#### Michael Johnston

Director Beatrice Hunter Cancer Research Institute, Professor of Surgery Dalhousie University

#### Nora Johnston

Director, Wellness Branch Alberta Health

#### Lisa Kan

Senior Director, Cancer Screening Programs BC Cancer Agency

#### Kami Kandola

Office of the Chief Public Health Officer, Department of Health and Social Services Government of the Northwest Territories

#### Jon Kerner

Senior Scientific Lead for Population Health and Knowledge Management Canadian Partnership Against Cancer

#### Eshwar Kumar

Co-Chief Executive Officer New Brunswick Cancer Network, Health and Wellness New Brunswick Department of Health

#### Stephen Lam

Lung Cancer Expert Terry Fox Research Institute, Senior Lead Researcher, BC Cancer Research Centre Chair of Lung Tumour Group, BC Cancer Agency Professor of Medicine, University of British Columbia

#### Jean Latreille

Directeur, Direction de la lutte contre le cancer Ministère de la santé et des services sociaux

#### Natasha Leighl

President Lung Cancer Canada

#### Neil MacDonald

Acting Assistant Deputy Minister, Family and Population Health Alberta Health

#### Paul MacEachern

Respirologist, Clinical Assistant Professor University of Calgary

#### Dawn MacIsaac

Acting Manager PEI Cancer Treatment Center Queen Elizabeth Hospital

#### Daria Manos

Thoracic Radiologist and Section Head, Chest Radiology, QE II Health Sciences Centre Halifax, Chair, Lung Cancer Screening Steering Committee Cancer Care Nova Scotia, Assistant Professor Dalhousie University

#### John Mayo

Director of Advanced Cardiac Imaging Vancouver General Hospital, Professor of Radiology and Cardiology University of British Columbia

#### Donna Maziak

Professor University of Ottawa Program Director, Surgical Oncology Division of Thoracic Surgery Ottawa Hospital

#### Anthony Miller

Professor Emeritus Dalla Lana School of Public Health, University of Toronto

#### Teresa Mrozek

Executive Director Cancer and Diagnostic Care Manitoba Health

#### Michelle Mujoomdar

Assistant Chief Scientist Canadian Agency for Drugs and Technologies in Health

#### **Renelle Myers**

Respirologist University of Manitoba Lead, Lung Cancer Screening Project, CancerCare Manitoba

#### Erika Nicholson

Director, Cancer Prevention and Early Detection, Cancer Care Nova Scotia

#### Robert Nuttall Assistant Director, Cancer Control Policy Canadian Cancer Society

## Lawrence Paszat

Emerging Evidence Scientist Institute for Clinical Evaluative Sciences

#### Gefei Qing Staff Pathologist, Winnipeg Health Sciences Centre Assistant Professor, Department of Pathology University of Manitoba

#### Heidi Roberts

Professor of Radiology University of Toronto Staff Radiologist and Section Head, Chest Imaging Joint Department of Medical Imaging UHN/MSH/WCH Site Director for Medical Imaging, Women's College Hospital

#### Réjean Savoie

Co-Chief Executive Officer New Brunswick Cancer Network Health and Wellness New Brunswick Dept of Health

#### Harmon Sekhon

Pathologist, Director of Cytopathology Deputy Head, Division of Anatomic Pathology Assistant Professor, University of Ottawa PI, Ontario Tumour Bank Ottawa-site, OICR

#### Kathy Simpson

General Practitioner of Oncology College of Family Physicians of Canada

Paul Sinclair INSINC Consulting Inc.

#### Nancy Staniland

Director, Cancer Screening Programs Population and Public Health Alberta Health Services

#### Martin Tammemagi

Professor, Epidemiology Faculty of Applied Health Sciences Brock University

#### Jana Taylor

Board Member, Canadian Association of Radiologists Practising Thoracic and Abdominal Radiologist, McGill University Health Centre Assistant Professor McGill University, International Early Lung Cancer Action Project

#### Kathryn Taylor

Member, Cancer Control, Lombardi Cancer Center Professor, Oncology, Georgetown University Medical Center

#### **Yvonne Taylor**

Provincial Leader Early Detection, Population Health Division Saskatchewan Cancer Agency Jon Tonita VP of Population Health Saskatchewan Cancer Agency

#### Vamsee Torri

Clinical Assistant, Professor of Medicine Allan Blair Cancer Center University of Saskatchewan

#### Ming Tsao

Molecular Lung Pathologist Princess Margaret Hospital University Health Network

#### Yee Ung

Disease Pathway Management Lead for Lung Cancer, Odette Cancer Centre

#### **Rosaire Vaillancourt**

Thoracic Surgeon Institut universitaire de cardiologie et de pneumologie de Québec

#### Elaine Warren

Program Director Cancer Care Program Eastern Health

#### Sherri Wright

Assistant Deputy Minister of Health Services Government of Yukon

#### Zhaolin Xu

Staff pathologist, Queen Elizabeth II Health Science Centre Associate Professor Dalhousie University

#### **Huiming Yang**

Provincial Medical Officer of Health, Healthy Living Medical Director, Screening Programs Alberta Health Services

## **CPAC Staff**

#### Susan Fekete

Director, Screening and Early Detection Canadian Partnership Against Cancer

#### Verna Mai Expert Lead, Screening

Canadian Partnership Against Cancer

#### Neetu Shukla

Screening Analyst, Screening and Early Detection Canadian Partnership Against Cancer

#### **Candice Anderson**

Screening Analyst, Screening and Early Detection Canadian Partnership Against Cancer

#### **Carol Irwin**

Coordinator, Screening and Early Detection Canadian Partnership Against Cancer

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<sup>x</sup> INSINC Consulting Inc., Guelph, Ontario, Canada, EDC Solutions, Atlanta, Gerogia, USA.



1 University Avenue, Suite 300 Toronto, Ontario, Canada M5J 2P1

Tel: 416.915.9222 Toll-free: 1.877.360.1665

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